Implementing Quality in Laboratory Policies and Processes

Using Templates, Project Management, and Six Sigma

Donnell R. Christian, Jr.
Stephanie Drilling

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Table of Contents

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Establishing the Need

I

Introduction 1

The credibility of a laboratory's reputation is directly affected by its quality assurance program. The key to a successful quality assurance program is the manuals, and associated documents define the program and its various components. Therefore, by extension, a laboratory's credibility is directly related to its operational and technical methods manuals.

The pathway to accreditation is paved by the pages of the documents that are comprised in those manuals. How rough the accreditation road is depends on the skill of the person or persons tasked with drafting the reams of documents required to develop, implement, and maintain a quality assurance program. The author's wordsmithing skills directly impacts the bumpiness of the ride.

In some ways, it is ironic. A laboratory's reputation and success are not based on hundreds of thousands of dollars of state-of-the-art instrumentation within its walls. The hundreds of years of combined education, training, and experience of the professional staff do not determine if a laboratory is accredited or if its results are universally accepted. In reality, a laboratory's reputation, the reliability of its results, and its ability to attain accreditation rely on the ability of an overworked, underpaid, midlevel manager who is in general disliked by the entire professional staff to draft policies and procedures that are clear and concise.

The sad truth is that this overworked, underpaid, midlevel manager, affectionately known as the quality assurance manager (QAM), may or may not have the skills and available resources to do the most critical job within the laboratory. In some cases, he is transitioning from the bench to a supervisory position. In other situations, the QAM duties are performed by a senior-level scientist as part of his "other assigned duties." In most instances, prior to their appointment, Quality assurance managers (QAMs) do not have the knowledge, skills, and abilities to prepare the documents that are so critical to the laboratory's credibility.

In many instances, the QAM position is a short-term or part-time appointment. This situation can lead to inconsistencies in policy content due to a lack of formalized procedures and differences in writing styles. The resulting policy and procedure manuals can resemble a patchwork quilt of documents without established content and formatting structures to compensate for the difference in writing styles.

Developing the manuals necessary to establish a quality assurance program is a monumental task. Converting what has historically been considered the laboratory's quality assurance program to one that conforms to the standards of a recognized accrediting body can be just as ambitious, or more so. The fact that you are reading this book is a testimony to your understanding of the task that is in front of you.

One must also examine the reason behind the preparation of policy and procedure manuals for them to have the maximum impact. Manuals developed to satisfy accreditation criteria tend to be less effective than manuals that are developed to enhance the quality of the laboratory's work product. This philosophy leads to a universal truth: Quality leads to accreditation. Accreditation does not lead to quality.

What Manuals?

To borrow a line from the movie *Blazing Saddles,* "Manuals, we don't need no stinking manuals," often seems to be the philosophy of the laboratory management and professional staff. They may begrudgingly accept the fact that policy and procedure manuals are a necessity for accreditation. However, policy and procedure manual use and incorporation into the operational culture of the laboratory may or may not exist.

How many times have you heard something like the following exchange?

New Employee: "Why do we put square pegs in round holes?"
Supervisor: "It's policy."
New Employee: "Are you sure? It does not seem like it would work very well."
Supervisor: "Trust me. I am sure. The section chief told me it was how they have been doing business since he began working here."

Some variation of this conversation routinely occurs in laboratories that do not have documented policies and procedures or a mechanism for making them part of the laboratory's operational culture. This mentality of lack of documentation leads to inconsistencies in the implementation of every task within the organization, leading to the generation of misinformation. Inconsistency of implementation leads to degradation of quality. Degradation of quality leads to loss of customer confidence, which ultimately leads to loss of revenues.

Let's analyze the previous exchange between the new employee and his supervisor. Which of the following problems is illustrated in the previous conversation?

A. The policy is stupid
B. There may or may not actually be a policy
C. The policy may or may not be documented
D. All of the above
E. None of the above

The best answer is "D, all of the above." Let's look at the options to decipher why "all the above" is the best response.

A: The policy is stupid. This is a true statement. Square pages do not fit into round holes easily. That is not the point. The point is the supervisor told the new employee that the company policy is to put square pegs into round holes. The procedure for doing it is a different discussion.

Utilizing documented policies and procedures is a form of standardization that provides a mechanism for uniformity. The policy or procedure does not have to be the best way to perform the task at hand. The only requirement is the ability to uniformly apply it to all factions affected by the policy or procedure.

The rationale behind utilizing a policy or procedure is to ensure the reproducibility of the examination results. Accuracy is not the prime consideration. The primary focus is to ensure the same result is achieved without regard to the analyst performing the examination or the facility in which it is performed. That is, when the policy or procedure is followed, a reproducible result will occur.

An example of the implementation of this point of view is the analytical methods required by the Environmental Protection Agency (EPA). At one time, EPA chromatography methods required the use of packed columns with specific stationary phases for use in all official regulatory examinations. The use of capillary columns with stationary phases with similar characteristics that produced more accurate results was unacceptable for official EPA reports. The laboratory had the option to perform the more accurate tests for the client. However, official reports required the use of the official procedure.

Again, in this example, the need for precision overrides the need for accuracy. At this point in time, not all laboratories had the capability to upgrade their instrumentation to include capillary technology. The EPA's overriding need, at the time, was to ensure the same analytical result was achieved regardless of the laboratory that was used—thus, allowing the comparison of Granny Smith apples to Granny Smith apples rather than to McIntosh apples.

B: There may or may not actually be a policy. This is also a true statement. The conversation does not provide enough concrete information to establish the presence of a documented policy or procedure. The information the supervisor provided the new employee was based on hearsay from the section chief.

Official policies and procedures must conform to certain criteria. Policies should:

- Go through a development, approval, review, and implementation process
- Be generally known and accepted
- Be documented

How these criteria are met will vary form laboratory to laboratory. For the sake of this example, there is no indication that any of the criteria have been addressed.

The document control process the "square peg in a round hole" policy went through is unknown. Whether the laboratory has a document control process at all is also unknown from the conversation of the supervisor and the new employee.

The laboratory director generating a memo stating that "from this day forward thou shall …" does not make the edict an official policy. The laboratory director has responsibility and latitude to influence how things are done within the organization under his charge. However, he cannot on a whim unilaterally make or change established official policy (unless there is an official policy that provides that authority).

There must be a process to create, modify, or rescind a policy to ensure policies meet the operational and quality assurance needs of the organization. This prevents implementing a policy that is a knee-jerk reaction to an isolated incident and that does not consider its long-term impact. The need for the policy must be established or evaluated. This is followed by determining the best way to address the need. Finally, the policy is approved and disseminated to the members of the organization.

The supervisor telling an individual to perform a task in a particular manner does not make it a policy. It can be construed as an order or a directive. It may be in the individual's best interest to perform the task in the manner his supervisor directs. Neither instance makes it a policy, even if the supervisor says it is.

Official policies and procedures take precedence over supervisory orders and directives. The policies and procedures hold the authority of the organization. That is not to say that supervisory directives do not contain a certain amount of authority and should not be followed when appropriate. However, official policies and procedures are the ultimate

authority when addressing a difference between what an individual is told to do and what they should do in a particular situation.

The fact that the task is commonly performed in a particular manner does not make it a policy. The argument that a task has been done a certain way for an extended period of time does not negate the fact that the method is not the best for the task, is "wrong," is contrary to an existing official policy, or does not exist as a policy at all. Policies cannot be grandfathered into existence.

This leads into the next statement.

C: The policy may or may not be documented. The supervisor made no offer of proof of a documented policy or a policy and procedure manual. The words "trust me" should set off alarms of all kinds. To establish the trust, the new employee should fall back on a legal adage and a sacrilegious financial proverb.

The rule of thumb in the legal arena is, "If it is not written down, it does not exist." Basically, if the laboratory has not documented a policy, it does not exist. Historical precedent and accepted practice can be used to formulate a policy. Accreditation bodies or the legal system do not acknowledge accepted practice as the "official" policy, even though some weight may be assigned to common practices.

Documenting policies can be also viewed by paraphrasing a financial adage. "In God we trust, everything else is documented." Oral history may be an acceptable manner of passing family traditions from generation to generation. However, it is not an acceptable way to relay official policies. Each transmission between individuals or administrative levels receives a certain amount of personal interpretation of what the transmitter believes the policy said or what he thinks it means.

This same principle is demonstrated in the game many of us played at summer camp. A one- or two-sentence statement is passed from person to person through a chain of individuals. The resulting statement never resembles the original statement. The comparison of the before and after statements can be quite comical at summer camp. However, misinterpretation of a policy or procedure that has been handed down through multiple individuals over a span of time can have devastating consequences in a laboratory.

Therefore, "all the above" is the best choice in this case.

Application

The series location of this book, *A Volume in the International Forensic Science and Investigation Series,* may appear to limit the application to "crime labs." However, if one broadens the definition or characterization of forensic science, it will become apparent that the principles used in a forensic laboratory's quality assurance program should be incorporated into every testing and calibration laboratory.

Forensic science traditionally refers to laboratory testing utilized in criminal investigations. The results of the tests are presented in court and ultimately affect the life and liberty of the parties involve. Therefore, a stringent quality assurance program, including well-documented polices and a procedure manual, is essential.

If you accept the premise that forensic science is laboratory examinations for the purpose of presenting the results in court, then it can easily be argued that all laboratory examinations could be forensic examination, because somewhere, someday the results

may be presented in court. In the litigious society we live in, this seeming distortion of a scientific discipline may be more fact than fiction.

The results of any laboratory examination have the potential to be presented as part of litigation. Laboratory examinations affect everyone's life. The food we eat, the medicines we use, the things we employ on a daily basis all undergo some type of laboratory testing. If something affects our life, liberty, or health, the laboratory examination associated with that thing will be part of the litigation. Therefore, every laboratory examination has the potential of being a forensic examination. This may be circular logic, but the dots do line up.

A Manual by Any Other Name

Policy and procedure manuals have a myriad of names. General Orders (GO), Standard Operating Procedures (SOP), Administrative Regulations, Policies and Procedures, and Technical Methods are just a few of the variations. Some organizations spend an inordinate amount of time devising cute acronyms to uniquely identify their set of operational manuals.

No matter what they are called, all manuals have the same purpose. They either document what needs to be done and how to do it, act as a reference, or support the implementation of a policy or procedure.

Manual Categories

Operational and technical manuals are the two general categories of manuals exist in the realm of laboratory. Each category has similar components. The only difference is the target audience the manual is directed.

Operational Manuals

Operational manuals are directed at the laboratory's overall function. They apply equally to personnel performing administrative tasks and to technical examinations. The policies and procedures within the operational manual category address the business of doing business.

Operational manuals are one or more groups of policies, procedures, and supporting documents that are directed at all factions of the laboratory. They apply to clerical personnel as well as those in professional roles. Technical employees apply these rules and regulations in the same manner as administrative workers.

Some organizations refer to their operational manuals as their administrative regulations. Other organizations refer to them as their GO. Regardless of the title, they group all of the policies and procedures that effect the "general" operation of the organization into a manual with one or more subdivisions. These directives have general application, although individual policies may affect one group of employees more than another.

This book breaks down the operational manual into four basic categories. The title of each may vary from organization to organization. Some institutions may debate whether some of the groupings should be included under the umbrella of an operational manual.

Other institutions may want to expand this list to include other topics. However, this book utilizes the following categories:

- Administrative
- Quality assurance
- Health and safety
- Sample control (property and evidence)

Technical Manuals

The technical methods manual is a group of guides used by an analytical section. The operational manuals provide guidance concerning the laboratory's generic operation and have applications to all personnel within the organization. The technical methods manuals define the specific requirements of individual examination areas. Unfortunately, there are laboratories that discount the need for each analytical section to have a comprehensive set of technical methods because of the misguided belief that the issues are covered in the laboratory's general polices and procedures manuals.

Each laboratory section has a separate and distinct function that aids the in the quest to fulfill the mission, goals, and objectives of the laboratory as a whole. The duties vary from section to section. Each section should have its own technical methods manual to address the differences in sample substrates, instrumentation, and analytical methods.

The quality of the laboratory's technical methods manuals is just as important as the quality of the laboratory's operational manuals. If one had to choose, one would logically deduce that the technical methods manuals should be given time and attention in an effort to be the more comprehensive set of documents, for the technical methods manuals drive the laboratory's operational machine. Unfortunately, this is not the case in many situations. The need for a quality set of operational and technical manuals is equally important.

Each analytical section has its own unique technical requirements. This is opposed to operational manuals, which have generic application relevant to any type of laboratory. The format and content of technical methods manuals are subject to more customization than operational manuals. Therefore, this book will not provide suggested policy and procedure wording. However, the manuals do contain certain similar components. These similarities exist regardless of the format, style, or detail of the content.

This book will generically address the topics each technical methods manual should contain. These topics include, but are not limited to, the following:

- Training
- Analytical procedures
- Quality assurance
- Documentation
- Inventories

Manual Components

A manual is a compendium of components that are embodied in a variety of controlled and noncontrolled documents. Each component has a specific purpose in relaying information or establishing the rules of engagement that drive the laboratory's operation and quality program.

An operating definition of each manual component must be established to ascertain the component's purpose. Some of the terms are utilized interchangeably when they have specific definitions. The terms *policy* and *procedure* are used interchangeably, just as *precision* and *accuracy* are, even though each term has a specific definition with a specific application.

The manual components that require definition include the following:

- Policy
- Procedure
- Supporting documents
- Static documents
- Forms

Policy

A policy can be defined as "a guiding principle, operating practice, or plan of action governing decisions made on behalf of an organization." They are used to ensure reproducibility. As such, a policy is a precision tool.

Policies are "Thou shall …" statements. They document the laboratory's general or specific concepts and philosophies of operation. Policies do not address implementation unless it is a component of the policy document.

Accreditation criteria are similar to policy statements. They have the "Thou shall …" status by nature of their defining within the accreditation process. As such, many laboratories have modified accreditation verbiage and adopted it as laboratory policy. The following is an example:

- ISO/IEC 17025:2005 (4.1.6)
  - Top management shall ensure that appropriate communication processes are established within the laboratory and that communication takes place regarding the effectiveness of the management system.

- Laboratory Policy
  - The AGENCY NAME management shall establish vertical and horizontal lines of communication within the laboratory and that communication takes place regarding the effectiveness of the management system.

Accreditation results from the implementation of quality practices. Quality does not result from receiving accreditation. Therefore, accreditation criteria should not be the only source of information used to establish the laboratory's policy manuals. Accreditation criteria are essentially a list of best practices. However, each laboratory will have additional situations that required a laboratory policy for purposes of continuity and ensuring the quality of their analytical results.

When drafting policy statements, the author and approving authority must understand and accept the rationale behind their existence. Policy statements need to be specific enough to ensure continuity and uniformity in their administration. However, they should not be so narrow as to be impractical to implement.

Procedure

As you can see from the example in the previous section, the policy addresses the accreditation criteria. The criterion states that the laboratory management must establish a line of communication within the laboratory concerning the effectiveness of the management system. The laboratory drafted a policy to address the criterion. This may seem to have satisfied the accreditation criteria. Unfortunately, the detail concerning how the laboratory management will implement the policy was not addressed. Procedures fulfill that function.

- Laboratory Policy
  - The AGENCY NAME management shall establish vertical and horizontal lines of communication within the laboratory and that communication takes place regarding the effectiveness of the management system.

- Procedure
  - The management team shall conduct regular meetings with section chiefs to disseminate information.
  - Section chiefs shall conduct regular meetings with subordinates to disseminate information.
  - Peer groups shall relay information to the management team.

Procedures are used to complement policy statements by providing instruction on implementation methodology. They are a quality tool used to ensure accuracy and precision by providing direction concerning the acceptable methods used to implement the policy and mandating that all personnel utilize the same procedure. Standardized procedures are used to ensure reproducibility, but accuracy is the primary focus.

Some policies no not require associated procedure. In some instances, the policy is specific enough not to require a procedure to provide implementation guidance. A policy stating, "All employees will only wear red socks," is self-explanatory and does not require implementation direction provided by a separate procedure. However, a policy statement such as, "The AGENCY NAME will establish and maintain a schedule in which employees are required to wear red socks," may require interpretation and implementation direction offered by a procedure.

As with the drafting of policies, drafting procedures requires a balance. The author and approving authority must balance the need for detail to ensure continuity of implementation with the need to provide the latitude to adapt to unforeseen circumstances. Restating excerpts from the previous policy example:

- Procedure
  - Section chiefs shall conduct regular meetings with subordinates to disseminate information, or
  - Section chiefs shall conduct meetings with subordinates on the 15th of each month at 3 pm to disseminate information.

The first example provides the section chief the discretion to conduct meetings when there is relevant information to be disseminated to his subordinates. The second example

mandates the section chief to conduct a meeting at a specific date and time, regardless of the need. Additionally, the laboratory would be in noncompliance of its own documented procedures if the 15th were to fall on a day that employees were normally not on duty and the meeting was not held at that specific time and day, unless there is an exception clause or addendum.

The point of this example is, beware of what you document. If it is documented, it is law. If it is law, it must be complied with without deviation. Specificity in documentation of procedures can be a good thing and has an appropriate application. However, drafting procedure documentation that allows for discretionary implementation while maintaining the integrity and intent of the policy it is augmenting can be more beneficial to the operation of the laboratory.

Supporting and Static Documents

Supporting and static documents are documents that the laboratory relies upon for its daily operation and contribute to the laboratory's quality programs in some manner. The content of these documents is outside of the direct control of the laboratory, but it can be an essential part of their operational policies or procedures. Examples of these documents are legal statutes, regulatory agency requirements, and administrative rules of the laboratory's umbrella organization.

Utilizing support/static documents is a method of deferring the document maintenance responsibility of certain policies and procedures to the administrator of the support/static document. The laboratory must establish a policy or procedure document that references the support/static document as the official policy or procedure. However, if the author and approving authority utilize the proper language, any changes in the references to the support/static document will be automatically incorporated into the laboratory's official policies and procedures.

The following is an example of language that can be used to cite a support/static document as the laboratory's official policy or procedure. "The AGENCY NAME will utilize the most recent revision of the UMBRELLA ORGANIZATION policy concerning … as its guiding document."

Utilizing the phrase "the most recent revision" implies that the laboratory's official policy automatically changes with the change of the umbrella organization's official policy concerning the activity. However, the information concerning what the changes in the support/static document are still requires dissemination. The updated support document must be added to the laboratory's document inventory, and the outdated revision must be removed. These documents are subject to the same document control procedures. The only difference is that the laboratory does not have control over the content of these documents. As such, these are noncontrolled documents and do not require approval through the laboratory's controlled document approval procedure.

Forms

Forms and worksheets are the ultimate in standardizations. The continuity in form and content in documenting the examination process is extremely useful as a quality assurance tool as well as an aid in the examination process. They provide the examiner an outline of the examination that is to be conducted as well as a place to document analytical results or observations.

Forms and worksheets are equally as useful for the technical and administrative reviewer. The technical reviewer knows where to look for the technical information used to form the examiner's conclusion and compare it to the results presented on the laboratory report. The administrative reviewer has specific sections to review to ensure the administrative tasks have been completed and information documented.

Forms and worksheets have a unique distinction in the controlled document community. Personal forms and worksheets that are created by individual examiners to simplify their examination documentation process are not subject to the laboratory's document control requirements. Forms and worksheets that the analytical section requires to be used to document the examination process are generally considered official laboratory documents and subject to the document control requirements established in the relevant operational or quality policy and procedure.

The controlled status of the document may change when an examiner places his personal forms or worksheets on laboratory letterhead. Placing personal forms and worksheets on laboratory letterhead or affixing the laboratory's seal or logo to these documents gives the perception that they are official documents whose use is sanctioned by the laboratory. The use of laboratory letterhead, seals, or logos on personal forms and worksheets should be addressed in an operational or quality policy to eliminate any issues that may arise from such use.

Who Writes the Manuals?

The responsibility for the creation and maintenance of the manuals used by the laboratory is defined by the laboratory's document control policy. The ultimate approving authority is usually given to the laboratory director, with recommendations from one or more sources. In many instances, the QAM is the person responsible for the maintenance of the laboratory's administrative and technical manuals.

The scope of the QAM's responsibilities does not provide much time to develop general policies and procedures. The QAM also does not have the breadth of knowledge required to prepare the technical methods manuals for every analytical section of multifunctional laboratory facilities. Therefore, the actual preparation and drafting of the laboratory's policies and procedures is dispersed among a number of individuals with the knowledge, skills, and abilities to draft these documents.

The drafting of all or a part of the laboratory's policies and procedures can be assigned to individuals outside the official quality assurance component of the laboratory. This is made possible by establishing a document control policy that institutes a review and approval process for all controlled documents, including the laboratory's administrative and technical manuals. Therefore, anyone can prepare the laboratory's official policy and procedure manuals as long as the content is factually actuate information that is presented in an approved format. This includes nonemployees that have been contracted to compile, collate, format, and prepare documents for review and approval by the laboratory's approving authority.

Overview of Quality Assurance 2

Quality assurance (QA), quality control, and Six Sigma are all buzzwords that in one way or another affect the day-to-day operation of a laboratory. The function of the laboratory does not matter. These concepts apply equally to a forensic laboratory that analyzes physical evidence or a water laboratory that analyzes drinking water or an in-house quality control laboratory.

The purpose of a QA program is to ensure the results of a laboratory's analysis are true, accurate, and reliable. This is important in establishing the faith and confidence of the laboratory's clients, whoever they may be. A forensic laboratory's results will impact an individual's personal liberty, having a rippling effect throughout the criminal justice system. The results of water testing will impact the health and welfare of an entire community. In-house quality control laboratories affect the quality of the product that is produced, which in turn is reflected in the confidence of their client or the consumers that will be purchasing their products.

As you can see, each laboratory has a vested interest in the quality of the results that are reported by its analysis. The outputs and end users may be different. However, the need for QA is the same.

The wonder of science is that the principles remain the same regardless of the focus of the examination. Scientific principles and good laboratory technique transcend the type of analytical laboratory. Additionally, scientific principles do not change when one crosses an international border. The available technology may differ from laboratory to laboratory, but the underlying scientific principles remain constant.

As with scientific principles, the basic principles of QA are applicable universally. They apply equally to forensic laboratories, water laboratories, and in-house quality control laboratories. These concepts are so universal, that the International Standards Organization (ISO) has established a standard that outlines the QA requirements for calibration and testing laboratories (17025).

What Is Quality Assurance?

We may have put the cart before the horse. We talked about how a universal principle equally applies to all laboratories. However, we neglected to define what this universal principle of QA is. Simply stated, *quality assurance* is:

> *a documented system of protocols to assure the accuracy and reliability of analytical results.*

The definition of QA is simple and is divided into two parts: documenting protocols, and ensuring accuracy and reliability. To this end, there is a four-prong test used to evaluate the protocols of a QA program. These criteria are the following:

- Is there an official policy or procedure that addresses the issue or analytical scheme?
- Is the protocol documented?

- Is the protocol followed?
- Does the protocol meet the needs of the laboratory or its customers?

All four of these questions must be incorporated into the development and implementation of a QA program. Having a policy or a procedure is one thing. Documenting the policy is another. Making sure everyone follows the policy as written is something else. Monitoring the relevance of a policy or analytical technique and how it affects the laboratory's end product is a different component.

Documentation

There is a legal adage that is applicable in the QA realm. If it is not written, it does not exist. The statement's simplicity addresses the first part of the QA definition, "A documented system of protocols…"

Documentation is the most universal of the two parts of the QA definition. The laboratory must document every protocol used to perform specific tasks so that each task or analysis is performed the same way by everyone in the laboratory. The task or analysis is immaterial. How the task or analysis is performed is immaterial. The key is that the protocols are documented.

Why do we need to document protocols? How many times have you heard the phrase, "everybody knows that…" or "it is common knowledge…" or "it is a policy"? And how many times have undocumented issues that everyone knows, or are common knowledge, or are policy been misinterpreted or manipulated to meets someone's perception of reality or further a personal agenda?

Protocols are documented to eliminate ambiguity. They are there to institute continuity and reproducibility in the end product. Documented protocols establish the laboratory's operational rule book that all employees are expected to adhere to.

Accuracy and Reliability

Reproducibility is the cornerstone of good science. Reproducible results are expected if a protocol is documented and followed. However, reproducibility is of no value if the results are incorrect. Reproducibility is like precision; one can be precise without being accurate. The aim of QA is to be both precise and accurate.

Reproducible results do not necessarily indicate accurate results. A QA program incorporates systems and mechanisms to establish that analytical results are accurate as well as reproducible. This is accomplished though establishing a series of protocols that affect every aspect of the analytical process. Everything from the way personnel are selected, to the procurement of chemicals and equipment, to the analysis itself is documented in a protocol that establishes continuity which in turn leads to precision and accuracy.

Dynamic System

A QA program is a dynamic system. It is a set of living documents that are continually modified to meet the needs of the laboratory and its customers. Analytical techniques change over time. Administrative policies and procedures are added and removed with

the change in management. Customers' needs or requirements shift. Legal issues affect the implementation of protocols. All of these issues result in the changes to the laboratory's protocols. As such, the QA program adapts to meet the ever-shifting quality demands.

QA Is Not Optional

A QA program is not optional. This is a strong statement and can be misleading. The world will not come to end if your laboratory does not have an official QA program. Laboratories have operated for years without them. However, it is in the best interest of the laboratory to have a viable QA program if it plans to be competitive and survive.

A documented QA program is not optional if the laboratory seeks accreditation. All accreditation bodies require some form of documented QA program. Accreditation may or may not be required for the laboratory to exist. However, it provides an external validation that increases the laboratory's credibility, which in turn will affect the number of its clients.

Quality Assurance Program Components

It slowly becomes apparent that a statement that appears simple on the surface can become complex as it is examined in detail. A quality program is like an onion. On the surface, it appears to be a simple sphere. However, when it is opened for examination, it reveals numerous layers that are all connected to a common core.

The components of a QA program include, but are not limited to, the following:

- QA manual
- Staff qualifications and training (initial and in-service)
- Proficiency testing (internal and/or external)
- Sample collection, handling, and storage
- Documented, standardized, and validated procedures
- Reagent and instrument reliability
- Authenticated reference material

Quality Assurance Manual

The QA manual is the laboratory's play book. It defines the generic quality protocols used by the laboratory. The QA manual, in combination with administrative and technical manuals, is used to address all of the laboratory's operational issues.

The laboratory's general QA manual provides broad guidance to what QA programs will be implemented within the laboratory. Additionally, each analytical section will have QA specific issues. Therefore, the technical manuals for each operational area should have a QA section that addresses their specific requirements.

The QA manual topics should include, but not be limited to, the following:

- QA program overview
  - Program objectives

  - Program definition
  - QA manager

- Audits, evaluations, and reviews
  - Quality system audits
  - Inspections
  - Record keeping

- Document control
  - Policy and procedure manuals
  - Manual development, maintenance, and control
  - Documentation

- Equipment and chemicals
  - Chemicals
  - Equipment
  - Reference materials
  - Weights and measures

- Personnel
  - Minimum qualifications
  - Training
  - Proficiency testing
  - Professional development

- Evidence/sample handling
  - Submission procedures
  - Processing procedures
  - Disposition procedures

- Corrective actions
  - Risks
  - Issues

- Laboratory information management system (LIMS)

Staff Qualifications and Training (Initial and In-Service)

A laboratory's staff is its most important resource. A modern facility equipped with state–of-the-art equipment is quickly nullified if the staff is unqualified or poorly trained. Therefore, the selection and training of personnel is critical.

The QA manual defines that only qualified personnel will be utilized to perform the various tasks the laboratory is responsible for performing. The specifics concerning the qualifications and training of personnel can be addressed in the QA manual or other laboratory operational or technical manuals. For example, the position descriptions within the administrative protocols may address the knowledge, skills and abilities required for specific job functions or categories. The training section of the analytical section's technical

manual will define the basic course of training that every new employee will receive prior to performing work for clients. The QA manual may define the professional development activities employees will be provided to ensure they maintain a current level of knowledge concerning their functional area within the laboratory.

Proficiency Testing (Internal or External)

Proficiency testing is a means of validating a number of different issues at once. Contrary to the popular belief of many laboratory managers, proficiency tests are more than a means of testing an examiner's skills. Proficiency tests are a means to demonstrate to the laboratory's management, as well as their clients, that the laboratory can achieve the correct result when an analyst is provided an unknown sample from an internal or external source. They authenticate the whole analytical system, not just a single component; that is, the examiner's competence.

Proficiency tests evaluate the competence of the analyst. The evaluation goes beyond the correct result obtained. The analyst's thought process, method selection, and analytical technique are examined during the proficiency test review.

Proficiency tests validate the method(s) used in the analysis. They are used to establish whether or not the analytical methods available to the laboratory are adequate to examine the samples that are presented in the proficiency test. They assist the laboratory in determining what modifications to their methods are necessary to enable them to hit the target value.

Proficiency tests establish the detection limits of the equipment and methods used. Failure to hit a target value may be a function of the equipment and not the analyst. Failure to obtain a target value due to equipment limitations may provide management the justification required to procure new equipment or modify the detection limits of their existing equipment to meet the parameters established by the proficiency test.

Sample Control (Collection, Handling, and Storage)

Sample integrity is just as important to a commercial laboratory as it is in a forensic laboratory. The mechanisms may be different. However the concept is the same. What happens to the sample during the collection process, how it stored, how it is handles during the examination process all influence the analytical results. Therefore, a QA program must address these issues.

Documented, Standardized, and Validated Protocols

Documented, standardized, and validated protocols are an essential component of a QA program. Documented protocols are necessary to remove ambiguity. Standardization is required to ensure everyone utilized the same protocol under the same analytical situation. Validation is required to ensure the protocol works under the analytical conditions available to the laboratory.

There are arguably multiple ways to approach an analytic problem. However, not every approach is deemed acceptable by the laboratory's management. Through a documented process, the laboratory management has established which types of analysis will be utilized and the conditions under which the examinations will take place. This standardization is essential to ensure reproducibility of results regardless of the analyst involved in the examination.

Analytical methods and equipment must be validated to ensure they function as designed. Reproducibility being the cornerstone of good science, analytical methods described in the scientific literature need to be validated to ensure they function as described in the reference. Equipment needs to be validated to ensure the results produced when examining known reference materials are consistent with the expected results. The results of these validation studies need to be documented, as everything else in a QA program.

Reagent and Instrument Reliability

The reliability of chemicals and equipment must continually be monitored as part of a QA program. Chemicals become contaminated. Reagents become outdated and do not function properly. Instrument calibration drifts or instruments do not function correctly. Mechanisms must be implemented to monitor the purity and the reactivity of the chemical and reagents used in the testing process. The calibration and functionality of the instruments used in the testing process must be continually monitored to ensure the reliability of the data they produce. As with validation, these results require documentation.

Authenticated Reference Material

Authenticated reference materials are required for equipment and creating reference libraries. This may seem like circular logic when considering that previous sections appear to require validation and confirmation of operation of analytical methods and equipment that has previously demonstrated their functionality.

The use of reference material from a known source—that is, "traceable standards"—provide a reference point on which all validations and reference libraries and identifications are based. These materials are obtained from vendors who adhere to strict QA protocols to ensure the authenticity of the materials. These materials are considered "truth" and do not require validation. As such, a laboratory cannot make a proper identification or validate its methods or equipment without authenticated reference materials.

Responsibilities

The implementation and maintenance of a QA program is a team effort. The program's function can be equated to the three components of a baseball team. Each group within the laboratory has specific responsibilities. If one member of the team shirks their responsibility, the whole team suffers.

A baseball team has three components: the owner, the players, and the coach. The laboratory's management plays the role of the front office; that is, the owners or general manager. The analysts are the team's players, implementing the various parts of the program. The QA manager coaches the analysts into using good QA techniques, just as a coach motivates his players to perform at their best.

Senior Management Responsibilities

The support of the senior management is an essential component of a successful QA program. Without their unconditional support, the program is doomed to failure. So essential

is their support, that the ISO 17025 accreditation requirements for calibration and testing laboratories have specific criteria.

4.2.2a the laboratory management's commitment to good professional practice and to the quality of its testing and calibration in servicing its customers;

4.2.2e the laboratory management's commitment to comply with this International Standard and to continually improve the effectiveness of the management system.

Old-school laboratory managers have historically failed to see the benefits of implementing QA systems, much less accreditation programs. They generally have viewed them as additional administrative duties that cut into the laboratory's productivity, ultimately affecting the bottom line. They only begrudgingly implement a QA program under the edict of their supervisors.

Over time, with training, education, and in some instances, attrition, these managers have come to see the benefits of QA programs. More important, they are slowly acknowledging their advantages.

Define Goals and Objectives

Just as a baseball team's owner defines the team's expectation, so does the laboratory's senior management. The laboratory's director and his senior staff define the laboratory's goals and objectives. This establishes the framework of the program as well as defining the expectation of the analysts.

Facilitate Deficiencies with Corrective Action

Senior managers have to make tough decisions. They have to take the appropriate corrective actions when deficiencies are brought to their attention. Ultimately, the senior managers are responsible for the QA decisions and the action or inactions of everyone on the team.

Deficiencies and problems do not go away. They only get worse with time. Trying to hide a problem only makes it worse. The problem will always be detected. The best way to mitigate the effect of a deficiency is the swift corrective action by the senior management.

The short-term affects of an immediate corrective action may be financially painful or briefly publicly embarrassing to the laboratory. However, the long term ramifications of intentionally ignoring a deficiency, no matter how insignificant, can destroy a laboratory's reputation or the career of one or more senior managers.

Provide Necessary Equipment and Training to Optimize Performance

Every baseball team needs equipment to play the game. Team Laboratory is no different. They require the best equipment available within the financial means of the laboratory. This not only includes providing a sustainable level of technology, but also includes providing the auxiliary support items required to optimize it use and the reference material necessary to insure the equipment functions properly.

Supporting the team extends beyond providing equipment and the items necessary to support it. The senior management must commit to providing training in it proper use and maintenance. Additionally, the management must commit to a professional development program to bring the best out of its players (the examiners).

Strive for Continuous Improvement

Laboratories are a dynamic working environment. The knowledge curve concerning scientific techniques and methodology has increased at an exponential rate over the last 30 years. It is the laboratory's senior management's responsibility to keep abreast of the technology and analytical methods utilized by their facility in an effort to improve the services they provide their clients.

A laboratory's QA program will need to change with every change in technology or analytical methods. The QA team will need to be reviewed and policies, procedures, and analytical methods modified on a regular basis to meet the needs of their clients and to address changes in statutory regulations, shifts in current QA theories, or changes in accreditation criteria. Therefore, the senior management should continually strive for self improvement to address all of these issues.

Recognize If It Is Not Formalized by Documentation, It Does Not Exist

QA program documents define the expectations and obligations of everyone in the laboratory. The laboratory's policies and procedures are the rules that define how to perform any task within the laboratory. Consistency in examination results will waver without this documentation, due to personal interpretations of analytical methods. This consistency in analytical technique is critical to ensure the precision and accuracy the laboratory's clients demand.

Managers have the right to expect the best from their employees. By the same token, employees are obligated to meet or exceed the expectations of the laboratory management. One of these parties will be disappointed unless there is a formal understanding concerning the expectations of each side. Documentation serves as the cement that solidifies management's expectations and the employees obligations.

Analyst's Responsibilities

The analyst is the most significant player of the QA game. The senior managers can demand programs be implemented. The quality manager can mentor and foster the implementation of the programs. However, if the analysts do not successfully implement the programs, the effectiveness of the QA program is marginalized. If the analyst constantly drops the ball by not properly implementing the QA programs, the quality game will be lost.

Analyst Acceptance

The analyst's acceptance of a QA program is more essential than the senior management's if the program is to be effective. The senior managers can get away with paying "lip service" to the program and the program will function. The analysts have to implement the programs on a daily basis. They have to live with the programs, so their acceptance is crucial.

Every laboratory analyst is on the front line of back log wars. Managers will deny it, but every analyst is evaluated on the number of samples he analyzes. To one degree or another, every analyst views QA as unnecessary busywork that reduces his productivity, affecting his evaluation and potentially his career. Therefore, analysts will be resistant to embracing the implementation of QA programs.

Analysts misunderstand the long-term effects of QA programs because QA is not taught as a core class in any university science program. Through education and training,

analysts realize that the implementation of QA programs has a positive effect on their work product. Additionally, they realize that everyone is subject to QA policies. Therefore, any adverse effect on their productivity is negated, because all analysts are required to implement the same QA policies.

Conduct Appropriate Laboratory Examinations

Analysts are responsible for conducting appropriate laboratory examinations. More important, they are responsible for conducting the examinations according to the appropriate "documented" procedure without modification. This is essential to establish continuity in the laboratory's work product.

As part of conducting the appropriate examination, the analyst is responsible for applying the associated quality control procedures, which are part of the QA program. These procedures serve as the check and balance to ensure the accuracy and precision of the results are maintained.

Identify Quality Issues and Risks and Potential Solutions

Analysts are in the best position to be able to identify risks and issues that will affect the quality of laboratory analysis. It is their responsibility to bring these risks and issues to the attention of senior management and the quality manager as soon as they become apparent. The managers are then responsible for addressing the situation as soon as reasonably possible.

The analyst should also suggest remedies to mitigate or eliminate the risk or issue. The analyst is in a good position to suggest resolutions to the potential risks or issues for the same reason they are in a position to be the first to identify them. They work with the situation on a routine basis, so their familiarity may provide the insight necessary to resolve the situation.

Quality Manager Responsibilities

The quality manager is the unsung hero of the QA game. At the same time, the position is the most feared and hated in the laboratory. He is the means in which the management's vision is effectively put into play by the analysts. Their position holds the broadest set of responsibilities of anyone in the laboratory. The position is so essential to the quality of a laboratory's analysis that the ISO requires that laboratories seeking accreditation under 17025 name a quality manager.

Keeper of the Documents (Document Control)

A QA program in essence is a paper mill that generates and collects records that document some component of the quality of the analyses that are performed by the laboratory. The records the quality manager maintains include, but are not limited to, the following:

- Audit records
  - Coordinating administrative audits
  - Coordinating and conducting inspections
  - Coordinating accreditation activities
  - Maintaining audit and inspection records

- Document control
  - Preparation and maintenance of operational manuals
  - Preparation and maintenance of technical manuals
  - Preparation and maintenance of training manuals

- Employee records
  - Training records
  - Proficiency testing
  - Testimony monitoring
  - Corrective actions

- Chemicals and equipment
  - Chemical inventories
  - Reagent preparation logs
  - Equipment inventories
  - Instrument calibration logs
  - Instrument maintenance logs

- Risk management (corrective actions)
  - Risk identification
    - Risk is a situation that could potentially affect quality if steps are not taken to avert situation.

  - Risk abatement
  - Issue identification
    - An issue is a situation that is affecting quality and must be addressed.

  - Issue resolution
  - Corrective action reports

It is apparent that there is more than enough work to occupy a quality manager's day. The unfortunate thing is that many laboratory directors do not appreciate the enormity of the quality manager's job. If a laboratory is fortunate enough to have a full-time quality manager, it is not uncommon for the laboratory director to assign him other duties with a higher priority.

In this instance, quality is not job one, to paraphrase a General Motors commercial. If it were, the other assigned tasks would take the backseat to the QA task of the quality manager. More times than should occur, the QA tasks are left unattended because the quality manager has been assigned other tasks that the director feels are more important than monitoring the quality of the laboratory's work. QA tasks do not regain priority until a risk becomes an issue, something dramatic happens that exposes a severe deficiency in quality, or laboratory accreditation is three months away and three years of document revisions need to be accomplished in three months.

Champion and Cheerleader

The quality manager must be committed to the QA program if it is to be successful. The program will exist and marginally meet the needs of the laboratory without this dedication.

However, the QA program needs a champion if it is to reach its potential and achieve the goal of continual self improvement.

The quality manager needs commitment and dedication to the program. He needs to sincerely believe in the benefits of the implementation and maintenance of quality programs. It will be hard for the quality manager to obtain approval and acceptance if the sincerity and commitment to the quality programs he is advocating are not apparent.

The quality manager should champion quality programs. He must continually remind everyone that "quality is job one," with emphasis on pride in the laboratory and its products. He should continually advise and remind the management of the benefits of quality programs. He should monitor and consult with the analysts to ensure they are implementing the quality programs as designed. Additionally, the quality manager should sing the praises of QA, reminding managers, analysts, and clients how the laboratory's quality programs benefit everyone.

A successful quality program can be equated to a successful party. Parties are generally more enjoyable (i.e., successful) when everyone participates. Quality programs are more successful when everyone (i.e., management, analysts, and clients) has input. The quality manager is the party host, ensuring everyone is involved. In essence, he acts as the annoying cheerleader-type party host that forces people to mingle, interact, and actively participate, ultimately benefiting the party/quality program.

Voice of Reason

The quality manager is the laboratory's voice of reason and moderation. As such, he is continually reminding everyone that quality programs are not something extra. They are the foundation of everything action of the laboratory. The quality manager is the laboratory's spokesperson that notifies the management concerning potential risks and detrimental issues.

This voice comes with significant responsibilities. The quality manager's opinions must be based on facts. He should never make assumptions and should double check all facts before presenting risks, issues, and recommendations to management for resolution. If he does not, management may take actions and implement policies that will cause more problems than originally existed.

The quality manager must recognize that no system is perfect. As part of the policy of continual self-improvement, his responsibility is to identify and prioritize quality concerns that are presented to the management.

Quality problems do not mysteriously appear or are not a result of fate. There is an identifiable cause to the problem. The quality manager is responsible for collecting and presenting the data reflecting the quality problem to the management. He should not minimize the potential affects or equally distort the potential damage in his presentation. He should use his voice to reasonably present the facts with the supporting data and his recommendations to the management for a resolution decision.

Quality Assurance Benefits

The benefits of implementing quality programs can be intangible and, as such, difficult to assess. Some managers view accreditation requirements as the only reason for

implementing quality programs. They do not see the fact that implementing quality programs that meet the needs of their customers is more importantly good business practice.

Many old-school laboratory managers feel that the time used implementing quality programs will affect the number of samples that are processed. They do not look at the long-term effect of not implementing these programs. In some instances, implementing quality programs will increase productivity.

Implementing quality programs reduces reanalysis time. Reanalyzing a sample more than doubles the processing time. That does not take into account the time required to detect and correct the issue that caused the sample to be reanalyzed.

Having an established quality program provides credibility to the laboratory and enhances its image within its analytical community. Many clients choose a laboratory based upon reputation. They are more likely to choose a respected laboratory with an active quality program over an unknown entity with unknown quality practices. Clients are less likely to bring samples to a laboratory whose results cannot be trusted. Quality programs help provide that trust.

In the world of forensic laboratories, quality programs reduce the challenges in court leading to testimony stipulations and minimizing analyst court appearances. The analyst cannot process samples while he is preparing for trial, giving depositions, traveling to court, waiting to testify, or providing testimony. Therefore, implementing a quality program increases sample output.

Quality Assurance Cost

Establishing and maintaining a quality program is not free or cheap. The costs of a quality program can be measured, even though the benefits may not be tangible and difficult to measure.

The cost of the maintenance of a quality program is estimated to be 10–20% of a laboratory's operating budget. This cost is significantly higher while the program is initially being established and during times when accreditation is being sought.

A significant amount of time and effort is dedicated to the preparation of a laboratory's polices and procedures. These documents serve as the foundation of the laboratory's quality program. Every aspect of its operation needs to be documented, so there is no question concerning how to address any given issue.

Another significant amount of time is dedicated to personnel issues. QA principles need to be taught, incorporated, and accepted by every segment of the laboratory. The time taken to teach and transition employees to a culture that embraces quality programs affects the laboratory's productivity.

Productivity Costs

QA programs do affect laboratory output. Fewer samples can be processed in a given amount of time because QA steps are part of the analysis. This leads to longer processing times. The laboratory's management should factor this processing time increase into the cost of analysis.

Prevention Costs

Quality programs have prevention associated costs. These costs are used to reduce or eliminate risks and issues that may ultimately cost the laboratory more if they are not addressed before they become a problem.

Staff members must be provided training in their area of responsibility. This training includes not only basic and refresher training, but any remedial training required to correct deficiencies when they are encountered. Additionally, the costs of other professional development activities, such as professional association dues and attendance of professional meetings, should be included in the cost of employee development.

Instrument maintenance and calibration is another cost associated with implementing and maintaining a quality program. The validation and calibration of instruments requires the procurement of traceable standards. In some instances, expert technicians are required to provide routine maintenance and calibration activities to the testing equipment. Both of these are costs that are not directly associated with the analysis of a client's samples, but must be factored into the cost.

Laboratory design can affect quality. Poor design may lead to contamination issues and require remediation. Inefficient layout may require changes in the laboratory's floor plan or reorganization of work space to increase efficiency and the associated quality. This is another cost associated with quality but not directly attributable to sample examination.

Preparation of the QA manual and the other administrative and technical manuals required for the daily operation of the laboratory requires time. Moreover, the maintenance of these documents requires time and effort to ensure the information they contain is the most current available. Additionally, there is a cost associated with the initial dissemination of these manuals as well as their associated updates.

Appraisal Costs

A QA program is a continuous state of appraisal. The combination of internal and external evaluations constantly monitors laboratory operations, looking for ways to improve them. This is all part of the goal of continuous self-improvement.

This constant state of reflection has a significant impact on quality but comes at a price. Appraisals, evaluations, inspections, whatever label you want to place on them, all cost time, resources, and in some instances, money.

Proficiency Tests

Proficiency tests are a mechanism in which the laboratory establishes the competency of its analysts. Some laboratories only utilize proficiency tests as part of an accreditation or certification program. Other laboratories do it because it is good business practice to be able to demonstrate to their clients that their analysts obtain the correct results when presented with a blind unknown test sample. Most do it for a combination of reasons.

Testing and evaluation takes time and resources beyond the time and resources used by the analyst to perform the test examination. Time and effort go into the preparation of the test. More time and effort must be exercised in the test's evaluation. If an external test is used, the cost of the test must be factored into the equation.

As stated previously, proficiency tests test the analytical system as a whole, not just the analyst. Unfortunately, too many laboratory managers use an incorrect result on a proficiency test to justify disciplinary action instead of as a quality tool. Rather, the managers should be evaluating why the system produced the incorrect result was achieved.

Even more resources must be expended if the test result does not achieve the test's target value. The time to evaluate why the examination missed the target is used. The time and cost of correcting or updating the defective equipment is an expense. The time and effort required to update, validate, and document new methods is another unanticipated cost. Time the analyst is not allowed to perform casework is lost, unproductive time. The time and effort used for remedial training and retesting is unproductive time as well.

Audits

Audits, inspections, evaluations, whatever the name, are a means of evaluation that is necessary for self-improvement. A laboratory cannot address problems if it does not know they exist. Audits and such provide the laboratory a mechanism to recognize risks before they become an issue and to identify issues before they become a problem.

Audits, even self-conducted internal audits, come with a cost. Internal auditors and inspectors must be taken away from their normally assigned tasks to perform the audit and draft the subsequent audit report. One or more days of analyst productivity is lost in preparing for the inspection. An additional day or more of analyst productivity can be lost during the audit itself. Finally, there is the cost associated with remediation of deficiencies detected during the audit.

External audits reduce certain costs at the expense of others. The use of external auditors allows the managers who would perform an internal audit to continue to execute their normal assigned duties, eliminating the cost of the loss of their productivity. However, there is a financial cost to using external personnel. The cost can be simply monetary by simply paying for an outside audit. Or the cost will be in the loss of future productivity because the laboratory is trading time with other laboratory managers.

Accreditation

Accreditation is an extreme form of an external audit. It is used to validate the laboratory's quality programs and compare them to a set of established criteria. It is also a means to demonstrate to the public that the laboratory meets a known standard of quality.

Accreditation has its cost. There are fees associated with the inspection process. Additionally, there are the time and resources that most be dedicated to preparing for the inspection and other accreditation activities. These costs can be discounted if one looks at them as the costs that would be normally encountered under the laboratory's quality program.

Some laboratories feel the cost of accreditation is unnecessary and that opening their operation to outside scrutiny would be detrimental. They believe that their in-house quality systems are more than adequate. However, there can be a cost for not participating in an accreditation system as well.

The Federal Bureau of Investigation's forensic laboratory maintained this attitude for years. They refused to participate in a forensic laboratory accreditation system they in part helped to establish. They felt that their internal quality mechanisms and the perceived need to keep their procedures proprietary outweighed the need for external validation. The FBI laboratory did not accept and embrace accreditation until a change within the highest

levels of the FBI management structure and bad publicity concerning the internal workings of the laboratory forced them to reevaluate their position on accreditation.

This change in philosophy ultimately was costly to the FBI laboratory. Policies and procedures had to be changed and documented. A whole culture and mindset within the laboratory had to be changed through training and education. Additional staff had to be hired to manage their quality programs. Hundreds if not thousands of man hours of productivity were lost during this transition. All of this could have been spread over time if they had accepted the inevitable nature of laboratory accreditation when it was first introduced.

Corrective Action Costs

There is always a cost associated with repair or maintenance of situations that affect operational performance. A laboratory is not different. A laboratory will incur corrective actions costs associated with repair, maintenance, or remediation of risks and issues that affect the quality of the laboratory's operation.

Ignoring a risk or an issue is not an option. The problem will not diminish or disappear. The problem will be enhanced over time. Minor issues will become major problems when it comes to light that the management knew the issue existed and failed to act. Hence, inaction is viewed as an action and can be viewed as an approval of practices that adversely affect the quality of the laboratory's output.

The investigation of potential risks and issues to determine how they will potentially affect the laboratory's quality takes time and resources. Developing and implementing a remediation plan to address valid risks and issues takes additional time. Finally, evaluating the remediation actions to see if they had the desired results is another cost of corrective actions. This sequence of actions takes time and resources away from laboratory productivity, but it must be done in an expeditious manner.

Other costs associated with corrective actions may include the reanalysis of samples that the issue may have had impact on. Revising or creating new policies, procedures, or analytical methods to address the risk or issue may be necessary. Retraining personnel to correct substandard performance or to implement new or revised procedures must be factored into the cost of taking corrective action.

Damage control is a hidden cost of a QA program. Admitting there was an issue will affect the laboratory's reputation (a cost). Openly expressing how the laboratory plans to address the issue can minimize that cost. However, hiding or denying the issue existed issue existed will only compound the initial cost associated with the issue but add an additional cost of the loss of trust due to lack honesty.

Cost of NO Quality Assurance

There is a cost associated with QA, whether it is implemented or not. The laboratory can pay the cost of implementing a QA program or pay the cost associated with not implementing it. Either way, the laboratory is going to pay. It is up to the management who gets paid and how much.

Negative Image

There is a business adage about negative publicity being ten times more powerful than positive publicity. Positive publicity creates and retains clients and customers. Negative

publicity repels far more that potential customers and erodes the confidence of existing clients at a much greater rate. Therefore, it is the laboratory's best interest to create and maintain a positive image and a viable QA program will help them do that.

Not having a viable QA program creates a negative image concerning the results produced by the laboratory. It erodes confidence in the results it generates. This erosion can have a snowballing affect. Lack of confidence can lead to media publicity. Media publicity tends to distorted facts, which creates a bigger problem. Given time and enough media attention, a simple fact that a laboratory did not perform a quality check on one reagent during an analysis can be distorted into a complete lack of confidence in the laboratory's ability to perform any type of analysis.

All laboratory results can potentially become part of criminal or civil litigation. In a legal system where credibility is essential, the lack of a QA program can be the difference between acceptance and disbelief. The "trust me, I am a scientist" is not sufficient in an adversarial legal system. The lack of a QA program will lead to unnecessary probing attacks on the laboratory's credibility by the opposing council.

Consequences

The lack of a QA program has many ramifications and consequences that have far reaching effects. In some instances, they can affect the life or liberty of individuals that are indirectly associated with the client or customer. In these instances, the existence of a QA program is essential to protect the life and liberty of those affected by the results generated by the laboratory.

How does the pharmaceutical laboratory justify not noticing that the wrong drug was placed into one of the company's preparations? How does a medical laboratory justify mixing samples to a person whose health was affected by the reported laboratory results? Who is going to give back the years of wrongful incarceration to an individual who has been convicted of a crime due to faulty laboratory results? These are real consequences that result on a recurring basis because of the lack of a QA program or not adhering to its procedures.

There are additional consequences and costs associated with mistakes that occur as a result of a lack of a QA program. The person who is ultimately affected adversely by a laboratory's incorrect results may be granted compensatory damages. In addition, punitive damages may be awarded, if it is determined that the presence of a QA program would have prevented the mistake and the laboratory knowingly did not implement a QA program that would have prevented the mistake. Finally, that laboratory will be forced to expend the cost of time, money, and resources to implement a QA program it should have had in place in the first place.

Quality Control

QA and quality control are often confused and used interchangeably. *Quality control* is defined as:

> *documented laboratory operations that ensure that the data generated are of known accuracy to a stated quantitative degree of probability.*

Simply stated, QA is a system. Quality control is a component of the system.

Quality Control Operations

Quality control operations are a series of procedures that document various laboratory operations. This creates a paper trail that demonstrates that the different components of the laboratory are functioning as designed before, during, or after the analysis in questions was performed. Quality control operations include, but are not limited to, the following:

- Document control procedures
- Audits and inspections
- Training procedures
- Proficiency testing
- Method validation studies
- Method standardization
- Instrument calibration and maintenance record
- Use of traceable reference samples
- Corrective action procedures

Quality Assurance Documentation

The objective of QA is simple. It is to provide a series of documented standardized protocols to ensure the quality of the analysis that the laboratory performs. As a result, every step of the analytical process is documented to ensure the accountability and traceability of the samples and their associated data. The accountability and traceability extends beyond the client's samples to the equipment, chemicals, and reference material used during the testing process. Additionally, there are procedures to ensure the protection of data from loss or alteration.

QA documentation can be divided into two basic categories of protocols and information. Protocols define tasks (policies) and the methods used to perform them (procedures). Information refers to all of the data that are acquired by the laboratory, without regard to its origin.

Protocols

A comprehensive QA program requires that a laboratory documents what it does and how it does it. The documentation process removes any ambiguity that may occur concerning how and why the laboratory functions the way it does. It also ensures that a task is performed the same way every time by every individual who performs it. This operational consistency is essential to guarantee reproducible results.

Performance consistency in administrative functions is equally important to their counterpart in the technical areas of laboratory analysis. Therefore, a set of policies and procedures must be drafted to address these functions as well.

Protocols are compiled in a series of policies and procedures. Policies define what needs to be done. Procedures define how the policy is to be implemented. These can take the form of a single narrative document or as a set of individual documents, each

addressing individual topics. The format is up to the discretion of the laboratory's management.

Protocols can be generally divided into two categories, operational and technical. Operational protocols apply to all factions of the laboratory. Technical protocols apply to the analytical tasks.

Protocol topics include, but are not limited to, the following:

- Operational protocols
  - Administrative issues
  - QA issues (general application)
  - Health and safety
  - Property and evidence

- Technical protocols
  - Training
  - Analytical methods
  - QA (specific applications)
  - Reference materials

Information

Information refers to all of the data that are acquired by the laboratory, without regard to its origin. Every action within the laboratory must be documented in some form. This serves a number of functions. First, it provides a record that the task in question was performed. Second, the information provided by these records can be utilized to improve or correct any of the laboratory's operations.

In a litigious society, it is important to be able to prove a task was performed and its results. The adage that if it is not written down, it does not exist, is extremely applicable in the realm of QA.

This adage applies not only to records that can potentially be introduced into a court of law, but to the maintenance of equipment or the ordering of supplies. Maintenance records give insight as to when preventive maintenance is required as well as providing the service engineer information he needs to diagnose problems when they occur. Supply records provide information concerning consumption trends that indicate need or can be used to determine expiration dates of chemicals or perishable reference materials.

Information can be used to establish the laboratory's due diligence. Training records establish the fact that analysts were provided the appropriate training and continuing education in the examination areas they are responsible for. Corrective action reports establish the fact that the laboratory was aware of a risk or issue, the steps it took to address them, and the result of the mitigation. Information establishes the facts that the chemicals and equipment used to perform the examinations were free of contamination and functioning as designed.

Information topics include, but are not limited to, the following:

- Results of calibration and maintenance
- Personnel training
- Validated analytical methods

- Reagent preparation logs
- Continuing education
- Peer review of all phases of laboratory operation

Summary

Establishing a quality program is much more than a checkmark on an accreditation punch list. Establishing and maintaining a quality program is simply good business. The benefits derived from these programs are immense. However, there is a cost.

The key to a successful quality program is a documentation system that is easy to understand and simple to maintain. The balance of this book will provide suggestions on how to develop and maintain the documentation for your laboratory's QA program.

Implementation Strategies

II

Project Management 3

Overview

If the key to a successful quality assurance program is the manuals and associated documents that define the program and its various components, then the key to the design and implementation of the laboratory quality assurance manuals and related quality system procedures (QSP) is the utilization of a systematic project management approach during their development. There are hundreds of books, Web sites, and programs devoted to the study and implementation of project management. The goal of this chapter is not to provide an all-inclusive discussion of project management and its application, but to provide a framework for the laboratory involved in an initiative to create these documents as part of their quality assurance program. To that end, this chapter will focus on an explanation of what project management is, why is it needed, and the specific tools and techniques that can be used to provide the systematic approach for the laboratory during the design and implementation of their quality assurance methods, manuals, and procedures. At the conclusion of each section, a listing of each project management template and best practice (BP) checklist referenced in the section will be provided.

What Is Project Management?

The Project Management Institute (PMI) in the "Guide to the Project Management Body of Knowledge" (PMBOK), defines project management as "the application of knowledge, skills, tools and techniques to project activities to meet project requirements" (PMI 2000). Project management provides a systematic approach to the management of projects, regardless of their size, duration, or complexity. At a minimum, project management does the following:

- Ensures that the product that the project is to deliver is clearly defined and understood by all parties.
- Enables the objectives of the project to be clearly defined and closely aligned to the business objectives of the organization.
- Promotes a structured and logical approach to planning and encourages more accurate estimating of time, cost, and other resources.
- Provides the project manager a means to manage project risk.
- Provides a consistent means to monitor and control.

What Is a Project?

The PMBOK defines a project as "a temporary endeavor undertaken to create a unique product or service."* Typically, a project is a one-time effort to accomplish an explicit objective by a specific time. Unlike an organization's ongoing operations, a project must eventually come to a conclusion. Over time, projects may be undertaken at all levels of the laboratory. Some of the projects may be short in duration. Some may require individuals from all levels of the laboratory. Others may involve only a single person. Examples of projects that may be undertaken by the laboratory include the following:

- Developing a new quality assurance manual and related procedures
- Developing or acquiring a new or modified information system
- Constructing a building or facility
- Implementing a new procedure or process
- Organizing the annual conference

So, what are the characteristics of a project? What makes a project different from the daily work carried out in the laboratory (e.g., processing physical evidence, sample control, and employee recruitment)? Generally, projects have a specific start and end date, an approved budget or cost constraints, assigned resources that may be in limited supply, and deliverables requiring definable tasks that may be unique in nature. Additionally, all projects will have some level of inherent risk and should provide some measurable benefit to the organization. Thus, a laboratory embarking on the design and implementation of the operational and technical manuals necessary for successful laboratory accreditation is said to be undertaking a project. The deliverables will most likely be needed by a certain date. The laboratory may have set aside a specific budget for the development of the policies, procedures, and static documents. Resources (or external vendors) will be required to do the development. There may be one or more risks related to the laboratory's ability to complete the task.

Project success is not guaranteed. If you search the Internet, you will find statistics showing 50%, 75%, and even 100% of projects fail. Project success is critical if not mandatory for the development of the quality documents in preparation for laboratory accreditation. By utilizing a systematic project management approach and understanding the critical success factors of the project, the chances of succeeding can be improved. A systematic project management approach, regardless of budget, level of effort, or benefit to the organization should employ the following success criteria:

1. Executive management support of the project
2. Laboratory personnel (users) involvement
3. Clear statement of goals, objectives, and requirements
4. Proper planning
5. Realistic expectations
6. Smaller project milestones
7. Competent staff

* *A Guide to the Project Management Body of Knowledge* (PMBOK® Guide)—Fourth Edition© 2008 Project Management Institute, 14 Campus Blvd., Newton Square, PA 19073–3299 USA.

What Are the Phases of a Project?

Over the years, those involved in managing projects have observed that projects have special characteristics that can be exploited to manage them more effectively. One of those areas somewhat peculiar to the project environment deals with project phases:

- Projects go through definite and describable phases.
- Each phase can be brought to some sense of closure as the next phase begins.
- Phases can be made to result in discrete products or accomplishments (e.g., design of quality assurance manual template needed before construction of the document) to provide the starting point for the next phase.
- The cost for each phase begins small and increases throughout the project, culminating in development, procurement, and the operations and support phases.
- Phase transitions are ideal times to update planning baselines, to conduct high-level management reviews, and to evaluate project costs and prospects.

Projects should be structured to take advantage of the natural phases that occur as work progresses. The phases should be defined in terms of schedule and also in terms of specific accomplishments. You should define how you will know when you are finished with each phase and what you will have to show for it.

PMI defines five major project phases: initiation, planning, execution, control, and closure. One could make the case that almost every project goes through these five phases.

- Initiation phase: The initiation phase is the first phase in a project's life cycle. It focuses on project definition and project feasibility. Activities in the initiation phase include analysis, requirements definition, estimating, and development of the preliminary project plan. The deliverable of the initiation phase is the project charter, which should be approved before moving into the next phase.
- Planning phase: The planning phase is when the detailed aspects of the project are determined, coordinated, and documented. The quality and quantity of work completed during the planning phase is critical to the project's success. Depending on the size and scope of the project, the planning phase may include several of the following: project organization, change management, issue management, risk management, quality management, schedule and task planning, communication management, vendor selection, test plans, deployment plans, training plan, and maintenance plans. The deliverable of the planning phase is the completion of a formal project and management plan and project kickoff.
- Execution: When the project gets underway and task orders are in various stages of completion, the project is in the execution phase. Project execution is where the concepts of planning turn into the realization of outcomes and where most of the project time is spent. It is also where the project is at its greatest risk for failure. The execution phase includes completion and testing of project work, user training, deployment and transition execution, distribution of information, and meetings.
- Monitoring/controlling: During the monitoring/controlling phase, the project manager works to ensure that project objectives are met by monitoring and

measuring progress. All measurements should be compared against the project plan developed in the initiation phase. The project manager will identify variances from the plan, identify issues, take corrective action, and continue risk assessments. Monitoring/controlling may overlap with other project phases.

- Closure: While the closure phase is not absolutely critical to the project's success, it is very important to the success of future projects and the success of an organization's project management office. Many of the closure phase best practices are designed to harvest the maximum knowledge, momentum, and goodwill from a project in ways that can benefit future projects.

Project Initiation

Overview

Project initiation involves the coordination of activities from inception through to planning to bring together the key information needed to start the project on a sound basis and to convey that information to all concerned with the project. These activities include analysis, requirements definition, estimating, and development of the preliminary project plan. In short, this is the "who, why, what, when, and how" part of the project. It defines all major aspects of a project and forms the basis for its management and the assessment of the overall success. The outcome of the project initiation activities is the project charter.

Project initiation is critical to the success of the project. Research indicates that most projects that fail have either skipped the project initiation phase altogether or have been through inadequate initiation processes. The project is initiated or defined to determine its viability. Essentially, a go/no go decision about its viability needs to be made by the end of the initiating process. For instance, this might be a decision as to whether a sustainable commitment can be made to the necessary resources if the project is to proceed. The steps for initiating the project will be presented in sequence; however, in reality this is an iterative process. You will find that in many cases you will need to go back through these steps several times until you have initiated or defined the project and have obtained a satisfactory level of agreement about the project objectives.

Who Is Involved?

At this point, the project is usually not formally established nor has a project manager been formally recognized. However, often the individual creating the project charter is formally recognized as the project manager upon the document's approval. In addition, the project sponsor may also be the "appropriate decision maker" identified in the project's concept stage. In practice, the project charter is developed by the project sponsor upon approval of the business case document. However, at the direction of the sponsor, the project charter may be developed by a separate individual or group. Often the project sponsor will identify a prospective project manager and delegate the creation of the project charter to that individual.

Early in the development of the project charter, it is important to identify potential stakeholders and critical partners, such as other project managers, partners, or vendors, and to meet with them to understand their expectations for the project and incorporate their input into the development of the charter.

Project Charter

Overview

The project charter (Template PMI-100) is a document that addresses stakeholder needs, clarifies the project objectives and goals, defines the project scope, identifies the duration and budget and funding sources, establishes project governance, and formally authorizes the project. The project manager obtains their authority to proceed and manage the project from this document.

In addition to the areas noted above, project charters at a minimum should include information related to the project title and description, assignment of the project manager and team, business objectives success criteria and constraints, business case, and approvals of the project sponsor and owners. It is important that all the key stakeholders (e.g., project owner, project sponsor, steering committee) are in agreement on all of the points above before proceeding to the planning phase.

Project Overview and Summary

The project charter, either directly or by reference to other documents, should summarize the project and its associated product. This section should provide enough information that an executive reading only this portion of the project charter would have a high-level understanding of the project. Typically, this description should answer who, what, when, and where in a concise manner.

BP I.1 PROJECT OVERVIEW AND SUMMARY

I.1(a) Summarize the business need for the project by describing the business problem that needs to be solved and the benefits the proposed solution will provide.

I.1(b) Identify the organization impact by summarizing the expected short-term and long-term results the project will generate. An example: Development of policies and procedures and a quality assurance and procedure manual that meets ISO 17025 standards will assist in the successful accreditation of the laboratory by American Society Crime Laboratory Directors (ASCLD)/LAB.

I.1(c) Summarize how the project aligns with organizational goals Example: The laboratory's strategic goals for 2009 include the successful accreditation of the laboratory by ASCLD/LAB. Development of a laboratory policies and procedure manual that meets ISO 17025 standards will aid in the achievement of this goal.

I.1(d) Define the project scope in terms of activities, locations and organization units, etc.

Project Goals and Objectives

Project objectives define the target status at the end of the project and should be the following:

- Specific
- Measurable

- Achievable (recently, acceptable is used regularly as well)
- Realistic given the current state of organizational resources
- Time terminated (bounded)

An example: Organize and provide administrative support to policies and procedure review committee, including the development and distribution of agendas and minutes at least two weeks before and after the meeting.

- Specific—says what the staff member will do (organize and provide admin support).
- Measurable— states to whom the admin support is to be provided for (the policy and procedure review committee).
- Achievable—assumes the staff member has a listing of all the relevant committees and its members, dates, venue, catering resources.
- Relevant—supports the executive management team in ensuring meetings are conducted throughout a given period.
- Timely—agendas and minutes to be distributed to committee members at least two weeks before and after the meeting.

Sample Goals and Objective Statement

1. Develop a quality system manual to meet the quality policy defined by the XYZ Police Department Crime Laboratory senior management in compliance with the accreditation criteria documents ISO/IEC 17025:2005 and the 2006 Supplemental requirements of ASCLD/LAB International by December 31, 2009.
2. Develop a series of QSP to support the intent of the quality policy and the committed quality objective of the XYZ Police Department Crime Laboratory as defined in the quality system manual by December 31, 2009.

BP I.2 IDENTIFY PROJECT GOALS AND OBJECTIVES

I.2(a) Review project initiation request.
I.2(b) Identify the project initiator.
I.2(c) What are the specific task(s) to be completed by the project?
I.2(d) How will we know if the project is a success? Note: this should be measurable.
I.2(e) Is the successful completion of the project achievable? Does the organization have the resources, expertise, and tools necessary to complete the tasks?
I.2(f) Is the project relevant to the strategic goals of the organization?
I.2(g) What is the estimated start and end date of the project?

Project Scope

The scope section of the project charter should summarize what the project is intended to achieve, in business and technical terms. This section describes the expected results of the project, accomplishments, outcomes, and/or products. It should summarize the functions

that must be in place when the project is complete and must identify the major deliverables. Remember to include both the inclusive and exclusive boundaries of the project, specifically addressing items that are in scope and out of scope.

These should be high-level requirements and will not include the details that will be identified during the planning phase of the project. Upon approval of the project charter, these requirements will be refined in the planning phase of the project and will serve as an input to the scope statement in the project management plan.

Sample Project Scope Statement

- Complete an assessment of the laboratory's current policies and procedure manuals to be performed by the laboratory's project management office and two technical advisors. The assessment should do the following:
  - Identify workflows for all significant laboratory processes.
  - Establish format and content of the manuals that will be developed.
  - Review current quality and technical systems for compliance with accreditation standards established by ASCLD/LAB or ISO 17025.
  - Identify measurable quality objectives for the laboratory that meet the intent of the quality policy.
  - Identify risks or issues and provide a description of the methodologies that will be used.
- Develop final implementation plan that incorporates the laboratory's needs and time requirements.
- Develop first and subsequent drafts of the quality management system documentation to meet the accreditation requirements of ISO/IEC 17025:2005 and the Supplemental Requirements of ASCLD/LAB-International. This deliverable will include a first and final drafts of the following:
  - ISO-aligned tier 1 quality system manual (QSM) that meets the quality policy defined by XYZ Police Department Crime Laboratory senior management in compliance with the requirements of the accreditation criteria documents ISO/IEC 17025:2005 and the 2006 Supplemental Requirements of ASCLD/LAB-International. The manual will include the necessary references to any tier 2 QSP needed to support the QSM. We anticipate twenty or more quality system procedures will be referenced.
- QSP to support the intent of the quality policy and the committed quality objectives of XYZ Police Department Crime Laboratory as defined in the quality system manual.

BP I.3 IDENTIFY PROJECT SCOPE

I.3(a) Identify the laboratory activities represented that might be impacted by the identified business need(s).

I.3(b) Identify and exclude those business activities impacted by the identified business need(s) that have previously been analyzed.

I.3(c) Identify laboratory entities represented in the data model which might be involved with the identified business need(s).

(Continued)

BP I.3 (CONTINUED)

I.3(d) Identify and exclude those laboratory entities involved with the identified business need(s) that have previously been analyzed.
I.3(e) Identify the locations represented in the quality assurance effort that might be involved with the identified business need(s).
I.3(f) Identify the organization units represented in the quality assurance effort that might be involved with the identified business need(s).
I.3(g) Determine whether any other project initiation requests in the Laboratory queue address the same business area as this request and whether they might be combined with this request to address a broader set of business needs.
I.3(h) Identify existing information systems included in the proposed project scope.
I.3(i) Identify existing files and other documents included in the proposed project scope.
I.3(j) Determine whether existing information systems, files, and databases are potential candidates to utilize, modify, or extend to satisfy the identified business need(s).
I.3(k) Determine the extent of the adjustments that need to be made to the proposed project scope and adjust the scope of the projected study or system as appropriate.

Durations and Milestones

The project charter should address the project timeline and executive milestones of the project. Executive milestones are key performance indicators of significant accomplishments or events in the project, such as the release of the product, presentation at a conference, or item that a project sponsor or stakeholder would like tracked. These may be as simple as milestones for the completion of each project phase as noted in the checklist below.

BP I.4 SPECIFY THE ESTIMATED DURATION OF THE PROJECT AND EXECUTIVE MILESTONES

I.4(a) What is the estimated start and end date of the project (note: these should be the same as noted in the project objectives above)?
I.4(b) What is the estimated date for the completion of the project plan?
I.4(c) What is the estimated start and finish date for the completion of the analysis or requirements phase?
I.4(d) What is the estimated start and finish date for the completion of the design phase?
I.4(e) What is the estimated start and finish date for the completion of the development or construction phase?
I.4(f) What is the estimated start and finish date for the quality assurance testing phase?
I.4(g) What is the estimated delivery date of deliverables?

I.4(h) Identify those factors that will hamper or enhance the pace of the project and adjust the timelines accordingly.
I.4(i) Identify the dependencies among tasks in the next stage of this project.
I.4(j) Include a statement related to resource availability.

Budget and Funding Sources

The project charter should summarize the source of funding for the project, provide an outline of how funding will be received, and include an estimation of the project costs. Internal costs, as well as the costs of compliance-related processes should be included. The project charter will also include a statement as to the degree of accuracy and confidence of the project's budget.

BP I.5 IDENTIFY FUNDING SOURCE(S) AND ESTIMATE PROJECT COSTS

I.5(a) Identify the expected costs/resources associated with the project. Prepare an estimate of funding required for the project.
I.5(b) Identify possible sources of project funding.
I.5(c) Prepare project funding request (if required).
I.5(d) Secure agreement with project sponsor regarding project scope, projected resource requirements, and required funding.

Alternatives Analysis

The project charter should include a discussion of alternative solutions considered during the analysis of the project if applicable. It should take into consideration factors such as: approach, feasibility, high-level cost estimate, advantages, disadvantages, risks, skill needs, hardware, software, technical resources, environment, migration requirements, and licensing. Identify the alternatives chosen and provide benefits and reasons for the choice.

BP I.6 SUMMARIZE ALTERNATIVE SOLUTIONS

I.6(a) Identify the alternatives chosen and provide benefits and reasons for the choice.

Assumptions, Constraints, and Risks

The project charter will need to address assumptions, constraints, and risks that should be taken into consideration during the development of project plan.

- Assumptions—An assumption is something taken for granted or accepted as true without proof. Summarize the assumptions that were taken into consideration in the development of the project Charter. Also summarize the compliance-related processes that the project will follow and the specific documents in which further

detail about the processes will be provided. This section should list the project assumptions that the project sponsor should be aware of before making a decision on funding the project. Example: This project assumes the availability of two full time technical advisors assigned to the project full time to develop project deliverables.

- Constraints—A constraint is an applicable restriction or limitation, either internal or external, to the project that will affect the performance of the project. Summarize the constraints that must be taken into consideration prior to the initiation of the project. This section should list the project constraints that the project sponsor should be aware of before making a decision on funding the project. Example: Project deliverables must be completed no later than December 31, 2009. The project budget is $250,000.00.
- Risks—A risk is defined as an uncertain event or condition that, if it occurs, has a positive or negative affect on a project's objectives. Summarize the high-level risks associated with the project and possible mitigation strategies. This section should list the risks that the project sponsor should be aware of before making a decision on funding the project, including risks of not funding the project. In the appendix of the project charter include an attachment summarizing any identified project risks. Example: Technical advisors assigned to the project do not have training and experience with ISO 17025. Impact is high. Mitigation strategy would include sending the technical advisors for training in ISO 17025 standards.

BP I.7 SUMMARIZE ASSUMPTIONS, CONSTRAINTS, AND RISKS

I.7(a) Summarize the assumptions that were taken into consideration in the development of the project charter.
1.7(b) List the project constraints that the project sponsor should be aware of before making a decision on funding the project.
1.7(c) Identify high-level risks with project impact and mitigation strategy.

Project Governance

Project governance includes the identification of project stakeholders (both internal and external to the project) and assignment of roles and responsibilities for these stakeholders. A stakeholder is a person or organization that is actively involved in the project or that could, positively or negatively, impact the achievement of the project objectives, or whose interest may be positively or negatively affected by the execution or completion of the project. This section should list the stakeholders that the project sponsor should be aware of before making a decision on funding the project as well as their roles and responsibilities.

BP I.8 IDENTIFY PROJECT STAKEHOLDERS

I.8(a) List the stakeholders the project sponsor should be aware of before making a decision on funding the project including their roles and responsibilities.

Go/No Go Decision

Every project should include a formal task for key project stakeholders to review the proposed project solution and related project charter, then based on the information provided either approve the project to go or be cancelled. It is essential that the project charter be completed prior to this step. The team responsible for the development of the project charter should schedule a meeting with the key project stakeholders. An agenda and a Microsoft PowerPoint presentation or the project charter document itself should be provided to the invitees with the meeting invitation, providing an opportunity for the invitees to review the information in preparation for the meeting. If a PowerPoint presentation is used, the key elements of the project charter should be addressed.

During the go/no go decision meeting, the project stakeholders should have an opportunity to ask questions. They may even request that additional information be provided at a later date. Activities during the meeting may include an evaluation of the cost/benefits of the project, forecast of funding, and timeline and other analysis.

After the go/no go decision meeting, a recap of the discussion, including the summary of all recommendations and findings, should be provided to each invitee. If verbal approval of the project was provided during the meeting, each invitee should be visited to obtain their signature on the project charter document. If deficiencies were identified during the meeting, they should be corrected in a timely manner and a second meeting scheduled if appropriate.

BP I.9 GO/NO GO DECISION POTENTIAL DISCUSSION TOPICS

1.9(a) Evaluate cost benefit analysis.
1.9(b) Evaluate risk analysis.
1.9(c) Evaluate strengths, weaknesses, opportunities, and threats.
1.9(d) Evaluate degree of end-user participation.
1.9(e) Forecast required funds and timelines for each development stage along with a schedule for confirming or revising each stage's funding.

Approval

It is absolutely essential to obtain the signatures of key project stakeholders on the project charter.

Project Initiation Templates and Best Practice Checklist

Templates

- PMI-100 Project Management Charter

Best Practice Checklist

- BP I.1 Project Overview and Summary
- BP I.2 Identify Project Objectives
- BP I.3 Identify Project Scope
- BP I.4 Specify the Estimated Duration of the Project and Executive Milestones

- BP I.5 Identify Funding Sources and Estimate Project Costs
- BP I.6 Summarize Alternative Solutions
- BP I.7 Summarize Assumptions, Constraints, and Risks
- BP I.8 Identify Project Stakeholders
- BP I.9 Go/No Go Potential Discussion Topics

Project Planning

Overview

What should be included in the planning phase? (Figure 3.1) A best practice approach will include the previously approved detail from the project charter, information related to the organizational structure of the project team and project governance, the scope of deliverables from the project, a description of the project management life cycle, and methodology that will be used and a set of instructions for each project management area. The instructions should address the management of change, risk, issue, schedule, budget, communication, procurement, resource, quality, and performance. The planning phase sets expectations for the project team and stakeholders and approval of the project sponsor, business owner, and key stakeholders is necessary before the project moves into execution.

The project manager is responsible for developing the project plan, schedule, and supporting documents necessary to start the project. During the project planning phase, he/she will collaborate with the business sponsor, business owner, key stakeholders, and project team to complete all of the necessary planning activities that are needed to make the project successful. The project manager should be familiar with the project scope and objectives, as well as be an individual in a position of authority that is able to effectively coordinate the activities of the team.

Many organizations utilize a standard project management plan template for internal projects. If your laboratory has a project management office or an information technology department, check with a member of their team to see if there is an approved project management template available for use on your project. If project management is new to your organization or a template is not available, then the project management plan detailed in this section should be used.

The size and level of effort needed to complete these activities and related plans should be directly proportional to the size of the project. There is never a one size fits all plan for managing projects. Some projects may be easily managed with a combined project management plan document similar to what we have included with this chapter. Other projects that involve many departments, resources, and numerous work streams are best managed with individual management plans. The project manager will use their knowledge and experience of the organization and in managing projects to develop and organize the project management plan documents for ease of use during the execution phase.

Other than setting aside enough time and resources to plan properly, one further tip for project success is to pay attention to the interdependencies of the various plans, making sure that when a change is made to one plan, the impacts are carried through to the other plans as needed.

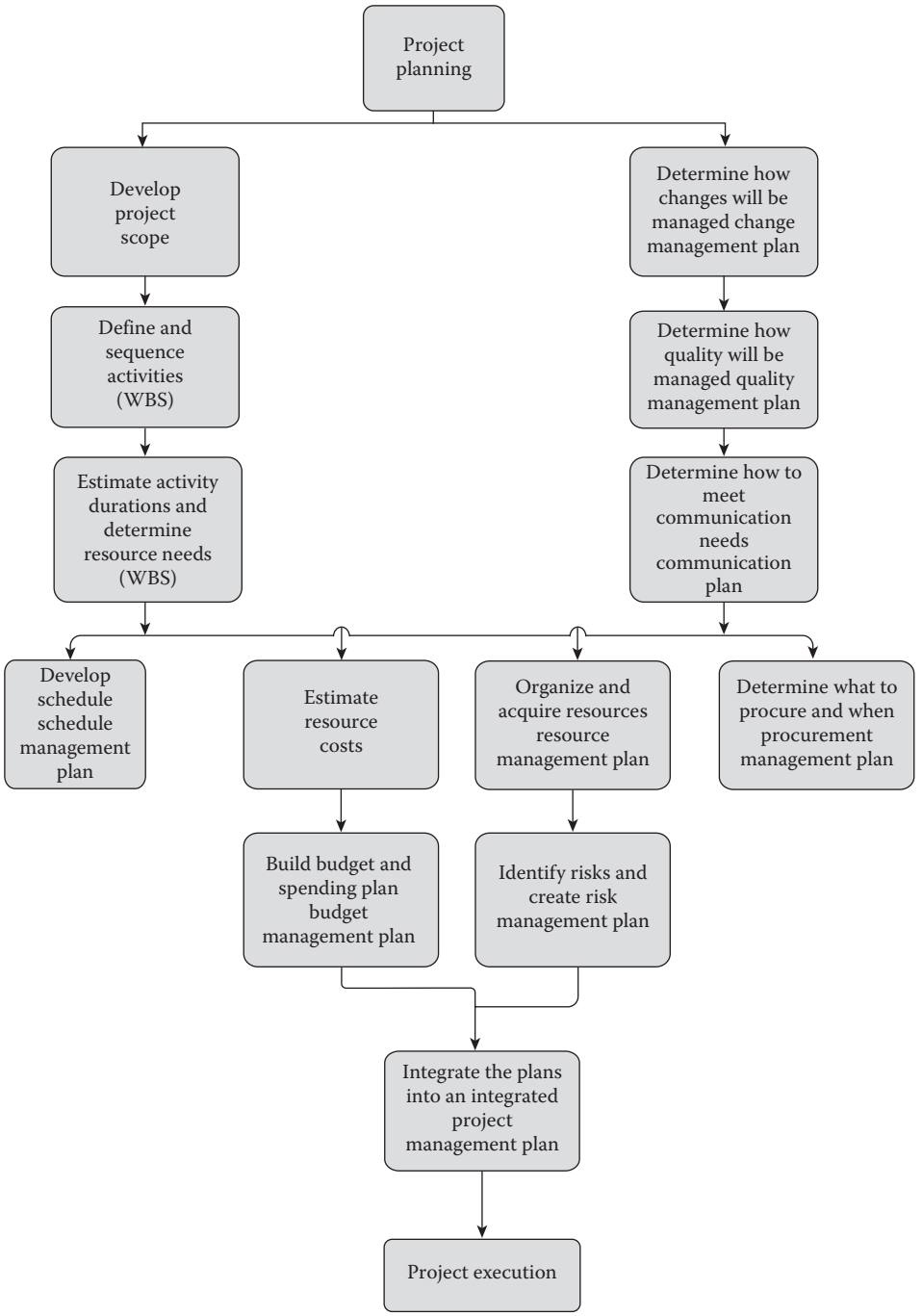

Figure 3.1 Project planning.

Preparing the Project Management Plan

Project Overview

Much of the information included in the project overview will come from the approved Project charter. The project overview should provide an executive summary, funding and sources, project constraints, dependencies, assumptions, and identification of initial project

risks and mitigation strategy. If the project charter has not been approved, the project manager should make every effort to complete this task before planning gets underway.

BP P.1 PROJECT OVERVIEW

P.1(a) Provide an executive summary or rationale for the project.
P.1(b) Identify the funding and sources for the project. Include the amount if known and any restrictions. Identify the approvers for the funding.
P.1(c) List the constraints or factors that will restrict the project by scope, resource or schedule.
P.1(d) List any dependencies that should be considered when planning the projects. Dependencies may be mandatory, discretionary or external.
P.1(e) Identify the assumptions used by the project manager and team in developing the project management plan.
P.1(f) Include the initial project risks, their probability of occurring, and impact to the project as well as mitigation strategy and contingency plan.

Project Authority and Organizational Structure

This section of the document should describe the roles and responsibilities of the project team. It also identifies the other organizational groups that are part of the project. At a minimum, information related to the stakeholders, project governance, and reporting to senior project leadership should be identified in this section.

- Stakeholders—The project manager will identify and list all of the major stakeholders involved with the project state why they have a stake. These stakeholders should be consulted throughout the project to ensure their needs are met.
- Project governance—An organization chart should be included to graphically depict the hierarchical configuration of those groups. During project execution, the organization chart and detail may be used to clarify interactions with the project team. A description of the roles for each member of the project team should also be provided. If there are any special considerations regarding contact between the project team, the project manager, and individuals from various organizations involved in the project, include those here as well.
- Executive reporting—Generally, the project manager will provide status reports and other information to the project sponsor and business owner. Other individuals from the organization's senior leadership may be included as well. The project manager should identify all individuals of the executive team that will receive project status reports and related information.

BP P.2 PROJECT AUTHORITY AND ORGANIZATIONAL STRUCTURE

P.2(a) Identify the project stakeholders and list their name, stake in the project, organization, or department and title. Additional information which may be included include address, telephone, and e-mail address.

P.2(b) Describe the organizational structure and provide an organization chart. Include a list of roles and describe any special considerations regarding contract between the project manager, team, and stakeholders.
P.2(c) Identify specifics related to executive reporting requirements.

Scope

Project scope is a detailed description of what must be delivered by the project. The scope statement should also include a detailed description of anything not explicitly provided. During the planning phase the project manager and his/her team will need to painstakingly identify exactly what the project must deliver. It may not be perfect, and in some cases, scope may change after the project starts. This is perfectly acceptable as long as the project manager has included and follows the set of instructions for managing changes to the project.

Anyone who has ever participated in or managed a project will have tales of how scope caused grief. Some projects begin work without the scope being fully defined. Team members may work for days and weeks with only a superficial outline of the requirements. When the project deliverables are shown to the project sponsor they find that is not what they wanted at all. Other projects begin with a detailed and accurate scope statement only to have the team and stakeholders keep adding functionality and features as the project moves forward. Pretty soon, the deliverable will not look anything like what was described in the project charter and the budget and timeline are out of control!

When identifying the scope of the project, attention should be given to the project objectives from the project charter. These should be in agreement with the scope in the project management plan. When writing the statement use clear and concise terms, not jargon. Address processes, internal entities, systems, customers, and outside entities that will (or will not) be part of the project.

BP P.3 PROJECT SCOPE

P.3(a) The project scope should include the business and technical objectives. The objectives identified in the project scope statement should be in agreement with the objectives identified in the project charter.
P.3(b) Provide a detailed description of anything not explicitly provided.
P.3(c) Identify the critical success factors. How will the team know the deliverables will meet the needs of the project sponsor and key stakeholders?

Project Deliverables and Phases

The project deliverables and methodology section of the document should include a description of the project management life cycle or project phases as well as a high level description of the deliverables and achievements that are expected.

Projects involving the development of policies, procedures, and static documents for the laboratory should include phases to support the analysis of the manuals and procedures

currently in use, design of format for the new manual and procedures, development of the new manual and procedures, quality assurance and peer review, and finally, acceptance by the project sponsor, business owner, and key stakeholder of the newly developed manual and procedures.

Work completed in each project phase is done concurrently with the efforts of the project management throughout the project management life cycle. Generally, work on project deliverables will begin during project planning with the analysis of the current state of the laboratories quality assurance manual and procedures, if any exist. This analysis should be started during planning to alert the project team to the level of effort that will be required to develop the new manuals and procedures. Although the project management plan may be completed before the analysis begins, it is likely that changes to the plan are required once analysis is complete and the team has a full understanding of the work that is to be done. In this and subsequent phases, it is essential to obtain the approval of the project sponsor and key stakeholders before moving to the next phase.

During project execution, the project team will design the format for the new quality manual and procedure templates. They should also establish a document inventory and control log to track revisions to the documents once they are completed, approved, and in use.

Once the design of the templates required for the development of the quality assurance manual and procedures have been completed, the team will begin development of the actual documents. Most laboratories will find it helpful to develop and obtain the first round of approvals for the quality assurance manual before the procedures are started. The quality assurance manual policies outline what has to be done in accordance with the standards. These policies will drive development of the procedures (how you do it.) During development, it is essential for the project manager and team to be familiar with the scope of deliverables. Particular attention should be paid to which units and subunits are to be included (e.g., crime scene, criminalistics, and identification services) to ensure nothing is missed. When developing the quality procedures it is necessary to consider procedures related to training, section specific, chemical, equipment and reference material, literature, forms and worksheets, and so forth.

Quality assurance efforts should begin during project initiation and continue through user acceptance and project closing (see Figure 3.2). Resources assigned to development

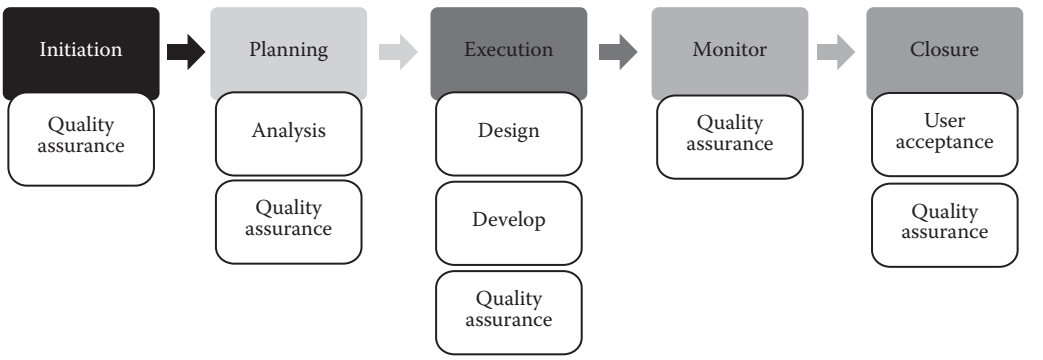

Figure 3.2 Project management alignment to project phases.

tasks should review their own work as they complete it. Additional administrative and technical reviews (peer reviews) should be scheduled and completed by someone other than the individuals responsible for the task. We recommend a minimum of three rounds of administrative and technical reviews when developing quality assurance manuals and related procedures.

BP P.4 PROJECT DELIVERABLES AND PHASES

P.4(a) Include a listing of each project phase (i.e., analysis, design, development, quality assurance, user acceptance) for the project. For each phase, provide a summary of the activities to be performed and identify the key deliverables to be provided.

P.4(b) For each key deliverable identified in P.4, provide a short description, deliverable acceptance criteria, specific standards for content and format, and procedures related to quality review.

P.4(c) For each key deliverable, identify the individuals who can approve the deliverable.

Project Work

When compiling the information included with project work, the project manager and team will need to develop the work schedule (typically known as the work breakdown structure, or WBS) to provide a time and cost estimate to complete individual activities, assign resources to the activities, and work out any other logistical issues related to completion of the work. Developing the WBS, schedule, and estimate can be done informally in a table or a spreadsheet when the number of activities is less than fifty, the relationships are not complex, and the analysis of the critical path is simple to assess. For more complex projects, a scheduling tool like Microsoft Project is highly recommended. A sample Microsoft Project file for a quality assurance methods, manual, and procedures development project has been included with this chapter (PMP-2 Project GANTT Chart in Microsoft Project.) The tool will provide the project manager the ability to combine critical path analysis and resource leveling based on the project calendar to establish the start and end dates for each activity. Whichever tool is selected, the project management plan should include a high level summary of the output.

One of the most important WBS design principles is called the 100% Rule. The *Practice Standard for Work Breakdown Structures*, published by the Project Management Institute defines the 100% Rule as follows: "the WBS includes 100% of the work defined by the project scope and captures all deliverables—internal, external, interim—in terms of the work to be completed, including project management. The work represented by the activities in each work package must add up to 100% of the work necessary to complete the work package."

Generally, a WBS contains work broken down to discrete tasks, called work packages. Each work package can be assigned to one or more resources. A general rule of thumb is to have work packages with durations of eighty hours (two one-week reporting periods) or less. A WBS can be represented in graphical tree form or in a task list. At most, include six

or fewer levels of tasks or subtasks. After tasks have been identified, the project manager with assistance from the team should provide the following:

- A duration estimate. Ideally, the individual most familiar with the task or responsible for its completion should be consulted. In some cases, the organization will have previously completed similar projects and estimates may be obtained using the historical actual values from those.
- Identification and assignment to a resource for completion.
- Identification and assignment of dependencies, if any.

The schedule should be adjusted to accommodate a realistic calendar, including holidays, flexible work schedules, and other work for each of the resources. Costs should be estimated for all resources to be used on the project. This includes all internal and external labor, materials, supplies, contracts, and other costs like team training, legal, and facility, if appropriate. Costs should be expressed in dollars. When estimating the cost of internal staff, a rule of thumb is to take an average staff salary times 150% for fringe benefits.

A project work schedule is not intended to be a static, one-time picture of the project plan. It must be regularly updated and maintained to reflect an accurate picture of current status. Plan not only for time to create the initial estimates and schedule, but also for time to revisit the estimates and schedule throughout the project life cycle.

BP P.5 PROJECT WORK

P.5(a) Include a listing of the milestone/deliverable level of the work activities required of the project. Each activity should include an identifier, description, objective, and associated milestone.

P.5(b) The project timeline is a high-level view of the project activities with a focus on project milestones. It should include an identifier for the activities, task name, assigned resource, effort/duration estimate, start and finish dates, and related dependencies if any.

P.5(c) Cost estimates for the activities identified in the timeline should be provided by resource. Resources can include people, equipment, material, technology, or processing cycles. These cost estimates should be matched with the actual billed amounts.

P.5(d) An organization chart of the project team should be provided which includes their role, responsibility, name and functional area.

P-5 (e) For each team member information related to their availability and cost should be provided. If nonpersonnel resources are required, that information should be obtained and provided in this section.

P.5(f) If there are any other logistical issues that should be identified for the project, they should be identified in this section. Training required by the project team would be an example.

Project Management and Controls

The project management plan should include a number of policies and procedures necessary for the successful management of the project.

- Change management plan: A change management plan protects the attainability of the project goals and objectives leading to the acceptance of all deliverables by the project stakeholders. When the original project scope was defined, assumptions and agreements were made as to what the project was going to produce. When deliverables are approved for during the project, estimates for cost, effort, and duration may no longer be valid. It is imperative that the processes defined in the change management plan identify how change requests are recognized and reconciled, and ultimately, the plan must be rigorously executed. The change control plan should fit the complexity, duration, and size of the project and agreement of its processes should be obtained from the project sponsor, business owner, and key stakeholders. Everyone on the team should understand how change requests are managed and ultimately, who has the authority to approve them.

BP P.6 CHANGE MANAGEMENT PLAN

P.6(a) Include instructions for how changes will be identified.
P.6(b) A project change request form is required and instructions for how team members will submit the form for approval should be included.
P.6(c) A project change request log is required and should be maintained by the project manager.
P.6(d) Instructions for the analysis of the change request should be included with the plan. The instructions should include the names and departments of individuals responsible for the analysis, the components for analysis, and instructions related to timeliness.
P.6(e) Identify which project stakeholders have authority to approve changes to the project and how that approval occurs. Example: Change requests are submitted to the project steering committee each Monday.
P.6(f) What is the process for communicating a change has been approved (or not) to project members?
P.6(g) Remember that all approved changes will have an impact on the project. The project manager will need to update project documents (requirements, schedule, cost, risk, etc.) to accommodate the changes.

- Risk management plan: Risk management is a process of identifying all the possible undesirable outcomes before they happen and then developing strategies that will avoid them or minimize their impact to the project. Common sources of risk include change in requirements, design errors, omissions and misunderstandings, poorly defined or understood roles, insufficiently skilled staff, and

impossible time frames. There are two basic activities in risk management. Risk assessment includes making a list of the potential dangers, assessing the probability of their occurrence and potential loss, and prioritizing from most to least dangerous. Risk control involves identifying techniques and strategies to mitigate risks, implementing the strategies and then monitoring the effectiveness of the strategies. Risk assessment and control is an ongoing activity throughout the life of the project.

When analyzing project risk, the team will consider several factors, including these:

- Possible events: What could happen?
- Probability: How likely is it to happen?
- Impact: How bad will it be if it happens?
- Mitigation: How can you reduce the probability (and by how much)?
- Contingency: How can you reduce the impact (and by how much)?
- Reduction = Mitigation X Contingency
- Exposure = Risk – Reduction
  - Exposure is the amount of risk you simply can't avoid. Exposure may also be referred to as threat, liability, or severity. It will be used to help determine if the planned activity should take place.
  - Often this is a simple cost versus benefits formula used to determine if the risk of implementing the change is higher, or lower, than the risk of not implementing the change.
- Assumed risk: If you decide to proceed (sometimes there is no choice; e.g., federally mandated changes), then your exposure becomes what is known as assumed risk.

BP P.7 RISK MANAGEMENT PLAN

P.7(a) Does the risk management plan describe how risks will be identified by the project and who should be involved in the identification process? (Best practice—everyone on the project team should be involved in looking for risks!)
P.7(b) How are risks to be categorized?
P.7(c) Who will perform the risk impact assessment and how will it be conducted? Does the project have a template for performing the assessment?
P.7(d) All risks should be prioritized. How will risks on this project be prioritized?
P.7(e) Who has the final authority concerning the mitigation project risks?

- Issue management plan: The primary goal of issue management is to ensure that issues are identified, evaluated, and resolved in a timely manner. Issue management (or corrective action management) describes the project's process for managing project issues. Issues are generated by things like unmediated disputes, unaddressed concerns, and unresolved decision making. Issues arise in

all project phases and may have tremendous negative impacts on the project if not addressed properly. Most issues will be completely resolved through the issue management process; however, some may progress through the change management process if their resolution impacts the project's charter. A project that proceeds without exercising an issue management plan is likely to experience team and client discord, scope creep, and negative schedule impacts. Issues should be reviewed for their impact to scope, schedule, and quality, and issue resolutions should be documented and communicated to all project stakeholders.

BP P.8 ISSUE MANAGEMENT PLAN

P.8(a) Include a process for raising an issue.
P.8(b) Include a process for logging and tracking issues.
P.8(c) Describe how issues are assigned for evaluation and planning of resolution.
P.8(d) Include a process for implementing issue resolution actions.
P.8(e) The issue management plan should be communicated to all project team members and stakeholders. Well-documented issue descriptions, resolutions, and action plans are key to successful issue management.

- Schedule management plan: The schedule management plan establishes how schedule management will be carried out in the project. It serves as guidance for the scheduling process and formats and defines the roles and responsibilities for stakeholders in those processes. It is not the detailed schedule information that will be included in your GANTT chart, Microsoft Excel spreadsheet, or other tool. Instead, the plan explains how that information will be captured, expressed, and modified. The schedule management plan should be coordinated with all other management plans. The schedule management plan should include details related to these things:
  - Scheduling process—The scheduling process may include both high-level and detailed descriptions of how the schedule and its components will be generated. The process includes information on when the schedule should be baselined and when certain types of documents (e.g., milestone charts, team calendars) should be updated.
  - Schedule responsibilities—The responsibilities should reflect who will be accountable for schedule updates and for capturing real-time information on project and task performance. This may also include who is in charge of the scheduling tools and who is conducting data entry.
  - Schedule parameters—Any noteworthy project schedule limitations (e.g., major milestones, finish date) should be identified here.
  - Schedule modification—This element of the schedule management plan ties in with change management in that it details how and when the schedule may be adjusted.

BP P.9 SCHEDULE MANAGEMENT PLAN

P.9(a) The schedule management plan provides a description of the scheduling process.
P.9(b) The schedule management plan identifies the individuals responsible for maintaining the project schedule.
P.9(c) The schedule management plan describes the process for modifying the schedule.

- Budget management plan: Every plan should include a budget. This involves assigning costs to each project activity on the project schedule, taking a snapshot or baseline, then tracking the actual amounts spent. This allows the project manager to present a time-based budget report. The budget management plan should provide minimally provide a summary budget for the project. The budget may be divided by project phase or deliverable, again depending on the requirements of the organization. The budget management plan will provide information about the process for modifying the budget as well as identify the individual responsible for managing the budget.

BP P.10 BUDGET MANAGEMENT PLAN

P.10(a) The budget management plan provides either a detailed or summary-level of the project budget.
P.10(b) The budget management plan provides a description of the budgeting process.
P.10(c) The budget management plan identifies the individuals responsible for maintaining the project budget.
P.10(d) The budget management plan describes the process for modifying the budget.

- Communication management plan: Communication planning involves determining the information and communication needs of the project stakeholders. What information is required, when it is required, what format, and who is responsible for providing the information should be addressed in the project management plan. The details from a sample communications plan are shown in Figure 3.4.
- Resource management plan: Resource planning is necessary to obtain the resources needed to complete project work. Some laboratories have a dedicated quality assurance staff that will be involved in the development of the quality assurance methods, manual, and procedures. Other laboratories temporarily assign individuals from various areas of the laboratory to do the work. These individuals generally have full-time duties, and assignment to the project will create extra work. A resource plan should address how these resources will be assigned, who they report to (the project manager or their

Communication plan			
Project	QSM Development	Project#	2007-051
Project manager	Andy Miller	Sponsor	Elliott Baxter, Lab director
Project artifacts	Sharepoint site	Updated	6/19/07

ID	Communication	Description	Frequency	Format	Owner	Recipient/ attendees
1	Project kickoff		Project start (include date when planned)	Meeting	Program manager	All hands
2	Change control governance		Weekly	Scheduled meeting	Project manager	Change control gov
3	Weekly project management report	Weekly meeting with the work stream leads	Weekly	PMR Deck	Project office	Project office+ workstreams
4	Biweekly status report	Biweekly status report to mark stansberry	15th and 30th	Meeting with status report document	Project office	Project office
5	Monthly tollgate	Monthly report to the project tollgate committee	Week of the 30th	Scheduled meeting with powerpoint	Program manager	Project office
7	Major milestone announcements		As completed	Email	Project office	All hands
8	Acceptance testing report		End of test	Document	Quality assurance lead	PMs and leads
9	Project close out report		End of project	Document	Project manager	Tollgate committee

Figure 3.3 Sample Communications Plan.

department head), and how the project work will be prioritized against their regular duties.

BP P.12 RESOURCE MANAGEMENT PLAN

P.12(a) The resource plan should include the number of staff required by skill level, the project phases in which the numbers of personnel and types of skills are needed, the source of personnel and the duration of need. Resource GANTT charts, resource histograms, spreadsheets, and tables may be used to depict the staffing plan by skill level, by project phase, and by aggregations of skill levels and project phases.

P.12(b) If project resources are obtained from multiple departments or organizations, the resource management plan should address who the resources are, their allocation to the project (e.g., part-time, full-time, etc.), who they report to, and how their project work is to be prioritized against their regular work.

P.12(c) The resource management plan identifies the individuals responsible for maintaining the resource management plan.

P.12(d) The resource management plan describes the process for modifying the plan.

- Procurement management plan: Procurement planning identifies which project needs can be best met by procuring products or services outside the project organization. In most cases, the laboratory will have written policies related to procurement. These policies should direct the procurement activities in the project. The information required in the project management plan are whether or not to procure, how to procure, what to procure, how much to procure, and when to procure it. The procurement plan should communicate how the procurement/contracts will be managed and may reference the organization's procurement code if it is available. Solicitation, if required, would be included in the execution phase of the project.

BP P.13 PROCUREMENT MANAGEMENT PLAN

P.13(a) If the organization has a procurement code, the procedures and standards contained in the procurement code should be followed in managing procurement activities of the project.

P.13(b) The procurement management plan provides a description of the procurement process.

P.13(c) The procurement management plan identifies the individuals responsible for maintaining the procurement plan.

P. 13(d) The procurement management plan describes the process for modifying the plan.

BP P.11 COMMUNICATIONS MANAGEMENT PLAN

P.11(a) The communication includes information about the project stakeholders that will receive project communications.

P11(b) The communications plan provides the location of shared project files and documents.

P11(c) The communication plan describes the process for both formal and information project communication.

- Quality management plan: Poor quality management is a major cause of project failure. Project quality should be addressed by the project manager and team early in the project. The project is concerned with quality from two perspectives, quality assurance and quality control. Quality assurance will address the activities and policies that are needed to provide assurance that the deliverables created in the project will meet the relevant standards they will be measured against. Quality control involves monitoring both the deliverables and the project management approach. A quality management plan documents how an organization will plan, implement, and assess the effectiveness of its quality assurance and quality control operations. Specifically, it describes how an organization structures its quality system, the quality policies and procedures, areas of application, and roles, responsibilities, and authorities.

BP P.14 QUALITY MANAGEMENT PLAN

P.14(a) The quality management plan describes the methodologies and to be applied to the project and product QA.

P.14(b) The quality management plan describes the review processes that will be used to verify quality of project work processes and project work products. Include details on assessments or reviews, when they will be conducted, who will conduct them, scope of review, success criteria, QA reporting formats, and review processes.

P.14(c) The quality management plan should Identify the QA deliverables and the timelines associated with those deliverables. For each checkpoint, include information such as checkpoint name, lead QA resource, QA deliverable, and planned start and end dates.

- Performance measurement plan: The project manager and executive sponsor will define the project metrics that will be used to control the project. Each project will need to have an established metrics program. Metrics are collected for measuring the progress of a project against its planned budget, schedule, resource usage, error rates, and so on. At a minimum, metrics must be established for time (schedule), cost (budget), and quality.

- Sample measurements include the following:
  - Budgeted cost of work scheduled—This is the performance baseline.
  - Schedule variance (SPI)—Budgeted cost of work product/actual cost of work product.
  - Cost variance (CPI)—Budgeted cost of work product/actual cost of work scheduled.
  - Estimate AT completion (EAC)—Budgeted actual costs/CPI.
  - Earned TO complete (ETC)—EAC minus actual costs.

BP P.15 PERFORMANCE MEASUREMENT PLAN

P.15(a) The performance measurement plan includes the listing and methodology of performance calculations for the project, how often measurements are to be taken, and how the results are reported.

- Configuration management plan: Configuration management determines how project information (files, reports, designs, memos, documents, etc.) will be managed (tracked, approved, stored, secured, assessed, version control) and owned.

BP P.16 CONFIGURATION MANAGEMENT PLAN

P.16(a) The configuration management plan provides the location to where all project files are stored, who has access, and what security requirements may exist.

P.16(b) The configuration management plan provide a detail of the revision process for project deliverables.

Project Transition

Once the project deliverables have been completed and accepted by the project sponsor, business owner, and stakeholders, a mechanism needs to be in place for the ongoing responsibility of the deliverables. In the case of laboratory policy and procedure manuals, some individuals or sections within the laboratory will need to be responsible for the ongoing care and feeding of the documents. To that end, the project manager and team will create a transition plan to identify to whom the documents will be transitioned to, when that transition will occur, and any related details of the transition itself.

A transition is a project and needs planning and management. The transition management component includes the development and management of a transition action plan, identification of the transition objective and outcomes, and engagement of resources necessary to complete the transition. Transition management is an ongoing activity throughout the life of the transition. It involves constant monitoring of activities to ensure

all tasks are completed on time, all risks are identified and mitigated, and all issues are addressed in a timely manner. Activities related to the transition planning will include the following:

1. Identify support group
   (a) Identify transition contact
2. Estimate support requirement with transition contact
   (a) Review project schedule and projected turn-over date
   (b) Review production requirements
   (c) Set expectations of responsibilities
   (d) Review training needs
   (e) Review support documentation needs
   (f) Review communication mechanisms
   (g) Review reporting requirements
3. Engage support people in knowledge transfer activities
   (a) Testing application
   (b) Participating in project meetings
   (c) Reviewing user and support documentation
   (d) Participate in user training, if appropriate
4. Turn-over meeting
   (a) Production issue management
   (b) Production escalation procedure
   (c) Production procedures

BP P.17 TRANSITION PLANNING

P.17(a) Is there a transition plan that addresses transition contacts, production requirements, expectations of responsibilities, training needs, support requirements, reporting, and transfer activities included with the project management plan?

P.17(b) Did the project manager walk through the transition plan with customers and technical support staff before executing the plan?

P.17(c) Did the stakeholders buy off on the transition plan?

Project Closure

Project closure always consists of administrative project activities and possibly procurement/contractual project activities if an external vendor is employed. Completing both sets of activities is a mandatory step in the project life cycle. Administrative activities include verification of deliverables and formal sign-off, lessons learned, recording the last hours against the project, archival of project documentation, and providing transition for the staff to other assignments. Procurement and contractual activities may include executing a procurement audit and formal acceptance of the project work products. The details related to project closure are found in the closure project phase.

Project Planning Templates and Best Practice Checklist

Templates

- PMP-100 Project Management Plan
- PMP-101 Project GANTT Chart in Microsoft Project

Best Practice Checklist

- BP P.1 Project overview
- BP P.2 Project authority and organizational structure
- BP P.3 Project scope
- BP P.4 Project deliverables and phases
- BP P.5 Project work
- BP P.6 Change management plan
- BP P.7 Risk management plan
- BP P.8 Issue management plan
- BP P.9 Schedule management plan
- BP P.10 Budget management plan
- BP P.11 Communication management plan
- BP P.12 Resource management plan
- BP P.13 Procurement management plan
- BP P.14 Quality management plan
- BP P.15 Performance measurement plan
- BP P.16 Configuration management plan
- BP P.17 Transition plan

Project Execution

Overview

Prior to project execution, the project management plan should have been developed and approved, and details shared with team members. The team should be prepared to begin work on assigned activities, and the project manager's focus will shift from discovery and planning to participating, analyzing, and observing. Project management activities during the execution phase will include tracking progress, reporting status, scheduling and holding meetings, and executing transition plans.

Project Communication

Effective communication is the key element to any successful project and should be scaled to fit the complexity, duration, and size of project. The communications plan should be referenced early in the execution phase to ensure the project team understands what information should be shared, how often, by whom, and what methods are most effective for various audiences. It is important that the project sponsor, business owner, and other key stakeholders approve and support the communications plan or it may not be used. Project participants should reference the communications plan so they know what to expect regarding the sharing of information.

Meeting Management

Project meetings take place for many reasons—status reporting, technical discussions, problem solving, decision making, planning, brainstorming, status delivery, and presentations. A project requires several specific types of meetings:

- Status reporting
- Work sessions
- Change management meetings
- Issue resolution meetings
- Daily meetings with the team members to review status, issues, and the day's activity (standup meetings)
- Others

To be effective, a project manager needs to get the most out of the many meetings he or she will organize and run during the course of a project. There are meeting management best practices that can help assure success for any type of meeting.

1. Before the meeting/meeting purpose, content, and participants
   - Do you really need to have a meeting?
   - Does the agenda outline the things to be discussed, the time allotted to each item, the nature of the item (e.g., discussion, presentation, decision), and the person leading the group during that item?
   - Are the right people invited to the meeting (e.g., people with the knowledge, decision makers, vital stakeholders)?
2. Before the Meeting/materials and facility
   - Prepare handouts.
   - Gather meeting materials (e.g., nametags, markers, writing materials, sign-in sheets, water, coffee).
   - Arrange for all audio/visual equipment needs.
   - Arrange seating and tables appropriately.
   - Confirm that the presenters will be there, and gather everything they need.
   - Confirm the facility availability.
   - Confirm the facility will hold all the people and accommodate the technology.
   - Test the technology before the meeting.
3. Before the meeting/roles and responsibilities
   - Make sure the facilitator is familiar with the meeting's purpose and content.
   - Be clear about who is running the meeting and setting the agenda compared with who is facilitating the discussion and making sure the ground rules are followed.
   - Determine the role(s) for the participants.
   - Decide whether you want a recorder to take minutes.
   - Decide whether you need a timekeeper to watch the time for each agenda item.
4. During the meeting
   - Start and end on time
   - What is the decision-making process (e.g., voting, consensus)?

BP E.1 PROJECT COMMUNICATIONS

E.1(a) Has the communications plan been reviewed (and approved, if necessary) by the project team and all internal and external stakeholders?
E.1(b) Do the project team members agree the plan includes the appropriate type and number of communications for them?
E.1(c) Is the communications plan being followed?
E.1(d) Are communications taking place in a timely manner?
E.1(e) Is feedback being solicited on a regular basis regarding the type and amount of project communications?
E.1(g) Do the project manager and team members document meeting minutes and distribute to attendees and absentees?

- Hold one conversation at a time
- Honor points of view that are different than yours
- No idea is stupid
- Speak openly and honestly
- Do not interrupt
- Do not monopolize the discussion

5. After the meeting
   - Do the minutes include a list of attendees, the topics discussed, the decisions, the action items with assignments, and the open issues?
   - Have the minutes been distributed to the interested stakeholders and invitees who were not able to attend as well as the participants?
   - Are the minutes available on-line to interested stakeholders?
   - Have follow-up communications been made to people with action items to make sure they understand their assignment?

Status Reporting

Status reporting is the component of the project communication plan that informs key project stakeholders of the critical aspects of the project's health, including schedule, scope, and cost. Good status reporting prevents surprises to project sponsors and stakeholders. The team should set a standing weekly meeting to discuss project status. Discussion in the status meeting should include the following:

- Review project plan versus actual
- Review current project risks and assign responsibility for addressing
- Review upcoming project milestones
- Review major accomplishments of the previous week
- Review plans for the coming week
- Review current action items, by project member
- Review upcoming meetings
- Review budget versus expenditures (if appropriate)
- Review impacts to the project management plans (change, risk, issue, schedule, budget, communications, resource, procurement, quality, performance, and configuration).

BP E.2 WEEKLY STATUS MEETINGS

E.2(a) Have all stakeholder information needs been addressed?
E.2(b) Have the statuses of milestones and deliverables, variances, causes, and mitigating actions been identified?
E.2(c) Has the scope status, including any critical change requests, been included?
E.2(d) Has the status of any sub-projects or interdependent projects been included?
E.2(e) Have communication activities been included?
E.2(f) Has the latest copy of the quality assurance report been included for reference?
E.2(g) Has the status of critical project risks been included?
E.2(h) Has the status of critical project issues been included?
E.2(i) Have quality improvement activities been included?
E.2(i) Has a copy of the status report been filed in a viewable project repository such as a project library?

Project Workbook

Many project managers find the number of project management tasks and associated forms and documents overwhelming. Indeed, trying to keep project documentation and reports in sync throughout the execution phase can be a full-time job in itself.

To compensate, many project managers find the use of a consolidated project workbook beneficial. Developed by the International Association of Project and Program Management, the workbook may be downloaded for free at http://www.exinfm.com/free_spreadsheets.html. The workbook includes a worksheet for each management area, including change log, issue log, risks, budget, resources, schedule, and quality. The workbook is meant to be used in concert with the project management plan and with a detailed GANTT chart or schedule if the project is large enough to require one.

Below is listed the name and description of each of the worksheets. It is suggested that the workbook follow the order of the project management plan document. However, the actual order can be sorted in whatever order is preferred by the project manager.

Worksheet	Description
A&C	The Assumptions and Constraints sheet allows you to track Project assumptions and constraints.
Action	The Action Items sheet allows you to track and monitor action items assigned to team members. Action items are tasks that must be done but are too insignificant from a time perspective to track in your Project schedule.
Budget	The Budget sheet allows you to track original budget, expenditures to date, and any cost variance.
CBA	The Cost/Benefit Analysis sheet allows you to review the proposed Project and potential alternatives and make a Project selection based on a greater ROI (return on investment).

Worksheet	Description
Chg Log	The Change Control Log sheet allows you to track all change requests that are in process or finalized.
Comm	The Communication Plan sheet allows you to detail your communication plan: how you are going to communicate, whom you will be communicating with, how often, in what format, etc.
Data	Filling out the Data sheet completes the header portion of all remaining sheets in the Project workbook.
Decision	The Decision Log sheet allows you to track all major decisions made during the course of the Project.
Deliver	The Deliverable Acceptance Log sheet allows you to track the status of deliverable acceptances.
Expectations	The Expectations sheet allows you to identify and track the expectations of various stakeholders.
Issues	The Issues Log sheet allows you to identify and monitor Project issues (unplanned events that have happened).
Miles	The Deliverable Milestones sheet allows you to identify major deliverable milestones and the due dates, objectives, assumptions, and constraints relevant to that deliverable milestone.
Minicharter	The Project Minicharter sheet can be used as a charter for small Projects or a summarization of a full charter for larger Projects.
R&R	The Roles and Responsibilities sheet shows the primary role of team members, any deliverables in which they are involved, and the percentage of time they are expected to work on the Project.
RAM	The Resource Assignment Matrix sheet shows you what type of resource is responsible for, or somehow involved with, each deliverable. The tasks listed are samples; you should update the RAM with tasks appropriate for your Project.
RCM	The Resource Commitment Matrix sheet shows how many effort hours each person on the Project has been allocated by month.
Risks	The Risk Management Matrix sheet allows you to identify, qualify, quantify, and prioritize risks (events that might happen; the uncertainty of a Project), create mitigation and contingency plans, and assign risks owners.
Roster	The Roster sheet provides contact information for all those involved on the Project.
Stake	The Stakeholder Analysis sheet allows you to identify stakeholders, their role, and their requirements.
Stoplight	The Stoplight Report sheet contains a status report that can be used to keep sponsors, team members, and stakeholders informed of Project progress.
WBS	The Work Breakdown Structure sheet includes the activities that must be completed during a Project, the effort required, all relevant dates, and the resources assigned to do the work.

Executing Transition Plans

The manuals are now ready to be used by the laboratory. By executing the implementation and transition plans, the project manager will be able to formally turn over the quality methods, manuals, and procedures to laboratory employees for their use with as little disruption as possible. Once the functionality and reliability of the manuals are shown to meet the acceptance criteria and the laboratory buys off on it, the ownership of the new

documents can be transferred from the project team to the laboratory team or individual(s) that will be responsible for the ongoing maintenance.

- Perform a formal turnover whether the project uses a phased approach or not.
- Conduct a walk-through of the transition plan with stakeholders right before execution of the plan.
- Obtain formal buyoff from the laboratory that the peer/quality assurance reviews have been successfully completed according to predetermined criteria.
- Complete product documentation in advance of transition.
- Establish a baseline of the product or service at the time of turnover, using change management, problem or issue resolution, or other processes to log and track changes to this baseline functionality.
- Notify customers of the implementation date well in advance.
- Implement the system or product on a smaller "pilot" scale to lessen impact to the business area in the event problems are experienced.
- Establish contingency plans to recover if the system/product fails upon cutover.
- Provide additional support staff when implementation is at full cutover.
- Keep the customer extensively involved in the deployment so they are aware of any potential disruptions to the production environment.
- Provide a convenient and publicized means (e.g., centralized help desk) for customers to report problems to the appropriate party (e.g., vendor, project manager, system administrator, etc.).
- Communicate status to customers, project team members, and stakeholders on a frequent basis so changes are expected and prepared for.
- Ensure business and technical support staff will receive training as close to the implementation of the product as possible (just-in-time training), if applicable.
- Create a written production turnover document and get buyoff from those who will be expected to maintain the new product (include contact information for critical project staff).
- Clearly outline maintenance roles and responsibilities for vendors and business and technical staff before transition takes place.
- Include specifics about transition to in-house staff if a vendor is involved in the initial system implementation.
- Identify and train in-house staff so knowledge transfer is effective.
- Plan for staffing levels and other facility or resource issues.
- Document all commitments to stakeholders that maintenance staff will be expected to honor.
- Document outstanding issues, problems, and change requests so maintenance staff have a clear understanding of the state of the product at the time of turnover.
- Defer decisions and work to maintenance staff unless project team participation is outlined in the maintenance and operations plan.
- Conduct project closeout activities prior to transition. Utilize lessons learned to help finalize the maintenance and operations plan. Brief maintenance staff on elements of the project closeout that will impact them or influence their activities.
- Make the project library and development materials/documentation available to the maintenance team.

BP E.3 EXECUTION OF TRANSITION PLANS

E.3(a) Have all test plans and peer reviews been successfully completed?
E.3(b) Has the project manager and team engaged support and production resources in transfer activities (testing, participating in project meetings, reviewing user and support documentation, and participating in training, if applicable)?
E.3(c) Have business and technical support staff been adequately trained to maintain new system/product?
E.3(d) Have arrangements been made for knowledge transfer from vendor to in-house staff?
E.3(e) Have stakeholders been notified well in advance of the implementation date?
E.3(f) Are contingencies in place to recover in case the system/product fails upon cutover?

Project Execution Templates and Best Practice Checklist

Templates

- PME-100 Microsoft Excel Status Workbook

Best Practice Checklist

- BP E.1 Project communications
- BP E.2 Weekly status meetings
- BP E.3 Execution of transition plans

Project Monitoring and Control

Overview

In previous sections of this chapter, we focused on what is required for sound project management. In the control phase, we will focus on the best way to complete those activities. The most important thing in the control phase is to be disciplined in following the plans that have been developed in the planning phase. It is also important to recognize the practical truth that the plans will not survive the execution intact. When a need to change one of those plans occur, and it will, the project manager will follow the process outlined in the change management plans.

Monitoring Project Work

At the onset of the project, the project manager and team members identified the project tasks and milestones, sequenced the tasks, estimated task duration and start and finish dates, and assigned the necessary resources to complete the work. This group of activities

forms the project work and schedule plan. As the project proceeds from the planning phase into execution, many factors may affect the plan. The project work and schedule plan may be revised due to external factors, change requests or work related to issues, risk management and quality, better estimates, or resource availability. It is important that the project manager baseline (take a snapshot) of the project before work commences in execution to allow for the monitoring and reporting of these changes. Any change made to the work plan after it is approved and baselined should be processed using the procedures outlined in the change management plan.

BP M.1 MONITORING PROJECT WORK

- M.1(a) Are project tasks less than or equal to two reporting periods (i.e., typically 80 hours)?
- M.1(b) Are there sufficient milestones in the project schedule to help gauge project progress?
- M.1(c) Does the project have a baseline set of estimates to measure project actual against?
- M.1(d) Has the project manager communicated the milestones and key deliverables/dates with project stakeholders?
- M.1(e) Does the project manager report the status as "0% complete" or "100% complete" rather than a partial "percent complete?"
- M.1(f) Do team members know their task assignments and completion dates?
- M.1(g) Does the project manager maintain a schedule of resource changes (vacations and other priority assignments that may impact the project assignment)?
- M.1(h) Have changes to the project work and schedule plan been communicated to everyone who needs to know?
- M.1(i) Does the project manager or someone on the team know how to use the automated project scheduling and tracking tools proposed for the project?
- M.1(j) If there are contractors on the project, are there milestones for tracking their deliverables, schedules, and acceptance?

Monitoring Project Risks

Project risk management involves identifying, analyzing, and mitigating project risks and should be started as soon as the project begins to form. For each risk, identify who is in charge of managing the risk and outline triggers and corresponding activities to be implemented to either prevent the risk from becoming a reality or to lessen the impact should a risk occur. The project becomes less vulnerable when the entire project team is familiar with the risk management process and can assist in continually monitoring for triggers and possible risks. If a risk becomes inevitable, it should be evaluated for inclusion in issue or change management plans. Use the WBS, review lessons learned, and check quality assurance reports to look for possible triggers or risks.

For each risk that has been identified, do the following:

- Determine the options and actions to reduce the likelihood or consequences of impact to the project's objectives.
- Determine the response based on a cost/benefit analysis (cost vs. expected effectiveness).
- Describe the actions to be taken to mitigate the risk and map to available resources.
- Describe the actions to be taken when the risk event occurs (contingency plan).
- Assign responsibilities for each agreed upon response.
- Assign a "due date" where risk responses are time sensitive.
- Include risk and trigger identification, risk review, and risk mitigation as standing agenda items on regularly scheduled project meetings.
- Communicate to stakeholders and sponsors when risk impact could change the project scope or impact project resources.

BP M.2 RISK MANAGEMENT ACTIVITIES

M.2(a) Does the project manager and all resources continually assess the project for risks? Perform preventive and/or mitigation activities on all high-ranking risks and pay particular attention to preventive measures could eliminate risk altogether?

M.2(b) Have all risks been logged, prioritized and analyzed and reported to the project sponsor, business owners and key stakeholders with the weekly project status report?

M.2(c) Are resources with decision making authority engaged in the risk mitigation process?

M.2(d) Encourage an environment that fosters open communication where project members feel at ease conveying project risks and consequences. (Don't shoot the messenger!)

M.2(e) Ensure risk mitigation plans are integrated with project plans (e.g., WBS, change management, issue management) when those plans affect project schedules, budgets, and deliverables.

Monitoring Project Change

Projects usually fail as a result of two problems. Either not enough time was spent defining the project scope or the change management plan was not rigorously executed. Without proper scope definition, any change management plan will be futile. Evoking the change management plan implies that a change is outside the scope agreed to in the project proposal. If that scope is unclear or leaves room for interpretation, then parties may find themselves in dispute whether a change request is in or out of scope.

Every request for project change should be funneled through the project manager. Each change should be assigned a number and logged into a change request log. Each request should be assigned to a member or members of the project team for investigation of the

cost, effort, and impact to the timeliness required by the change. Once these details are known, the project manager will meet with the project sponsor and key stakeholders to discuss the project impact and obtain their approval or disapproval to proceed. Review the change management flowchart, Figure 3.4.

The project manager should actively monitor the change request log and should do the following:

- Notify stakeholders and project team members of resolution of change requests.
- Document the resolution or course of action in the change request log. If the sponsor does not agree to the change request, then the request should be closed as "not approved."
- Enter modified tasks in the project schedule and modify baseline project planning artifacts based on change request resolution.

The project manager should also consider doing the following:

- Freezing change requests. The freeze can be implemented at various times, but usually are done no later than the beginning of testing. At this point, the team needs to focus on testing the current solution.
- Holding change requests that come out of user acceptance or testing on a backlog and dealing with them as enhancement requests after the solution is implemented.
- Holding everyone accountable for the change management process.
- Rejecting the temptation to use estimating contingency for scope changes.
- Identifying a dispute resolution process that addresses change requests that cannot be resolved by the change management plan.

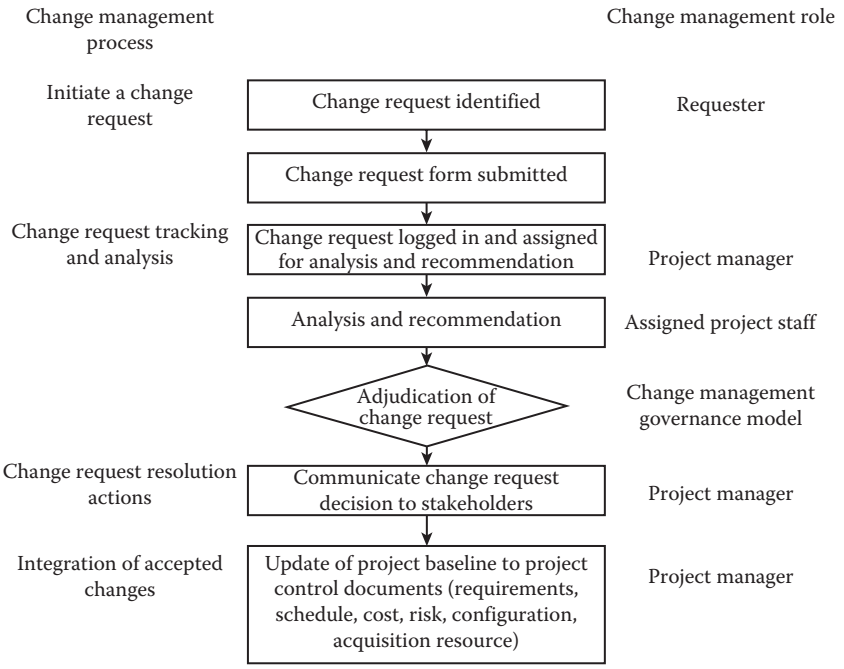

Figure 3.4 Change management process.

Monitoring Project Issues

Issues may result from resource conflicts, poor communication, unanticipated events and a host of other sources. It is important that all issues be funneled to the project manager so that he/she can work to resolve them quickly to keep the project moving forward.

The issue management plan developed earlier should have a detailed process for managing project issues. The issue management plan should include instructions for logging, tracking, escalating (where necessary) and resolving each issue and should be agreed to by project stakeholders.

A sense of urgency is required when managing issues. Each week the project manager should follow-up on open issues during status meetings and other discussions that are held. All issues should be assigned to a resource that is accountable for their resolution. Sometimes is may be helpful to group and prioritize the issues, especially when several issues are identified in a very short time. These issues may stem from a common project. Involve the team members responsible for activities related to the issue. If an issue must be escalated to senior team members and key stakeholders, remember to provide alternative solutions to assist them in decision making.

BP M.4 MONITORING PROJECT ISSUES

M.4(a) Are issues assigned a priority (related to impact to the project) monitored and evaluated on a weekly basis?
M.4(b) Are alternative solutions considered where practical?
M.4(c) Are resources with decision-making authority engaged in the issue resolution process?
M.4(d) Are the escalation processes followed when necessary?
M.4(e) If the issue results in a change to the project plan, is the change management process followed?

Monitoring Project Quality

Just as a quality assurance plan is necessary to ensure successful laboratory accreditation, a project quality assurance and control plan is necessary to ensure the project is on track with deliverables that are in scope, on schedule, and within budget. Project quality should be conducted using independent quality reviewers that report to the project sponsor. The project manager should not be the individual completing project quality assurance reviews.

Quality Assurance

The independent and regular review of project performance will validate the project manager's assertion that the project is progressing in a satisfactory manner. Frequent reviews (quality audits) of project documentation should be conducted and the results compared against the requirements in the quality management plan. The objective of these reviews is to identify lessons learned that may improve project performance and increase the likelihood for project success. Quality assurance efforts and reports should

BP M.3 MONITORING PROJECT CHANGE

M.3(a) Are change requests being monitored and evaluated on a weekly basis?
M.3(b) Are changes submitted in a timely manner to the project manager?
M.3(c) Are the requested changes in scope with the project?
M.3(d) Has the project manager and team completed the impact analysis (cost, effort, duration) for each change request?
M.3(e) Has the project manager reviewed the pending change request with the project sponsor, business owner, and key stakeholders?
M.3(f) Are stakeholders with decision-making authority engaged in the reviews?
M.3(g) For approved changes, have the impacts of the change requests been reflected in changes to other project control documents (project charter, charter, staffing plan, scheduling and task plans, etc.)?

be prepared according to the instructions provided in the quality assurance plan document, and quality assurance representation should be available at key meetings and project activities.

Quality Control

Quality control involves review of project deliverables to determine if they comply with relevant quality standards. There are a number of tools and techniques available for managing project quality. For a laboratory embarking on the development of quality methods, manuals, and procedures, inspection of the deliverables and peer reviews are most relevant. Quality control should be performed throughout the project. Each team member is responsible for the quality of their work and should carefully review their work before submitting it for inspection and peer review.

BP M.5 MONITORING PROJECT QUALITY

M.5(a) Does the project work and schedule plan include tasks related to project quality assurance?
M.5(b) Has the project sponsor assigned an independent quality assurance resource to evaluate the project?
M.5(c) Is the project quality assurance plan being followed?
M.5(d) Were lessons learned from previous projects (where applicable) reviewed and incorporated in the current project?
M.5(e) Has the project manager scheduled quality assurance reviews?
M.5(f) Do individuals responsible for project quality have access to all required materials and project information?
M.5(g) Are quality assurance reports included with the weekly project status reports, and is a member of the quality assurance team on hand during the weekly meetings with project stakeholders?
M.5(h) Is documentation and recommendations reviewed at the appropriate levels?
M.5(i) Are external/internal providers or contractors complying with quality controls?

Project Monitoring and Control Templates and Best Practice Checklist

Templates

- PMM-100 Change Request
- PMM-101 Change Request Impact Analysis
- PMM-102 Issue Notification

Best Practice Checklist

- BP M.1 Monitoring project work
- BP M.2 Risk management activities
- BP M.3 Monitoring project change
- BP M.4 Monitoring project issues
- BP M.5 Monitoring project quality

Project Closure

Overview

After either achieving its objectives or being terminated for other reasons, the project requires closure. From the beginning, the project manager and his/her team must know the criteria for project completion. Project closing consists of verifying the project's completion criteria have been met and other administrative activities. Before a project is considered complete and resources are released and final payment to suppliers made, the project must wrap up loose ends such as verifying that all deliverables have in fact been delivered and approved, outstanding issues are assigned for closure, lessons are documented, deliverables have been transitioned for ongoing maintenance, and formal acceptance has been received from the project sponsor, business owner, and key project stakeholders. Common lessons learned from skipping or poorly executing the closing phase are the following:

- Failure to obtain sponsor sign-off creates a never ending project.
- Poor close-out has caused problems with transitioning deliverables into maintenance, and this causes the inability or low capability to maintain the product.
- Lack of a project data repository (i.e., project books, archived lessons learned) prevents future projects from repeating similar mistakes made on other projects.
- Outstanding issues were dropped or later became bigger problems to deal with.
- Failure to reward/acknowledge team successes causes low morale problems, making the reassignment of staff problematic.

Verification of Deliverables and Formal Acceptance

The first step of the close-out process is the project sponsor's, business owner's, and key stakeholders' acceptance of the final deliverables of the project. This is a critical and important step, because it signifies that all stakeholders agree that the scope of the project and its deliverables are complete and were delivered as agreed upon by all parties. Acceptance should be based upon the success criteria defined in the initiating (project charter) and planning phases of the project. This acceptance should be formal, meaning that physical sign-offs should be obtained by the project sponsor, and the project steering committee, as appropriate.

BP C.1 VERIFICATION OF DELIVERABLES AND FORMAL ACCEPTANCE SIGN-OFF

C.1(a) Review project charter, scope documentation and related requirements, and design documentation. Are all deliverables complete and delivered as agreed upon in these documents? If there are deficiencies, the verification of deliverables must not take place until they are.

C.1(b) If verification of deliverables is complete, obtain formal acceptance and sign-off from the project sponsor, business owner, and other stakeholders. Typically, the same individuals that signed the project charter should formally accept and sign-off on project deliverables.

Procurement Audit and Contract Closeout

A structured review of the procurement process that was utilized during the project from the planning of purchase, acquisition, and contract administration stages is necessary to ensure the organization's procurement procedures have been followed but also to identify successes and failures that warrant recognition in the preparation or administration of other procurement contracts on the project, or on other projects within the performing organization.

Most forensic laboratories will follow the audit and contract closeout procurement standards and guidelines established by their governing authority. In some cases, the contract terms and conditions agreed to by the laboratory and external contractor will prescribe the specific requirements for contract closeout.

In the absence of audit and contract closeout standards, the following activities should be considered if an external contractor provided goods or services in support of project objectives. During the review, it is important to ensure organizational standards were followed. If deficiencies are noted, notice of corrective action may be required and comments related to deficiency should be noted during lessons learned activities.

BP C.2 PROCUREMENT AUDIT AND CONTRACT CLOSEOUT

C.2(a) Review of contract document to ensure all terms have been met.

C.2(b) Review bid procedures (i.e., invitation to bid and solicitation). Were all standards followed?

C.2(c) Review request for proposal procedures. Were all standards followed?

C.2(d) Review proposal receipt, evaluation, and award of contract procedures. Were all standards followed?

C.2(e) Do the contract terms provide for an audit of the contractor's records pertaining to the project? If yes, are there project circumstances that required an audit?

C.2(e) For projects where an audit of the contractor's records is required, schedule and conduct the audit and prepare a report of the findings.

Lessons Learned

In addition to communicating the closure of a project in writing, it is also advisable to have a mechanism for group review and assessment of the project. Lessons learned should draw on both positive experiences—good ideas that improve project efficiency or save money—and negative experiences—lessons learned only after an undesirable outcome has already occurred. Lessons learned sessions are a valuable closure mechanism for team members, regardless of the project's outcome. Lessons learned and comments regarding project assessment should be documented, presented, and openly discussed with the intent of eliminating the occurrence of avoidable issues on future projects. The lessons learned session is typically a meeting that includes the following:

- Project team
- Stakeholder representation, including external project oversight, auditors, and/or QA
- Executive management
- Maintenance and operations staff
- Project support staff

BP C.3 DOCUMENTATION OF LESSONS LEARNED

C.3(a) Did the delivered product (e.g., quality manual and procedures documentation) meet the specified requirements and goals of the project?
C.3(b) Are the project stakeholders satisfied with the end product(s)? If not, why not?
C.3(c) Did the project meet budget requirements? If not, why not?
C.3(d) Was the schedule met? If not, why not?
C.3(e) Were risks identified and mitigated? If not, why not?
C.3(f) Did the project management methodology work? If not, what could have been done to improve the process?
C.3(g) What bottlenecks or hurdles were experienced that impacted the project?
C.3(h) What procedures should be implemented on future projects?

Update and Archival of Project Documents

Historic project data are important source of information to help improve future projects. All records, both electronic and hard copy, should be stored according to the laboratory's record retention guidelines. The technical records will be turned over to the personnel responsible for maintenance and operation of the system or program after it has been deployed. The project archive includes a description of the files being stored, the application used to create the archived materials, the location where they are stored, and a point of contact for further information. Typically, at a minimum, the following project data are archived:

- Project charter
- Project plan
- Project management control documents

  - Correspondence
  - Meeting notes
  - Status reports
  - Contract files
- Technical documents
- All checklists
- Information that had been placed under configuration control
- Lessons learned
- Postproject review/evaluation

BP C.4 UPDATE AND ARCHIVAL OF PROJECT DOCUMENTS

C.4(a) Have the hard copy artifacts been stored according to laboratory standards?
C.4(b) Have project artifacts that may be useful for future projects been made available to the project library archive?
C.4(c) Does the folder structure used to store electronics documents meet laboratory standards?
C.5(d) Does the archive include a file that describes the artifacts included?
C.4(e) Do individuals responsible for the maintenance of the deliverable have access to the archive?

Release of Resources

The release of project resources should not be completed until an evaluation has been completed for each team member, discussed with the team member, and passed to the human resource function or the team member's department head. Additionally, the project manager should facilitate some type of celebration of project successes.

Project Closure Templates and Best Practice Checklist

Templates

- PMC-100 Project Closure Report Template

Best Practice Checklist

- BP C.1 Verification of deliverables and formal acceptance sign-off
- BP C.2 Procurement audit and contract closeout
- BP C.3 Documentation of lessons learned
- BP C.4 Update and archival of project documents

Overview of Six Sigma

4

OVERVIEW

At the heart of every laboratory quality assurance program should be standards, procedures, and a fact-based methodology used to develop processes and measure quality. Six Sigma is one such methodology.

The name Six Sigma is taken from the approach's statistical roots. If a product or process achieves a Six Sigma–level of consistency, then it is experiencing only 3.4 defects per million opportunities (DPMO). In other words, Six Sigma products and processes are 99.99966% free from defect. Six Sigma has been in existence for over thirty years. It has been implemented in numerous laboratories, including Los Alamos National Laboratory, Quest Diagnostics, Abbott Laboratories, and University of Nevada Las Vegas (UNLV) Biotechnology Center Forensic DNA Profiling Training Service Laboratory, to name a few.

In Six Sigma, the laboratory uses a proven, five-phased approach known by the acronym DMAIC (e.g., define, measure, analyze, improve, control) to gain improvements in process and product quality specifically to do the following:

- Define the problem area in objective terms
- Measure the performance of products and processes
- Analyze the problems to identify root causes
- Improve the results by redesigning processes and reducing variation
- Control the processes to ensure the improvements are permanent

Why is the implementation of Six Sigma, or *any* quality assurance tool, important to the success of the forensic laboratory? Every quality assurance tool is essential in ensuring the reliability of the results of the examinations performed by the laboratory. The reliability of the results of a forensic examination that protects a person's liberty is second only to the reliability of the examination results that affect a person's health. Therefore, every effort should be made to ensure the reliability of the results of examinations that influence a precious thing. Six Sigma provides that tool.

Consider this: Philosophically, the function of forensic science is to extract the truth beyond a reasonable doubt. However, there is a school of thought that insinuates that forensic laboratories are incapable of obtaining this level of confidence. As Michael Saks states in his 2001 *Arizona State Law Journal* article, "As it is practiced today forensic science does not extract the truth reliably. Forensic science expert evidence that is erroneous (that is, honest mistakes) and fraudulent (deliberate misrepresentation) has been found to be one of the major causes, and perhaps the leading cause, of erroneous convictions of innocent persons."*

* Saks, Michael, et al. (2001), "Model Prevention and Remedy of Erroneous Convictions Act," *Arizona State Law Journal* 33: 665–718.

The following headlines refer to errors in crime laboratories throughout the United States. These stories appear to support Saks's assertions.

- Detroit* (2008)—The Detroit police crime lab was shut down by the city's new mayor and police chief after a preliminary audit indicated about a 10% rate of inaccuracies related to ballistics evidence testing involving firearms.
- Baltimore† (2008)—In August 2008, the city police department's crime lab director was dismissed after it was determined that crime analysts had been contaminating evidence with their own DNA.
- Seattle‡ (2004)—A report in the *Seattle Post-Intelligencer* found that forensic scientists at the Washington State Patrol laboratory had contaminated tests or made other mistakes while handling DNA evidence in at least 23 cases involving major crimes over a three-year period, including eight instances in which analysts contaminated samples with their own DNA.
- Houston§ (2003)—DNA testing was suspended in the Houston Police Department DNA department after nine crime laboratory employees were disciplined after an audit revealed that thousands of cases had to be retested because of errors in DNA analysis and possible contamination of samples.

In addition to analyst error, forensic laboratories must juggle backlogs in critical analytical services. "The rapid adoption of DNA technology has led to the passage of legislation, which expanded the use of DNA databases worldwide. This expansion has included an increasingly wider range of qualifying offenses warranting the sample submission of convicted offenders; in some jurisdictions, individuals arrested for certain crimes and, in some instances, the sampling of alien detainees. As the database has grown, so has the ability to solve crimes by searching against the database, resulting in a significant increase in the number and types of crime samples submitted for comparison."¶ Public crime labs are overwhelmed by backlogs of unanalyzed DNA samples. As DNA technology continues to evolve, crime labs are forced to continually validate and implement new procedures and, in turn, provide additional training and assistance to ensure the optimal use of DNA evidence to solve crimes. This combination of errors and backlogs resulting from inefficient processes can have serious negative consequences in a criminal court proceeding.

The resolution for these issues is to implement a factually based quality and process improvement program that is championed by senior leadership in the laboratory to address corrective action, preventive maintenance, and ongoing process improvement.

Our goals for this chapter are simple:

1. Introduce the use of Six Sigma as a fact-based methodology and set of quality tools, and provide a short overview of is history, of its context in the lab. There are hundreds of books written about Six Sigma and thousands of Web sites devoted to its use for you to explore in greater detail.

* http://abcnews.go.com/TheLaw/wireStory?id=5884750
† http://www.baltimoresun.com/news/maryland/bal-te.md.lab21aug21,0,5612027.story
‡ http://www.seattlepi.com/local/183007_crimelab22.html
§ http://truthinjustice.org/baltimorepdlab.htm
¶ Frappier, Roger, Calanddro, Lisa, and Schade, Lisa Lane (February/March 2008) "Improving Forensic DNA Laboratory Throughput: Enhanced Data Analysis and Expert Systems Capability"

2. Provide a few relevant examples for you to consider as you develop your quality manuals.

History

The term *Six Sigma* comes from the field of statistics. Sigma is a Greek symbol that denotes standard deviation—in other words, *variation* around the mean value, typically on a bell curve. Its origin as a measurement standard can be traced back to the early industrial era and to Carl Frederick Gauss (1777–1855)*, who introduced the concept of the normal curve metric. Six Sigma as a measurement standard in product variation could be traced back to the 1920s to Walter Shewhart, who showed how three sigma deviations from the mean required a process correction.

The "first wave," or modern use, of Six Sigma† as a quality methodology originated at Motorola during the late 1980s as a result of a Japanese firm's ability to turn around a TV Motorola plant. Under Japanese management, the factory soon produced TV sets with one-twentieth the number of defects that were produced under Motorola management. The success of the Japanese firm to reduce product defects caused Motorola to take quality seriously, and when Bob Galvin became Motorola's CEO in 1981, he challenged his company to achieve a tenfold improvement in performance over a five-year period.

At Motorola, the team of Mikel Harry and Bill Smith discovered that products built with fewer nonconformities were the ones that performed the best after delivery to the customer.‡ Challenged by executives from the company, Galvin and Harry developed a four-stage problem-solving approach: Measure, Analyze, Improve, Control (MAIC). Later, the MAIC discipline became the road map for achieving Six Sigma quality and was launched as the firm's long-term quality program, called the Six Sigma Quality Program.

After implementing Six Sigma, in 1988, Motorola was among the first recipients of the Malcolm Baldrige National Quality Award. Since then, Six Sigma has constantly caught the attention of industry. In 1993, Harry moved to Allied Signal, where he developed a methodology for a leadership team to select high financial leverage projects. At Allied Signal, an entire system of leadership and support systems began to form around the statistical problem-solving tools of Six Sigma.

Not long after Allied Signal began its pursuit of Six Sigma quality, Jack Welch, then the chairman and CEO of General Electric (GE), began to get interested in Six Sigma. An analysis completed at that time showed that if GE, then running at a three to four sigma quality level, were to raise its quality to Six Sigma, the cost-saving opportunity would be somewhere between $7 billion and $10 billion, or 15% of sales.§ Working with the Six Sigma Academy, Welch launched Six Sigma at GE. At that time, he called Six Sigma the most ambitious undertaking the company had ever initiated. GE incorporated Six Sigma into its culture, from the CEO down, and in less than two years, it realized impressive results in invoice defects, disputes, medical scan times, and other key operational areas.

The "second wave" extended Six Sigma into transactional and services applications and organizations during the 1990s and has also met with remarkable success. A number

* http://en.wikipedia.org/wiki/Carl_Friedrich_Gauss
† http://www.galvinpower.org/about/galvin.php?id=10
‡ http://www.pqa.net/ProdServices/sixsigma/W06002009.html
§ http://en.wikipedia.org/wiki/Six_Sigma

of high-profile service companies have demonstrated equally impressive results in company-wide deployments, including Unisys Corp in 1988 and Asea Brown Boveri in 1993. It was Asea Brown Boveri that gave Six Sigma its final finishing touch by putting emphasis on customer satisfaction.

Where Does Sigma Sigma Fit?

In all organizations, initiatives based on strategic goals and objectives identified by performance measures, risk, or other management activities are underway to improve processes. Enabling these initiatives are different groups of standards and quality tools such as ISO, Information Technology Infrastructure Library (ITIL), DNA Advisory Board Guidelines, ASCLD/LAB Accreditation Standards, Local Health Board Standards, and quality assurance programs. We call this relationship of management initiatives and quality enablers for continuous process improvement *laboratory transformation governance* (see Figure 4.1).

The end goal of laboratory transformation governance is to create a framework for continuous process improvement leading to a laboratory environment where improvements are based on business (customer) drivers, with an end result that can be measured against documented standards.

In this framework, the laboratory has several management areas providing the strategic goals and directions governing the implementation of process improvement. These management areas are the following:

Performance measures—Performance measurement can be best understood by considering the definitions of the words *performance* and *measurement* according to the Baldrige* Criteria:

> Performance refers to output results and their outcomes obtained from processes, products, and services that permit evaluation and comparison relative to goals, standards, past results, and other organizations. Performance can be expressed in both nonfinancial and financial terms.

Measurement refers to numerical information that quantifies input, output, and performance dimensions of processes, products, services, and the overall organization (outcomes). Performance measures might be simple (derived from one measurement) or composite.

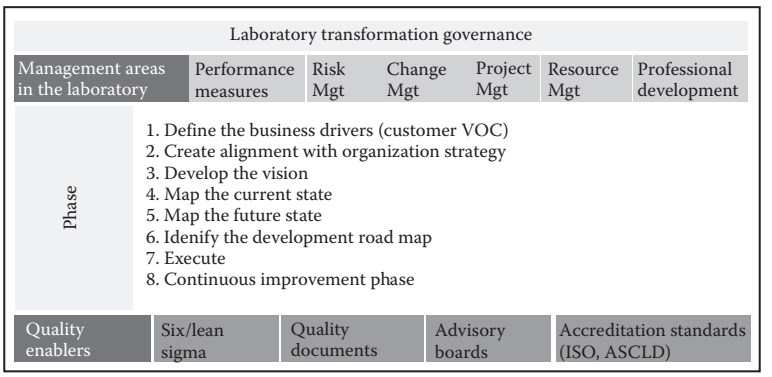

Figure 4.1 Laboratory transformation governance.

* http://baldrige21.com/BALDRIGE%20GLOSSARY/07%20Performance.pdf

In the context of a laboratory, these may include case productivity, proficiency testing, courtroom monitoring, customer satisfaction, and the ability to meet the goals and objectives of the parent organization or agency.

Risk management—Risk management is the laboratory's direction for managing the probable material effects in an uncertain environment, including planning, assessing, developing options, monitoring, and documentation of documenting potential risks.

Change management—Change management is the laboratory's direction for managing change throughout the laboratory system, including the goals, the way people think, norms, systems, and processes.

Resource management—Resource management is the laboratory's direction for managing its resources, including its staff, staff levels, equipment, chemicals and consumable items, facility issues, and management of funds associated with these consumables.

Project management—Presented in Chapter 3, project management is the laboratory's direction for management of projects from initiation and planning through execution, controlling, and project closure. Project management is concerned with the management of resources, schedules, scope, quality, cost, procurement, and so on.

Personnel development—Personnel development is the laboratory's direction for the strategic investment in the education, certification, and development of laboratory personnel.

So, where does Six Sigma fit into this picture? Six Sigma is a quality enabler. If ISO and ASCLD/LAB standards and Advisory Board Guidelines tell you what the laboratory must do, then Six Sigma in conjunction with the laboratory's quality documentation will provide the road map for getting it done.

What Does It Mean to Be at Six Sigma?

We said earlier that Six Sigma is used by statisticians to denote the standard deviation for a set of data. The standard deviation provides an estimate of the variation in a set of measured data. The goal of Six Sigma is to produce a process where there are no more than 3.4 DPMO. What is a defect and how would you define opportunities within Six Sigma? A defect is anything that is outside of the customer's specification, while an opportunity is the chance for a defect to occur during the process. Let's take a look at a simple calculation. Suppose a large state laboratory completes 100,000 blood alcohol tests in a year. At the end of the year, the laboratory director is informed that the defect rate for the year was 15 defects per 100,000. When using a Sigma calculator, the results are as shown in Figure 4.2.

Current numbers

Total	Good	Defects	Conversion
100,000	99,985	15.00	99.98500%

Current sigma level		
Good yield (%)	99.98500%	Good/total
DPU defects (%)	0.015%	Defects/total
DPU	0.000	(Total – good)/total
DPMO	150.0	DPU × 1,000,000
Sigma level	5.1	Refer to sigma chart

Figure 4.2 Sigma level calculation for blood alcohol tests.

What exactly do these numbers mean? DPMO is "defects per million opportunities." As the number of defects decrease in a process, the level of sigma increases.

Sigma Level	DPMO
6	3.4 defects
5	233 defects
4	6,210 defects
3	66,807 defects
2	308,537 defects

Six Sigma literally means the number of standard deviations away from the mean, or the average, as indicated on a bell curve. This is also known as the normal distribution. Thus, when calculating the mean, Six Sigma allows for 3.4 DPMO. Ideally, if the laboratory completes 1,000,000 alcohol tests in a year, only 3.4 of the tests should be defects. For a sample size of 100,000 with one opportunity to fail per test, then *all* 100,000 of the tests would need to be completed defect-free to claim Six Sigma. The remainder of the tests fall under the "normal distribution" as indicated on the bell curve. In our alcohol test example, the sigma level is 5.1.

When looking at Figure 4.3, LSL is "the lower specification limit" and USL is "the upper specification limit". Again, Six Sigma allows for six process standard deviations between the mean in the process and the customer's specification limit. As the process sigma level increases from zero to six, the variation in the process around the mean will decrease. The shift of 1.5 is considered a standard in industry to account for process variation over many cycles.

This is a lot to process at this basic level, but in essence, Six Sigma and the role of the laboratory professional is to quantify the process performance, which is the short- and long-term capability, taking the process entitlement and process shift, to create the right strategy in order to reach the determined performance objective. We have included a Microsoft Excel spreadsheet to assist you in your calculations of Six Sigma and DPMO. In the spreadsheet, we use the Excel function NORMSINV. NORMSINV is a function that delivers the inverse of the cumulative normal distribution. You enter the "probability that a value Z is up to..." and it returns that value Z (in terms of "sigma," because it is the standardized distribution with average 0 and sigma 1):

$$= \text{NORMSINV}(1 - ((\text{D9}) / (\text{B9}))) + 1.5$$

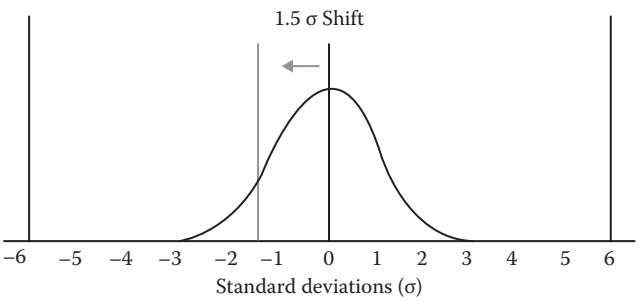

Figure 4.3 Normal distribution with 1.5 shift.

where D9 = 15 and

where B9 = 100,000.

Staffing for Six Sigma

Depending on the size of the laboratory, the resources involved in Six Sigma initiatives may include individuals directly responsible for completing daily casework, a group of individuals hired specifically to address Six Sigma initiatives, or some combination of laboratory employees and Six Sigma consultants (see Figure 4.4).

The Six Sigma organization should be led by an executive council providing the vision and its unequivocal support for the program. Regardless of the organizational structure, there are specific functions, responsibilities, and training requirements for the various individuals working on Six Sigma projects in the laboratory.

Executive Council

The executive council will include the executive leadership for the organization. Depending on the size of the laboratory, this may or may not include the laboratory director or other senior managers. The initial task of this group is to plan and execute the implementation of Six Sigma in the organization. The direction or "vision" to implement Six Sigma must start at the top and be communicated down to all employees. The executive council must set clear and realistic objectives for Six Sigma that should be translated into actionable tasks

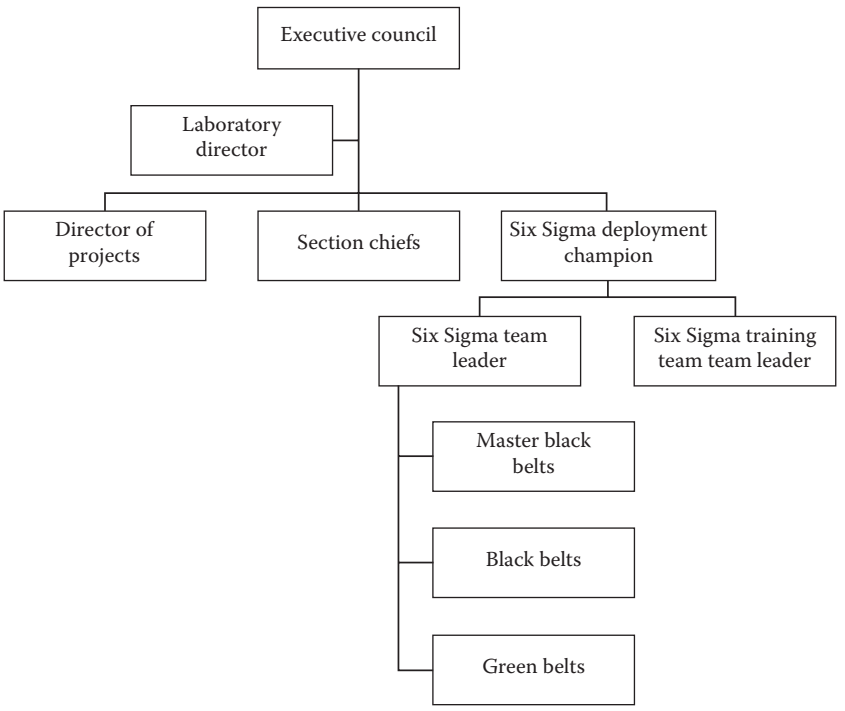

Figure 4.4 Sample Six Sigma organization chart.

and should hold itself and others accountable for the success or failure of the organization's efforts. At a minimum, the function and responsibilities of the executive council include the following:

Function	Responsibilities (10% Time)	Training
• Sets the vision for the program • Creates the mandate for improvement • Initiates and funds the activities • Establishes and maintains reporting structure	• Identifies champions in each functional area • Performs a monthly review of projects by champion • Measures champion results	• Executive overview (four hours) • Champion training (two days)

Deployment Champion

The deployment champion may also be known as the project sponsor. In most organizations, the champion is a senior manager who oversees the Six Sigma program and is accountable to the executive council for the success projects. In some cases, the laboratory director may be the champion. In other organizations, it may be a bureau chief or some other individual or agency employee.

The champion's role is to provide the Six Sigma working team with clear guidelines for their projects, ensure funding is in place to procure the necessary resources and required items, coach and approve changes in the team's project charter and/ or project scope, and, where necessary, remove roadblocks and advocate for the team's efforts to the executive council.

Function	Responsibilities (10% Time)	Training
• Communicates the vision of the program • Creates the mandate for improvement • Provides direction and removes barriers • Achieves financial results and communicate success	• Identifies black belts and green belts • Identifies and approves all Six Sigma projects • Performs a biweekly review of all projects • Measures black belt performance	• Champion training (two days)

Master Black Belt

The master black belt takes a leadership role as mentor to the laboratory's black and green belts and advisor to the executive council. A master black belt is a proven change agent, leader, and facilitator and one who has successfully led many Six Sigma initiatives or complex projects. He/she needs exceptional communication, negotiation, and statistical skills. Generally, master black belts provide coaching and expert advice in areas ranging from project and change management to statistical measurement. The master black belt may also lead Six Sigma education and training efforts for laboratory employees.

While it is best for the laboratory to internally develop associates to the master black belt position, it is not always possible. For this reason, many laboratories will enlist the aid of an external consulting firm to fill this role.

Function	Responsibilities (10% Time)	Training
• Provides technical expertise on Six Sigma and Lean methodology to black belts and green belts • Works in support of the black belt and champion • Assists in education and training activities	• Works daily with team members, black belts, and champions • Participates in the review of projects • Monitors all Six Sigma projects	• 15-day black belt training, two years minimum as a black belt, and a master's degree in a related field

Black Belt and Green Belt

At the heart of the Six Sigma projects are the black belts and green belts. Black belts are generally 100% devoted to Six Sigma initiatives for a period of two years and are skilled in change and process improvement. Ideally, individuals selected for this role have technical and managerial experience, are excellent communicators, write well, understand the DMAIC methodology, and easily function at all levels of the organization. The black belt working with the project manager will develop the project charter, lead the Six Sigma team, mentor team members in the design and analysis of experiments, help team members prepare for reviews, and coach green belts leading projects.

Green belts are assigned to Six Sigma project on a part-time basis (on average 20%), either as a team member for a complex project or as a project leader for a smaller initiative. Green belts are the mainstay of the laboratory's Six Sigma pool and are typically chosen from a group of experienced managers. On smaller initiatives, the green belt will perform most of the same tasks as the black belt discussed above.

Function	Responsibilities (20–100% Time)	Training
• Black belts 100% dedicated for two years to process improvement, green belts 20% • Works on improvement projects with other green belts and team members • Achieves financial results for each project, goal of $350K+	• Uses the DMAIC methodology to create breakthroughs in performance • Reports progress to the champion • Holds team meetings and provides excellent project management • Works with the master black belt	• 15-day black belt training and five-day green belt training

All Employees/Team Members

All laboratory employees may be called upon to participate in Six Sigma initiatives. Team members carry out instructions for data collection and analysis, participate in meetings, and provide subject matter expertise when called on. These members should be the employees in the laboratory that are willing to challenge the status quo and are not afraid to ask dumb questions.

Generally no more than four to six members (not including the black and/or green belt and project manager) should be involved in an initiative. Depending on the size and scope

of the initiative, these individuals should expect to devote two to four hours per week in data collection and team meetings.

Function	Responsibilities (5–10% Time)	Training
• Works to achieve excellence in daily work • Participates in Six Sigma projects • Supports team activities • Identify its opportunities for improvement	• Participates in Six Sigma activities as requested • Completes action items as assigned by the team • Attends team meetings	• One-day Six Sigma employee training

Implementation of Six Sigma in the Laboratory

So, how does a laboratory start a Six Sigma initiative?

Unfortunately, a laboratory does not become a Six Sigma organization with champions, black belts, and green belts overnight. Preparation is key, and absolute for success. Ideally, the laboratory can come up to speed in approximately four months. (See Figure 4.5).

Phase I—Implementation	
Month 1	Establish the executive council
Month 2	Organize leadership training
Month 2	Integrate organization change management (assumes exists)
Ongoing	Integrate data governance (assumes exists)
Months 2–3	Develop systems for establishing close communication with customers, employees, and suppliers, complete base studies
Months 2–3	Establish a framework for continuous process improvement along with a system for monitoring progress and success—assumes update
Months 2–3	Choose business processes to be improved—Six Sigma projects are conducted to improve business performance linked to customer requirements and measurable results
Phase II - Plan the program	
Month 3	Select experts and professional services including training vendor
Month 4	Perform detailed planning activities
Month 4	• Define the deployment plan. • What are the deployment goals at a business, operations, and process level? • Which processes (value streams) are critical to business performance? • How do processes deliver value to customers? • Which metrics and current performance levels will be used? • How will we measure the key value streams? • Are our measurements accurate? • Standardize the new approach—write the procedures. • Develop the management plan
Month 4	Define the communications plan
Month 4	Conduct organization change management readiness survey

Figure 4.5 Six Sigma implementation plan.

Initiation and Deployment Planning

Success is not guaranteed but can be greatly enhanced by ensuing the following are included:

- Clear need, strategy, and goals for improvement
- Involvement by senior leadership and laboratory management
- Procedures for selecting strategic improvement projects
- Good improvement methodology (DMAIC!)
- Dedicated and trained associates (black belts, green belts, champions, employees)
- Periodic reviews by various levels of management
- Communication, communication, and more communication
- Recognition, reward, and celebration

Program Cost

There is a cost to implementing any quality program, and Six Sigma is no exception. In 2003, *Quality Digest* surveyed a group of 250 companies that had implemented Six Sigma. Their findings are shown in Figure 4.6.*

Project Selection Techniques

Not every project is a candidate for a Six Sigma initiative. It is the responsibility of the executive council and senior leadership to ensure that Six Sigma initiatives are focused on the right goals and to ensure staffing and access to interdepartmental resources are available. The laboratory must develop a method to prioritize potential projects for selection. The laboratory might select projects based on their return on investment, level of effort, impact to the organization and/or desirability. In Figure 4.7 projects are compared based on level of effort, impact and desirability in order to determine their probability of success. The size and location of the bubble provides a visual representation of the estimated project success. In the example, Project 9 which is assumed to have the highest probability of success.

Yearly cost of Six Sigma implementation based on company size

Stand-alone business			Part of larger organization				
No. employees	No. of cos.	Avg. cost	No. employees	No. of cos	Avg. cost	Avg. no. emp.	Cost/emp.
1–50	4	$22, 750	1–100	5	$32,340.00	54	$598.89
5–100	8	$60,650	101–500	20	$120,055.25	321	$374.00
101–250	6	$124,166	501–1,000	21	$121,190.48	733	$165.33
251–500	7	$39,285	1,001–2,500	27	$451,925.93	1,798	$251.35
501–1,000	3	$166,667	2,501–5,000	38	$681,447.37	3,960	$172.08
			5,001–10,000	27	$944,118.52	8,125	$116.20
			10,001–25,000	21	$3,075,476.19	16,747	$183.64
			25,001–50,000	35	$5,317,142.86	39,228	$135.54
			50,001–100,000	20	$2,073,250.00	74,250	$27.92
			>100,000	15	$6,825,473.21	217,142	$31.43

These number are based on the roughly 250 respondents who provided cost data.

Figure 4.6 Yearly cost of Six Sigma (http://www.qualitydigest.com/nov03/articles/01_article.shtml).

* (http://www.qualitydigest.com/nov03/articles/01_article.shtml).

Six Sigma project selection grid

Rating scale criteria should be defined and agreed to prior to rating the projects

		Scale: 1–5			Range: 1–25
Proj #	Project name	Effort	Impact	Prob of success	Desirability index
1	Project A	5	4	4	3.2
2	Project B	2	3	4	6.0
3	Project C	3	5	4	6.7
4	Project D	3	2	3	2.0
5	Project E	3	1	2	0.7
6	Project F	2	3	5	7.5
7	Project G	5	1	3	0.6
8	Project H	2	3	1	1.5
9	Project I	1	5	4	20.0
10	Project J	4	4	2	2.0

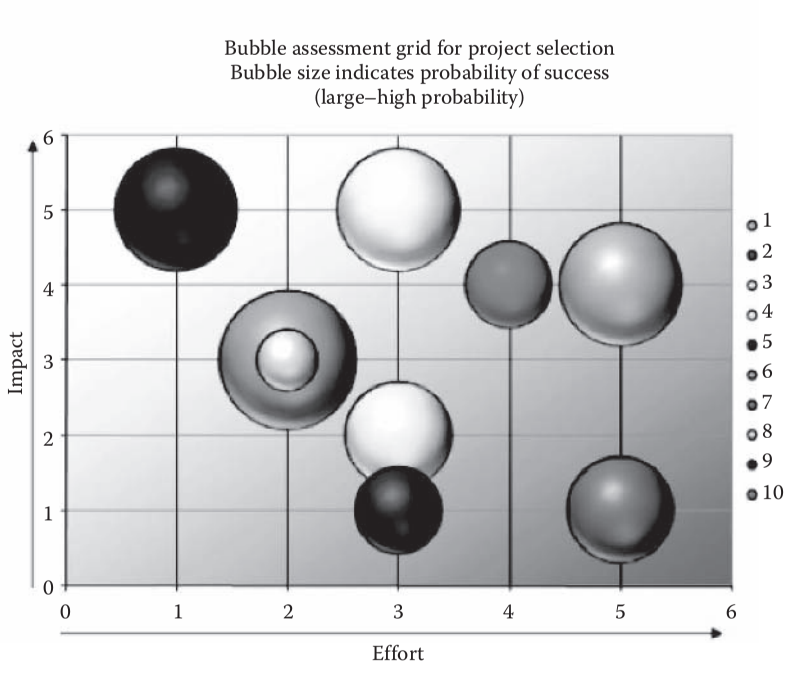

Figure 4.7 Sample Six Sigma project selection matrix.

Six Sigma Foundation—DMAIC

Overview

DMAIC is an acronym for the five phases of a Six Sigma initiative (Define, Measure, Analyze, Improve, and Control). The DMAIC structure enables project teams to identify the root causes of process variation and then design and implement solutions to control those causes. Once implemented, the solutions are measured and controlled to validate if the goals and objectives of the project have been met. Each step in the DMAIC process is recommended to ensure the best possible results.

A formal review should be conducted at the end of each phase. The formal review allows the team to present their project status and results to the executive council, who make a go/no go decision for the next phase of the project. These reviews increase project visibility, promote buy-in by the laboratory's managers, provide for timely and complete communication, reduce financial and implementation risks, and force teams to rigorously apply the DMAIC methodology.

Define

In the define phase, the project team will identify the issue and why it is a problem. A goal statement, or "desired future state," is also identified.

Let's review the following example:

Problem: The caseload backlog in the drug section (testing of blood alcohol samples) is twenty-five days.
Case for change: The delay in analyzing evidence causes delays in filing of cases by the district attorney.
Goal statement: Reduce caseload backlog for blood alcohol tests to less than two days.

Measure

In the measure phase, the team will identify all the potential causes that are impacting the laboratory's output (in this case, the number of days backlog in the drug section) and will collect data/information about it. Potential causes include the following:

- Property and Evidence is late in notifying the lab of pending samples to examine.
- It takes more than a week for each report to make it through administrative review.
- There are not enough analysts to perform the examinations.

Analyze

In the analyze phase, the team continues to review the potential causes and works to determine which ones have the most significant impact on the laboratory's output (caseload backlog) and drills down to identify their root causes. For example, the team may believe staffing levels is a significant contributor to the backlog. Perhaps they have discovered the number of blood alcohol cases submitted to the laboratory in the current year is 30% higher than in the previous year and the laboratory has not engaged additional staff to cover the increase. The team needs to examine the evidence (data) to identify the deeper reasons or root causes behind the factors they have identified.

Improve

Once the team identifies the root causes that are contributing to the laboratory's backlog, they will brainstorm and use other tools to develop and pilot potential solutions. A few questions the team will explore during the improve phase include:

- What is the possible root cause of the problem or defect?
- How can the root cause be prevented or eliminated?
- What changes in process need to be changed and once changed, how do we know the changes will be effective?
- What are the next steps?

In our example, one solution might include suggesting an increase in staffing levels.

Control

Control is a very important phase. During the control phase, the team implements the solutions and monitors to make sure that the improvements can be sustained! If additional staff were hired to resolve the backlog, then the caseload backlog should decrease incremental to the number of new staff hired. For example, let's say the laboratory hired two additional analysts with the expectation that the backlog of cases would be eliminated in 60 days. At the end of 60 days, the team reviews and sees that, indeed, the backlog has been reduced from 25 days to two days, as desired. At the end of six months, the team again monitors the result and sees the backlog has again increased, this time to ten days. The team will be able to identify where the process got "out of control" and drill down to determine what went wrong and what is required to get it back in line.

The DMAIC process provides the framework/approach for improving the laboratory's processes and reducing error. It is not perfect. Things to keep in mind as the project team is working through the process are the following:

- Choose appropriate projects.
- Identify and manage scope at the appropriate level.
- Utilize the project management approach discussed in Chapter 3 for managing the project. Six Sigma is a quality enabler. It is not a project management tool!
- Listen to customers. The laboratory's customers include interdepartments, funding agencies, law enforcement, and the courts.
- Use consistent information across phases and resist the urge to use jargon and acronyms.
- Identify the root cause of the problem and create a program that addresses the problem and only the problem. Validate that the program met project goals.
- Address organization change management. To succeed, projects must include tasks and activities to address change, create a sense of urgency, build coalition between stakeholders, remove obstacle, plan for short-term wins, and, most important, anchor the changes in the laboratory. The individuals managing the project must articulate and commute the vision for the project goals to all stakeholders.
- Plan for risk.

Define

Overview

What activities occur during the define phase of a Six Sigma initiative? In some respects, the design phase is similar to that of the project management initiation phase. During this phase, the team works to define the goals and scope of the project, create a similar vision for each team member, and provide an estimate of the potential benefits and impact to the laboratory and the customer. This involves selecting a project from among several potential projects and setting realistic, measurable goals. The influence and support of the champion help to develop commitment and set the scope of the project. The black belt mentors the project team in the use and selection of tools, facilitates activities, documents the process and selects the right people for the team. At this step, there is opportunity for the champion and black belt to make sure the right people are on the team. There is also emphasis to determine customer needs through an analysis of the "voice of the customer."

In terms of project selection, typically somewhere in the organization a red flag was raised identifying the need for a Six Sigma initiative. Perhaps operational reports reviewed by laboratory senior leadership indicate an extensive backlog in cases or an increase in corrective action reports related to DNA analysis. Regardless of their source, the circumstances requiring the laboratory to kick off a Six Sigma initiative will generate a number of activities, including these:

- Identification of the problem or initiative
- Provision to staff the initiative
- Conducting the initial (or current state) analysis
- Finalizing objectives and goals
- Refining the Six Sigma charter
- Presenting the business case and related information to leadership for approval to move to the next phase

The purpose of a current state analysis is to identify the underlying causes of variability in the process. Since many types of data could be collected and considering the fact that the teams have only a limited amount of time in which to collect these data, selection of appropriate data becomes paramount in importance. The following guidelines will help the team decide what data will be most important to them:

- Ask, "What is wrong with the process as it is today?" By utilizing brainstorming sessions, flowcharts, interviews, and other tools, the team documents the current state of the process and identifies the major problems. These problems may be varied: poor quality, duplicated steps, unnecessary approvals, time delays, lost documents, high failure rates, customer complaints, and unsatisfactory outcomes, to name just a few. These suspicions can be validated or discarded with appropriate data.
- Ask, "What don't we know?" This may mean collecting data on the volume of transactions, the number of times data are reentered, the actual wording of laws and regulations, etc.

A final rule of thumb is to be very selective and go after a few, three, or four, key facts that will do the most to highlight what is wrong with the current state. Go first after

data that already exists and avoid the temptation to begin lengthy studies that cannot be completed in the available time. One hundred percent sampling is not necessary. Absolute precision is not important—just reasonable approximations.

Here are some key questions:

- Why must this project be done NOW?
- What is the business case for the project?
- Who is the customer?
- What is the current state?
- What is the desired future state?
- What is the scope of this project?
- What are the tangible deliverables?
- What is the due date?

Define Phase Deliverables

At the end of the define phase, the project team should have the following:

- A clear statement of the intended improvement (project charter).
- A high-level map of the processes suppliers, input, process, output, and customers (SIPOC) [e.g., supplier, input, process, output, customer].
- A list of what is important to the customer critical-to-quality (CTQ) [e.g., critical to quality].
- An understanding of the project's importance to the laboratory's strategy.
- A tollgate review.

The primary deliverable from the define phase is the project charter and a presentation of the business case (we call this a tollgate review) to the executive council requesting their approval to proceed to the next phase.

Six Sigma Charter

The Six Sigma charter is used to control and manage the Six Sigma initiative. Although the project charter we explored in Chapter 3: Project Management could be used for a Six Sigma initiative, it is overkill for managing these types a projects. Instead, a one- or two-page document that includes the following information is sufficient:

- Purpose of the project—This is a brief statement outlining the primary outcome of the project. Example: Reduce caseload backlog in the drug section.
- Business need—This section answers the "Why do we care?" question. Example: A backlog of cases delays court proceedings.
- Problem statement or current state—The problem statement summarizes the problems to be addressed. It should also state the current or historical conditions related to the project. For example: The current caseload backlog is 25 days. The target is two days. The caseload backlog currently averages *X*. This is important because caseload backlog in the drug section delays resolution court case.
- Who is the customer? Example: The customer is the law enforcement agency conducting traffic enforcement.

- Objective or desired future state—The objective is a more specific statement. For example: The laboratory must reduce caseload backlog by two business days within 120 days.
- Scope—The scope is the specific area(s) to be addressed. The project should be scoped for completion within a two- to four-month period. Use a WBS (as discussed in Chapter 3) to break down the project into its discrete parts. Review the state of the equipment in use and staffing levels and evaluate the need to examine every sample. Remember to review statutory requirements. Example: An analysis of procedures in Property and Evidence, the Drug Section, technical review, and administrative review will be conducted, as well as a review of the current statutory requirements related to disclosure of blood alcohol drug tests.
- Roles and responsibilities—The roles and responsibilities area should provide information about the project stakeholders and team members. Here is an example:
  - Stakeholders: Property & Evidence, Submitting Agencies, Quality, Project Office, Drug Section, Legal.
  - Sponsor: Section Chief Drug Analysis.
  - Black Belt: Tom Lang.
  - Team Members: Mitch Ames (GB), Robert Pike (Section Lead), Perry Todd (Quality), Janet Anderson (Project Manager).
- Resources include not only laboratory associates but also processes, equipment, and databases that may be needed to complete the project.
- Milestones/Measures
  - Deliverables.
  - Time frame—The project charter will provide dates for the key project milestones. A detailed schedule (GANTT chart should be attached). For example:
    - Date Project Charter Signed: 2/28/2009.
    - Anticipated Completion Date: 4/30/2009

Tools and Techniques

Several tools are available to assist the project team answering these questions. The tools most commonly used in the define phase include these:

- Stakeholder analysis
- CTQ tree analysis
- SIPOC process map
- Flowcharts
- Pareto diagrams

Stakeholder Analysis

In an effort to mitigate the resistance to change when the improvement is implemented, it is crucial to identify the stakeholders early on and to develop a communication plan that addresses their needs. A communication plan is a written document that describes:

- To whom project information should be addressed, types of information that should be communicated objectives

- How the information should be communicated
- When the information should be communicated
- How the project will measure the results of the communication

Regular communication creates more buy-in, helps to identify better solutions, and reduces project risk.

Typical stakeholders include section chiefs, resources who work in the process under study, upstream and downstream departments, customers, suppliers, legal, law enforcement agencies, and finance.

Critical-to-Quality Tree

The purpose of a critical-to-quality tree is to convert customer needs/wants to measurable requirements. For example: Due to reliance on forensic testing to help solve crimes, a federal law enforcement agency created a project to address backlogs and quality concerns in one of their DNA laboratories. In one laboratory, they examined the failure of a former technician to complete steps designed to detect contamination in the DNA testing process.*

By analyzing Critical-to-qualities (CTQs) and performing a broader assessment, the team concluded that certain DNA analysis unit protocols and practices were vulnerable to inadvertent or willful noncompliance and that certain protocols lacked sufficient detail, failed to inform the exercise of staff discretion, failed to ensure the precision of manual note taking, and were outdated (See Figure 4.8). Based on their analysis, the group developed recommendations that include: (1) replacing vague sections of the protocols with comprehensive guidance and descriptions of the best practices currently in use; (2) adding workflow and decision aides to protocols to assist staff members in exercising proper judgment during the DNA testing process; (3) providing guidance to staff members in the case

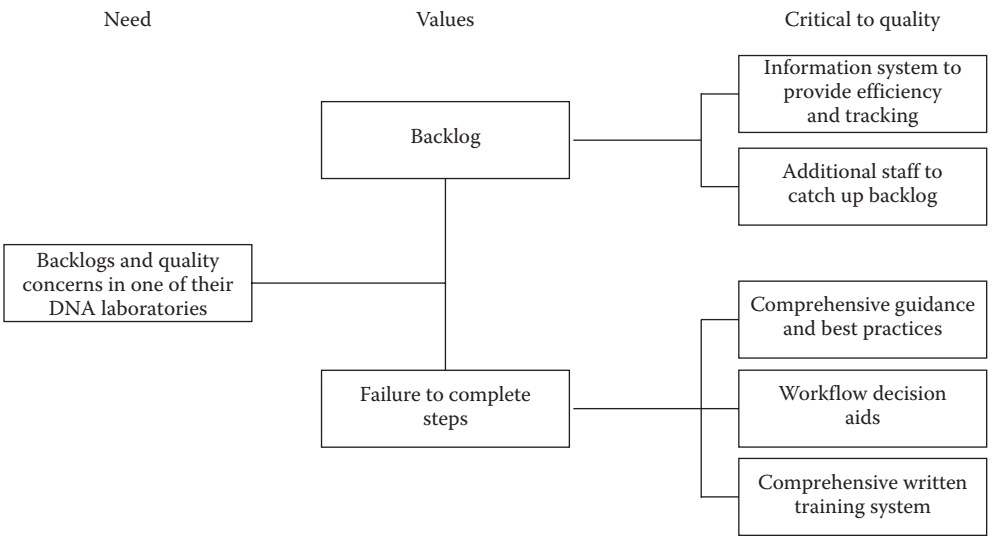

Figure 4.8 CTQ analysis.

* http://www.usdoj.gov/oig/challenges/2004.htm#9

documentation and case file review; and (4) updating protocols to reflect current methods within the unit. A mandate to develop comprehensive, written training curriculum and complete implementation of an information management system to improve efficiency and evidence-tracking capabilities was also noted.

These requirements became the focus for improving customer satisfaction. The laboratory took a general, difficult-to-measure need (to address backlogs and quality issues in a DNA forensic laboratory) and developed specific, measurable, and actionable requirements to drive improvements in customer satisfaction.

Suppliers, Inputs, Process, Output, and Customers Process Map

A SIPOC allows the team to identify the required inputs to make a process successful and tells them who provides the required inputs, what the steps are to complete the tasks, and what the expected results (deliverables) should be. The resulting information is placed in a chart or a table with enough detail to allow examination of how the output of the process or any subprocess is connected with which inputs and of how the actual process differs from that intended.

Let's return to our caseload backlog project:

Problem: The caseload backlog in the drug section is twenty-five days.
Case for change: The delay in analyzing evidence means delays in when district attorneys can file cases.
Goal statement: Reduce caseload backlog for blood alcohol tests to less than two days.

Leadership in the laboratory could "assume" the reason for the backlog is the result of not enough analysts to perform the analysis of the samples and write the reports. However, if we perform a SIPOC mapping of the process, there are several other culprit processes to consider.

SIPOC Mapping of Blood Alcohol Examination Case

Suppliers	Inputs	Processes	Outputs	Customers
Submitting agency	Evidence sample	Logged in and case number assigned	Request for examination	Submitting agency
Property & Evidence	Request for examination	Notification to lab management there is evidence to analyze	Notification to pick up	Lab management
Lab management	Notification to pick up	Assign work	Assignment notification	Examiner/analyst
Examiner/analyst	Assignment notification	Notify the property room they are coming to get the sample	Transfer request	Property & Evidence
Property & Evidence	Transfer request	Retrieve sample	Entry in chain of custody log	Examiner/analyst
Examiner/analyst	Evidence sample	Perform the examination and write the report	Sample, transfer request and report documenting the results	Split process begins for the sample, transfer request and report

Split process continued for the evidence sample				Split process—sample
Property & Evidence	Transfer request and evidence sample	Documented exchange	Entry in chain of custody log	Property & Evidence
Property & Evidence	Evidence sample	Notify submitting agency	Transfer request	Submitting agency
Submitting agency	Transfer request and evidence sample	Documented exchange	Entry in chain of custody log	Property & Evidence
Split process continued for the report				**Split Process—report**
Technical review	Report documenting the result	Read and ensure the data justifies the results and analytical methods are in compliance with authorized policies and procedures	Approval (or disapproval)	Administrative review
Administrative review	Approved report documenting the result	Make sure admin information is correct	Admin approval and report documenting the result	Submitting agency

After completing the SIPOC mapping, we can see there are several processes that, on their own or in combination with others, might result in the backlog. Consider the following:

- Property and Evidence takes more time than is necessary to notify the lab that a sample is ready for examination after the case has been logged.
- There are problems with the samples themselves. Perhaps a high number of samples were received by Property and Evidence and transferred to the lab but had issues (incomplete seals, container or other "issues?"). These samples are shuffled between the lab and Property and Evidence, and are included in the backlog count.
- Perhaps there is a problem in administrative review, and reports are not being reviewed in a timely manner.
- There are not enough analysts to complete the volume of blood alcohol tests performed by the laboratory.

Flowcharts

A flowchart is a graphical or symbolic representation of a process. Each step in the process is represented by a different symbol and contains a short description of the process step. The flowchart symbols are linked together with arrows showing the process flow direction.

Pareto Diagram

The basic underlying rule behind Pareto's law is that in almost every case, 80% of the total problems incurred are caused by 20% of the problem cause types, such as people, machines, parts, processes, and other factors. Therefore, by concentrating on the major problems first, the team can eliminate the majority of the problems. This is called the "vital few over the trivial many" rule.

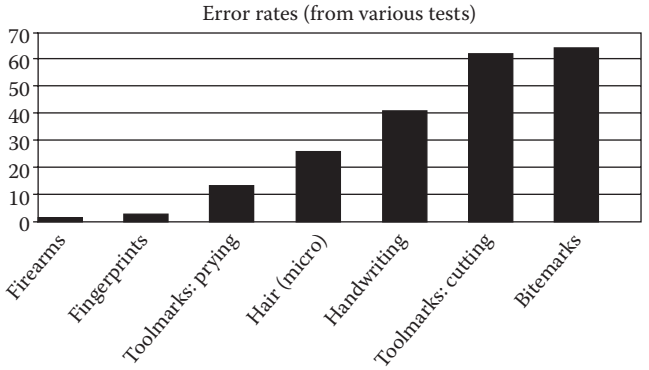

Figure 4.9 Error rates from forensic processes. (Risinger, D. Michael, Saks, Michael J., Thompson, William C. and Rosenthal, Robert, *Cal. L. Rev.*, 90, 1, 2002.)

Using a Pareto, the project team can decide which fault is the most serious or most frequent offender.

Consider Figure 4.9. A study was completed where an attempt was made to associate an error rate with various forensic disciplines. Based on the table, and considering Pareto's law, projects could be undertaken to review forensic processes related to Bitemark, Toolmarks, and Handwriting cases. (Total cases are 210. Eighty percent of the cases is 168. The sum of Bitemark, Toolmarks, and Handwriting cases equals 165.)

Measure

Overview

The purpose of the measure phase is to fully understand the current state by refining the project definition, identifying inputs (X's) and outcomes (Y's,) evaluating the measurement system and creating the baseline of process capability. It is important that the measurements used be useful and relevant to identifying and measuring the source of variation. During this phase, the team will do the following:

- Drill into the processes identified during the define phase. The team is looking for the detailed processes and the relevant CTQ characteristics.
- Identify the list of potential measurements.
- Establish process capability baseline.
- Validate the measurement system capability including where errors in measurements can occur.
- Measure the inputs, processes, and outputs and collect the data.
- Validate that the problem exists based on the measurements.
- Refine the problem or objective (from the analysis phase).
- Identify the specific performance requirements of relevant CTQ characteristics.

Using our blood alcohol project let's review some of the key questions:

- What is the process? For example one process may be "analysis of blood alcohol sample by the examiner/analyst."

- Which Inputs affect outputs (CTQs) most? Samples with complete seals and container integrity.
- Which outputs affect CTQs most?
- What are the key metrics for this business process? What is the performance of the current state process?
- Are the metrics valid and reliable?
- Do we have adequate data on this process?
- Is our ability to measure/detect sufficient?
- How is our current process performing?
- What is the best that the process was designed to do?

Deliverables of the Measure Phase

In addition to the tollgate review, a detailed process diagram should be developed to provide more information about process and identify "hidden" steps. Each step in the process should be addressed and reviewed to see if it is value added, non–value added, or business value added. A business value added step might be related to a regulatory or statutory requirement. Key measures (e.g., calculation of lead time, process cycle efficiency, and sigma level including yield and capability) for the baseline process need to identified, agreed upon, and estimated.

A plan for collecting data including the evaluation of the measurement system should be developed and executed (see Figure 4.10). Evaluation of the measurement system, often labeled a gage study, allows assessment of the accuracy with which measurements can be made. Similar to measuring analytics in the laboratory, instrument repeatability, reproducibility, and lower limit of detection are critical parameters. In this phase, baseline measurements are made of numerous Xs and Ys.

Tools and Techniques

The most applicable tools at this phase include the following:

Process mapping—Also known as "swim lanes," process maps are used to understand the current processes and enable the team to define the hidden causes of waste. A process map is a bit like a flowchart. During the measure phase, the team uses process maps to document sub or lower levels of processes. As in the flowchart, each task will be represented by a symbol. Decisions should have only two outcomes (yes or no), and points may be assigned where measurements are taken. Consider the partial process map of the "Wanted Person" scenario from the San Diego PD, shown in Figure 4.11.

Prioritization matrix—The prioritization matrix provides a way of sorting a diverse set of items into an order of importance. It also enables their relative importance to be identified by deriving a numerical value of the importance of each item. Thus, an item with a score of 100 is clearly far more important than one with a score of 25, but is not much more important than one with a score of 92. Items are compared and scored against a set of key criteria, and the scores for each item are then summed.

Design of experiments (DOEs)—DOEs is a systematic approach to investigating a system or process. It may be used in the measure, analyze, and improve phases of a Six Sigma initiative. Using DOE, the project team will develop a series of structured tests in which planned changes are made to the input variables of the system or process. The effects of these changes

Data Collection Plan										
Define what to measure			Define how to measure			Who will do it?	Sample plan			
Measure	Type of measure	Operational definition	Measurement of test method	Data tags needed to stratify the data	Data collection method	Persons(s) assigned	What?	Where?	When?	How many?
Name of parameter or condition to be measured	X or Y attribute or discrete data, product or process data	Clear definition of the measurement defined in such a way as to achieve repeatable results from multiple observers	Visual inspection or automated test? Test instruments are defined. Procedures for data collection are defined.	Data tags are defined for the measure, such as: time, date, location, tester, line, customer, buyer, operator, etc.	Manual? spreadsheet? computer based? etc.	State who has the responsibility?	What measure is being collected	Location for data collection	How often the data is collected	The number of data points collected per sample

Figure 4.10 Data collection plan.

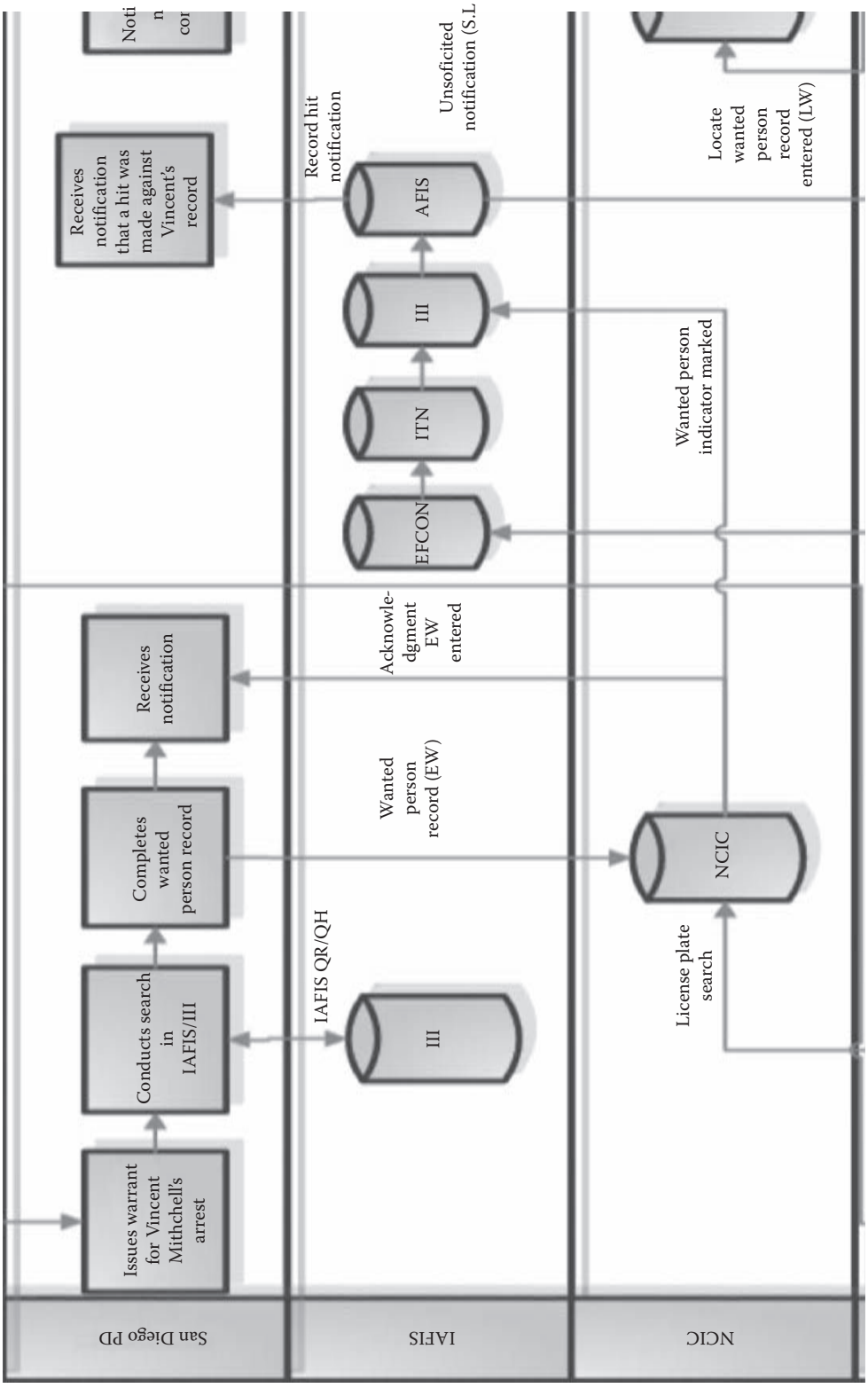

Figure 4.11 Swim lane process map (http://colab.cim3.net/file/work/fsam/Step3/step3_Target_Business_Process_Swim_Lane_Diagram.doc).

on the predefined output are then assessed. DOE is a perfect tool to identify the main contributing factor of a problem or how well a system or process performs under stress.

DOE utilizes a seven-step process:

1. Set objectives
2. Select process variables
3. Select an experimental design
4. Execute the design
5. Check that the data are consistent with the experimental assumptions
6. Analyze and interpret the results
7. Use/present the results (may lead to further runs or DOEs)

For example: Let's assume you are creating a new cake recipe and you are optimizing baking requirements (similar to optimizing gas chromatograph parameters for general forensic application). You can save time by performing a DOEs test.

First, determine the "factors" you want to test and establish the high-low settings for each factor in your study. Let's suppose you have four factors (a four-factor experiment):

Factor	Low	High
Pan shape	Round	Square
Ingredients	two eggs	three eggs
Oven temperature	325 degrees	375 degrees
Cooking time	35 minutes	45 minutes

Let's say that you'll rank each resulting cake on a 1–10 scale for overall quality.

You then use the +/– values in the orthogonal array to perform a test of every combination (16 total):

- High: all high values (+ + + + = square pan, three eggs, 375 degrees, 45 minutes)
- Low: all low values (– – – – = round pan, two eggs, 325 degrees, 35 minutes)
- In between: every other combination ("+ + + –", "+ + – –", and so on)

An orthogonal array approach allows the team to identify the effect of many different parameters on performance.To optimize your results, you might want to run more than one test of each combination and enter your data into a DOE template (many are available for free on the internet) and observe the interactions.

Analyze

Overview

In the analyze phase, the team analyzes the measurements collected in the measure phase so that hypotheses about the root causes of variations can be generated and subsequently validated. It is at this stage that practical business problems are turned into statistical problems and analyzed as statistical problems.

Here are some key questions:

- How many observations are required to draw conclusions?
- If an input is changed, does the output really change in the desired way?
- What is the level of confidence?
- Is the current state as good as the process can do?
- Who will help make changes?
- What resources will we need?
- What could cause this change effort to fail?
- What major obstacles do I face in completing the project?

Deliverables of the Analyze Phase

During the analyze phase, the project team analyzes the data identified in the measure phase. Specifically, the team uses tools to do the following:

- Identify process failures that lead to a defective output
- Analyze root causes to hypothesize reasons for defects
- Analyze data to link the variation in the output measure to some of the inputs

Tools and Techniques

There are many tools for process analysis, more than for any other aspect of Six Sigma. Of these tools, the cause-and-effect (C&E) diagram and failure-mode-and-effects analysis (FMEA) and HESRA are particularly useful in this phase. Other important tools include five why's, scatter diagram, and regression analysis.

Cause-and-Effect Diagram

The C&E diagram (fish diagram) is the brainchild of Kaoru Ishikawa, one of the founding fathers of modern management. The C&E diagram is used to explore all the potential or real causes (or inputs) that result in a single effect (or output). Causes are arranged according to their level of importance or detail, resulting in a depiction of relationships and hierarchy of events. This can help you search for root causes, identify areas where there may be problems, and compare the relative importance of different causes.

Causes in a C&E diagram are frequently arranged into four major categories (See Figure 4.12). While these categories can be anything, you will often see these:

- Manpower, methods, materials, and machinery (recommended for manufacturing)
- Equipment, policies, procedures, and people (recommended for administration and service)

These guidelines can be helpful but should not be used if they limit the diagram or are inappropriate.

Failure Modes and Effect Analysis

FMEA is a procedure used for analysis of potential failure within a system using classification for levels of severity (effect of failure). Beginning in the analyze phase and continuing through to the control phase, the FMEA project team performs the following nine-step process (Sample spreadsheet provided in Figure 4.13):

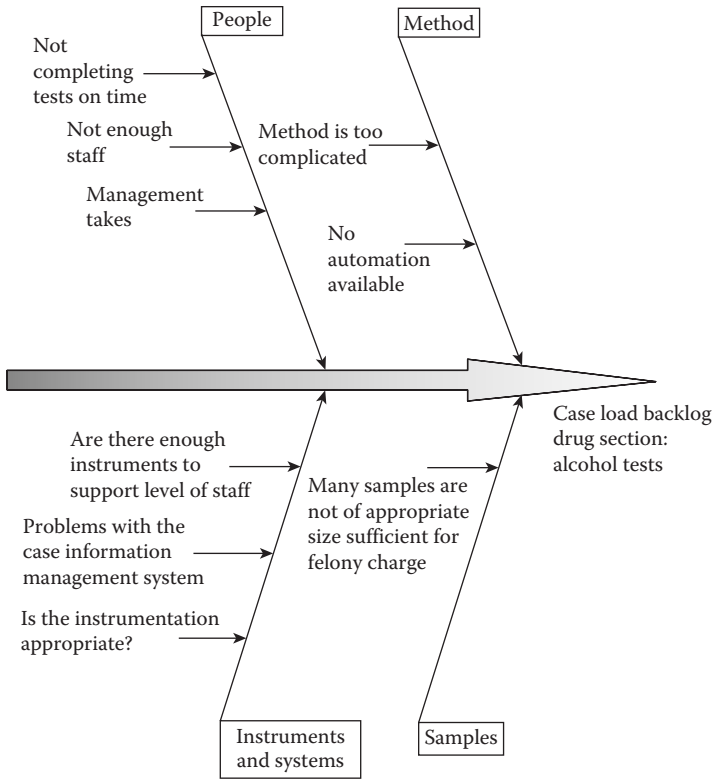

Figure 4.12 Cause-and-effect diagram.

1. Selects a high risk laboratory process
2. Organizes the FMEA team that will conduct the analysis
3. Maps the laboratory process
4. Identifies the potential failure modes within the process
5. Prioritizes the risk of each process breakdown or failure
6. Determines the root cause of each failure
7. Develops mitigating strategies and redesigns the process to address the root cause of each failure
8. Implements and evaluates the effectiveness of the mitigating strategies within the redesigned process
9. Monitors the effectiveness of the mitigating strategies

Human Error and Safety Risk Analysis (HESRA)

The fact of the matter is, errors exist. From crime scene to courtroom, several opportunities exist for errors to occur, from carelessness and incompetence to bias (unconscious or not), fraud, and just plain old honest mistakes. HESRA used as an analysis tool in the laboratory is an important breakthrough to uncover and address human error.

Let's consider the Dror et al.* Study in which the team used suggestion to induce fingerprint experts to unwittingly reverse earlier and correct judgments of a match. In this

* Dror, I. E. & Charlton, D.(2006) Why experts make errors p. 56.

Function	Potential failure mode	Potential failure effects	SEV	Potential causes	OCC	CRIT	Current controls	DET	RPN	Actions recommended	Resp.	Actions taken	PSEV	POCC	PDET	PRPN
What is the process step under investigation?	In what ways does the process step go wrong? what is the reverse of the process step?	What is the impact on the customer or internal requirements? what is the opposite of the little y's (in-process outputs) of the step under investigation?	How severe is the effect to the customer?	What causes the failure mode? what are the opposite of the x's (inputs) of the step under investigation?	How often does cause occur?		What are the existing controls and procedures (inspection and test) that prevent the cause? Should include an SOP number.	How well does the control detect the cause?		What are the actions for reducing the occurrance of the cause, or improving detection? Should have actions only on high RPN's or easy fixes.	Who is responsible for the recommended actions?	What are the completed actions taken with the recalculated RPN? Be sure to include completion month/year				
Identify output failures and impacts				Assess inputs and prioritize						Determine actions and impact						

Figure 4.13 FMEA spreadsheet.

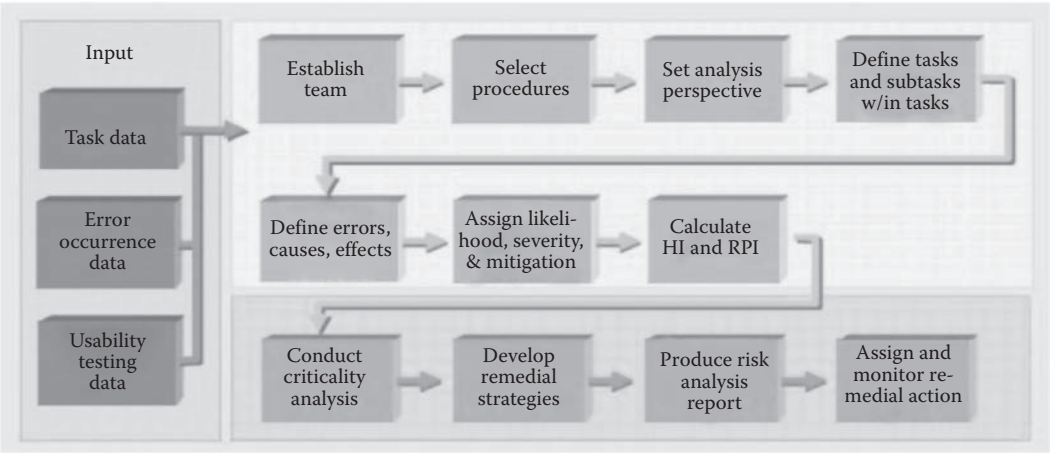

Figure 4.14 HESRA workflow.

study, five experienced fingerprint examiners were asked by a colleague to evaluate the Mayfield prints after it was known that the Federal Bureau of Investigation (FBI) had misidentified them. In reality, they were given prints they themselves had found to match in previous cases. After reviewing the samples, four of the examiners came to a different result than their original one. Three now concluded that the latent didn't match the known (although they had come to the opposite conclusion in the real case), and a fourth now said the latent was too small and smudged to reach a conclusion.

How does HESRA work?

Human error and safety risk analysis is based on FMEA. A Sample HERSA workflow is shown in Figure 4.14. This type of analysis looks at human errors rather than component failures. HESRA does the following:

- Identifies the relative likelihood of particular errors
- Does not depend on past history, but can use this information
- Relies on relative, ordinal scaling
- Ranks orders error modes
- Identifies critical single component failures
- Can utilize detection/mitigation (or not, similar to FMEA)
- Produces a task breakdown as a by-product

The analysis considers tasks and assigns attributes to each potential error mode: likelihood of occurrence, severity of outcome, and likelihood of detection/mitigation. These ratings are used to calculate a hazard index (HI) and a risk priority number (RPN). The HI and RPN are then used to perform a rough rank order of risks and to address the most critical.

Five Whys

Five whys analysis is a problem-solving technique that allows you to get at the root cause of a problem fairly quickly. It was made popular as part of the Toyota Production System. Application of the strategy involves taking any problem and asking, "Why—what caused this problem?" By repeatedly asking the question "Why" (five is a good rule), it is possible to peel away the layers of symptoms to identify the root cause of a problem. Very often the first reason for a problem will lead you to another question and then to another. Although

this technique is called five why's, you may find that you will need to ask the question fewer or more times than five before you find the issue related to a problem.

Let's review the following example:

1. Why did the technical reviewer send the Infrared spectrophotometers (IR) to the quality assurance manager? Since the unknown IR could not be superimposed on the reference standard.
2. Why could the unknown IR not be superimposed on the reference standard? Since the crystal lattice on the sample was different.
3. Why was the crystal lattice of the sample different? Since a different sample technique was used?
4. Why was a different sample technique used? Personal preference of the analyst.
5. Why was the personal preference of the analyst allowed? Because there was no documentation stating which sample techniques were preferred, or acceptable for use with this particular examination.

Scatter Diagrams

Scatter diagrams are used to investigate the possible relationship between two variables that both relate to the same "event." A straight line of best fit, using the least squares method, is often included.

These are some things to look for in a scatter plot:

- If the points cluster in a band running from lower left to upper right, there is a positive correlation (if x increases, y increases).
- If the points cluster in a band from upper left to lower right, there is a negative correlation (if x increases, y decreases).
- Imagine drawing a straight line or curve through the data so that it "fits" as well as possible. The more the points cluster closely around the imaginary line of best fit, the stronger the relationship that exists between the two variables.
- If it is hard to see where you would draw a line, and if the points show no significant clustering, there is probably no correlation.

Regression Analysis

Regression analysis is used to determine if a dependent variable can be adequately predicted by a set of one or more independent variables. Regression analysis involves finding the line of best fit through a series of points. The calculation to find the line of best fit uses the least squares method and the outcome is a regression equation. Regression analysis should always be carried out in conjunction with correlation analysis to find the goodness of fit.

Types of regression analysis include the following:

Linear regression	A linear relationship with one input and one output
Logistics regression	The output is a probability
Multiple linear regression	A linear relationship with several inputs

Example: An agent for a residential real estate company in a large city would like to predict the monthly rental cost for apartments based on the size of the apartment as defined by square footage. A sample of 25 apartments in a particular residential neighborhood was

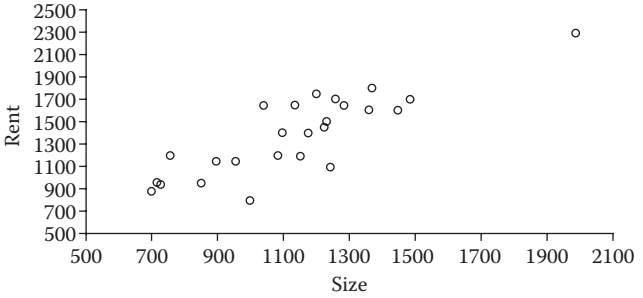

Figure 4.15 Regression sample scatter graph.

Summary output

Regression statistics	
Multiple *R*	0.85
R square	0.72
Adjusted *R* square	0.71
Standard error	194.60
Observations	25

Anova

	df	SS	MS	*F*	Significance *F*
Regression	1	2268776.545	2268776.545	59.91376452	7.51833E-08
Residual	23	870949.4547	37867.3676		
Total	24	3139726			

	Coefficients	Standard error	*t* Stat	*P*-value	Lower 95%	Upper 95%
Intercept	177.121	161.004	1.100	0.282669853	–155.942	510.184
Size	1.065	0.138	7.740	7.51833E-08	0.780	1.350

Figure 4.16 Regression summary output sample.

selected to gather the information. The data is entered in two columns (Rent and Square Fee) using Excel and plotted. The pattern (See Figure 4.15) suggests a linear relationship.

Looking at the data generated in Excel (Figure 4.16), we can determine that the regression equation is Rent = 177.121 + 1.065 × Size, which means that for every additional square feet, rent goes up by $1.065. On application, if the real estate agent wishes to predict rent when the apartment size is 1000 square feet, the following regression equation can be used:

$$\text{Rent} = 177.121 + 1.065 \times \text{Size}$$

$$\text{Thus, when Size} = 1000$$

$$\text{Rent} = 177.121 + 1.065 \times 1000 = \$1242 \text{ (rounded)}$$

Improve

Overview

During the improve phase, the project team pilots the selected solution and plans are made for full scale implementation. The Improve phase focuses on developing ideas to remove

root causes of variation, testing validating, and standardizing those solutions. During this phase, the project team does the following:

- Identifies ways to remove causes of variation
- Verifies critical inputs
- Discovers relationships between variables
- Establishes operating tolerances that are the upper and lower specification limits (LSLs) (the engineering or customer requirement) of a process for judging acceptability of a particular characteristic, and if strictly followed will result in defect-free products or services
- Validates the solutions. The validation process should consist of the following:
  - Define the scope of the analytical procedure.
  - Identify the analytical procedure performance characteristic(s) that must be validated.
  - Select experiments to determine the required performance characteristic(s).
  - Conduct experiments to determine required performance characteristics.
- Document, review, and maintain analytical procedure validation results.
- Optimize critical inputs or reconfigure the relevant process.

Here are some key questions:

- What specific activities are necessary to meet the project goals?
- Once we know for sure which inputs most affect our outputs, how do we control them?
- How many trials do we need to run to find and confirm the optimal setting/procedure of these key inputs?
- In what manner can the old process be improved and what is the new process?
- If there are subprojects, how will I integrate them?
- Are there any unanticipated consequences?
- How much have DPMO decreased?

Deliverables from the Improve Phase

In addition to preparing and delivering the tollgate review, the team will review and test possible solutions, select the best solutions, and design the implementation plan.

Tools and Techniques

Consensus and management buy-in at this phase is absolute. Without acceptance by all stakeholders involved in the process, it is unlikely that full implementation will succeed. Throughout this phase, remember that the primary purpose of these tools is to communicate and help in building a shared understanding and consensus.

Prioritization matrix—The project team may have several "alternatives" to consider once they reach the improve phase. Each alternative must be evaluated using objective and data-driven methods.

Process mapping—Discussed in greater detail during the measure phase, this tool helps to represent the new process subsequent to the improvements.

Design of Experiment (DOE)—This is a planned set of tests to define the optimum settings to obtain the desired output and validate improvements.

5 S's Method—The 5 S's method is a process of creating workplace cleanliness and organization including visual signals. By eliminating the unnecessary, establishing a place for what remains, and cleaning up remaining equipment, tools, and storage devices, clutter is reduced and needed items are readily found. Visual management involves the use of visual cues (e.g., road traffic signs and signals) to ensure things happen and improve documentation. It is a simple tool allowing the project team to develop processes that improve safety and communication, reduce space requirements, reduce time wasted, and increase compliance of processes and procedures. The process includes the following five steps:

- Sort: Organize and separate needed from unneeded
- Straighten: Arrange and identify for ease of use
- Shine: Clean and look for ways to keep it clean
- Standardize: Maintain and monitor the first three S's
- Sustain: Discipline, stick to the rules, and maintain motivation

Control

Overview

Putting a solution in place can fix a problem for the moment. The activities completed during the control phase are designed to insure that the problem does not recur and that the new processes can be further improved over time.

Standardization is a primary goal of the control phase. Establishing standard measures will help the laboratory to maintain performance and to correct problems as needed, including problems with the measurement system. This includes the following:

- Definition and validation of the monitoring and control system.
- Development of standards and procedures—The project team will return to the laboratory's quality documents and ensure they have been updated to reflect the standards and procedures addressed in the project.
- Implementation of statistical process control—Create, modify, and use data collection systems and output reports or dashboards consistent with the control plan.
- Determination of process capability—Use the same measures from the define and measure phases in order to provide comparability and monitor impact in a consistent way.
- Development of the transfer plan and subsequent to the process owner.
- Verification of benefits, cost savings/avoidance, etc.
- Closeout of project with sponsor.

Here are some key questions: Once defects have been reduced, how do we ensure that the improvement is sustained?

- What systems need to be in place to check that the improved procedures stay implemented?
- What do we set up to keep it going even when things change?
- How can improvements be shared with other relevant people in the company?

Deliverables of the Control Phase

At the end of the control phase, the project deliverables should meet the goals and objectives established by the project charter. The project team will deliver the final tollgate review to the executive council and obtain user acceptance of all deliverables.

Tools and Techniques

The tools most commonly used during the control phase include the following:

- Process capability analysis (CPK) and control charts
- Flow diagrams
- Charts to compare before and after improvement (Pareto charts)

Process Capability Analysis

Use of control charts is one method by which the laboratory will demonstrate process stability. By reviewing control charts the project team will be able to see whether the process method is stable or whether accuracy is being maintained. Once the process is stable, the project team will move toward capability.

Control charts are easy-to-use charts that make it easy see both special and common cause variation in a process. There are many different subspecies of control charts that can be applied to the different types of process data that are typically available. All control charts have three basic components:

- A centerline, usually the mathematical average of all the samples plotted
- Upper and lower statistical control limits that define the constraints of common cause variations
- Performance data plotted over time

Since analytical methods do not have specification limits in the classic industrial sense, the project team may also consider the use of observed analytical methods from the Association of Official Analytical Chemists (AOAC) and American Society for Testing and Materials (ASTM) collaborative studies. Since these values represent the variation found among a pool of laboratories, they could be used as method "specifications" for process capability calculations.

Line Graphs

Line graphs display process performance over time. Upward and downward trends, cycles, and large aberrations may be spotted and investigated further. In a line graph, events, shown on the *y*-axis, are graphed against a time period on the *x*-axis. For example, a line graph in a laboratory might plot the number of cases processed against the type of case or month of year. The results might show that there are more delays during the summer months or that a particular test is repeatedly backlogged. Investigating this phenomenon could unearth potential improvement needs. Line graphs can also be used to track improvements that have been put into place, checking to determine their success.

CONCLUSION

We hope we have provided a case for the forensic laboratory to seriously consider six sigma as a quality management tool. Implementation of six sigma as a quality tool in the laboratory may improve the ability to increase the reliability of the results of forensic examinations. In this chapter we have provided the history and background of six sigma, detail on how to implement a six sigma program in your organization and DMAIC examples relevant to the forensic laboratory. We challenge you to consider Chapter 4 as your guide to when responding to or developing quality assurance efforts.

Outsourcing Quality Assurance Programs

5

Introduction

The spotlight on the use of forensic evidence has increased exponentially in the last few years. This focus is accompanied by an increased demand on the forensic laboratory's quality systems, which are required to ensure the reliability of their results.

Gone are the days of "Trust me, I am from the crime lab." A voluntary proficiency testing program of the 1970s implied that there were serious concerns about the quality of work performed in the country's crime laboratories. The O. J. Simpson case publicly embarrassed one of the nation's largest laboratories. Additionally, there are numerous unfortunate cases in which the questionable work of a small number of individuals was allowed to be introduced into court as "scientific truth" because of a lack of appropriate quality systems required to catch errors, omissions, false statements and blatant perjury.

The American Society of Crime Laboratory Directors (ASCLD) began to investigate how to ensure the quality of their product and methods of self policing. As a result the ASCLD/Laboratory Accreditation Board (LAB) was formed in 1981 and accredited its first laboratory in 1982. As of May 2009, there are 359 laboratories accredited by ASCLD/LAB.* Included in the accredited laboratories are 181 state laboratories, 117 local agency laboratories, 22 federal laboratories, 12 international (non-US) laboratories and 27 private. There are 85 crime laboratories accredited under the ASCLD/LAB-*International* Testing Program, 2 crime laboratories accredited under the ASCLD/LAB-International Calibration Program, and 272 crime laboratories accredited under the ASCLD/LAB Legacy Program.

The concept of outsourcing quality assurance is not unique. The accreditation process itself could arguably be considered outsourcing the evaluation or auditing of a laboratory's quality systems. The laboratory pays an independent third party, ASCLD/LAB or International Standards Organization (ISO), to "certify" that they meet the criteria established by the accrediting body. The "criteria" are based on set procedures and standards adopted in other laboratories and accepted by court systems. Evaluations are conducted on the physical facility, security, evidentiary procedures, training, safety, technical procedures, and documentation. This certification verifies that the laboratory in question has implemented a defined set of quality systems to ensure the reliability of its results.

Outsourcing all or a portion of a laboratory's day-to-day quality assurance duties is a simple extension of the accreditation concept. An independent entity interacts with the laboratory's quality systems. The difference being, the contract quality assurance provider partners with the laboratory and makes recommendations on how to improve the quality systems used. In some cases the independent entity may have the authority to implement and maintain quality programs as a staff function of the laboratory director.

* www.ascld-lab.org/dual/aslabdualhistory.html

Services

The forensic facility determines the type of quality assurance services it chooses to outsource. The outsourced program can be as simple as performing an annual audit or the preparation and maintenance of the facility's operational manuals. The program can be so large as to require a full-time quality assurance manager and requisite support staff. The extent of the services to be outsourced depends on the facility's needs and budgetary constraints.

Forward-thinking laboratories outsource many of the functions they do not have the time, resources, or expertise to perform. They may elect to perform routine maintenance activities and outsource the complex activities. For example, laboratories routinely contract the installation and maintenance of the scientific equipment they utilize on a daily basis while they perform the routine maintenance activities (e.g., changing septums). Establishing a professional services contract to outsource the administration of all or a part of the laboratory's quality systems is a simple extension of the maintenance contract principle.

Program Management

The ASCLD/LAB accreditation manual lists the designation of a quality manager as an essential* element of the accreditation process.† The ISO 17025 standard mentions the designation of a specific individual as the quality manager.‡ In both cases the burden is placed on management in general to ensure the tasks associated with a quality assurance program are conducted.

The quality assurance manager's status within the laboratory depends upon the accreditation criteria utilized. The ASCLD/LAB criteria do not specifically require that the quality manager position, or the associated tasks, be held or performed by employees of the laboratory. The ISO standard requires "a member of staff as quality manager (however named)."

The ASCLD/LAB criterion requires only that an individual be designated as the quality manager. The criterion does not require the quality manager be an employee of the laboratory. The criterion could be satisfied and the position could be outsourced if the laboratory's policies and procedures allow it to be. However, the interpretation of whether or not the quality manager position may be outsourced under ASCLD/LAB criteria may vary with inspector.

The ISO standard is more definitive on this topic. "A member of the staff" is a definitive statement. The "however named" portion of the standard interjects a level of ambiguity.

* Standards that directly affect and have fundamental impact on the work product of the laboratory or the integrity of the evidence.

† ASCLD/LAB criteria 1.4.2.2. "Is an individual designated as the quality manager?" *2003 Manual*, American Society of Crime Laboratory Directors, Laboratory Accreditation Board.

‡ ISO Standard 17025, Section 4.1.5.j. "Appoint a member of staff as quality manager (however named) who, irrespective of other duties and responsibilities, shall have defined responsibility and authority for ensuring that the quality system is implemented and followed at all times; the quality manager shall have direct access to the highest level of management at which decisions are made on laboratory policy or resources."

The standard may be met if a contractor is considered a staff member. As with the ASCLD/LAB standards, the laboratory's administrative policies and procedures and quality manual will be the source document that determines if a contractor is considered a staff member and thus eligible to be the quality manager. A simple addition to the manual explaining the laboratories use of contractor positions will usually suffice.

Placing the responsibility of management of the quality assurance programs on an entity outside the direct control of a law enforcement agency or one of its components is not a unique concept. Independent civilian review boards were put into place to monitor activities and provide a check and balance for the police agencies entrusted to protect and serve the public. Peace Officer Standards and Training (POST) agencies have been established in states nationwide to act as the quality assurance arm of the law enforcement officers in the states they serve.

Independent agencies such as these were established to provide an objective review of the policies and procedures used by the law enforcement agencies they serve. In some instances, self-policing by the organization failed to identify or address issues of concern, so an independent entity was established. It is believed that oversight by an independent entity, removed from the internal politics and local influences, will not overlook issues of concern.

In large organizations, the quality assurance section typically operates autonomously. In some instances, it is a staff function of the agency's administrator. The administrator provides recommendations and implements the required corrective actions. This frees the agency to utilize its technical personnel in a more productive manner. Outsourcing the quality assurance functions would achieve the same result. A laboratory could maximize its technical resources by not diluting them with administrative tasks.

Quality Documents

The preparation and maintenance of a forensic facility's quality assurance documents consumes more unproductive man hours than any single facet of the quality program. These duties are generally carried out by examiners with casework responsibilities and little or no quality assurance experience. Their time would be more productively spent working to reduce the laboratory's backlog than the administrative busy work of drafting, formatting, editing and preparing administrative manuals.

More times than not, the manual preparation or maintenance is conducted in anticipation of an accreditation or reaccreditation inspection. Typically, it is a frantic effort to update the documented policies, procedures, and analytical methods to meet one or more accreditation criteria. It is not uncommon for a forensic facility to use one of the following scenarios when dealing with quality assurance document preparation:

Operational Manuals

- Approximately six months before the inspection, a manager is removed from his normal duties and assigned to draft or update operational manuals.
- Or, a manager is assigned to dedicate a percentage of his time to draft and update methods manuals.
- Or, the quality assurance manager (if one exists full time) drafts or updates the portions of the operational manual necessary to meet the accreditation requirements.

Methods Manuals

Approximately six months before the inspection, a senior-level examiner is removed from case work duties and assigned to draft or update methods manuals.
Or, a senior-level examiner is assigned to dedicate a percentage of his time to draft and update methods manuals, effectively removing him from casework.

Training Manuals

There does not seem to be any consistency in training manual format. In some cases the training manual consists of a reading list, comments about mentoring and a statement that the examiner will pass a proficiency test prior to beginning casework. The other extreme presents a detailed list of reading, lectures, practical exercises, and proficiency tests that are required prior to an examiner beginning casework. Both instances satisfy the accreditation criteria for having a training manual. Both cases require an examiners time, which could be focused on casework, to draft and update the training manuals on a regular basis.

The quality documents that are generally required for accreditation include the following:

Administrative policies and procedures*, †
Quality assurance manual‡, §
Evidence manual
Health and safety program¶
Methods manual for each analytical discipline**, ††
Training manual for each analytical discipline‡‡, §§

Writing Assistance, Inc., a group of freelance technical writers, estimates that the time required to prepare original technical, operational, or procedure manuals ranges from

* Numerous criteria outline in Section 1. "Laboratory Management and Operations" of the ASCLD/LAB accreditation manual.
† Numerous criteria outlined in Section 4. "Management Requirements" of the ISO 17025 criteria.
‡ ASCLD/LAB criteria 1.4.2.1. "Does the laboratory have a comprehensive quality manual?"
§ ISO 17025 Section 4.2.1. "The laboratory shall document its policies, systems, programs, procedures and instructions to the extent necessary to assure the quality of the test and/or calibration results."
¶ ASCLD/LAB criteria 3.4.1. "Does the laboratory have an effective health and safety program documented in a manual?"
** ASCLD/LAB criteria 1.4.2.7. "Are the technical procedures used by the laboratory documented and are they available to laboratory personnel for review?"
†† ISO 17025 Section 5.4.1. "The laboratory shall have instructions on the use and operation of all relevant equipment, and on the handling and preparation of items for testing and/or calibration, or both, where the absence of such instructions could jeopardize the results of tests and/or calibrations. All instructions, standards, manuals and reference data relevant to the work of the laboratory shall be kept up to date and shall be made readily available to personnel."
‡‡ ASCLD/LAB criteria 1.3.3.1. "Does the laboratory have and use a documented training program in each analytical area for employees who are new, under training or in need of remedial training?"
§§ ISO 17025 Section 5.2.2. "The laboratory shall have a policy and procedures for identifying training needs and providing training of personnel. The training program shall be relevant to the present and anticipated tasks of the laboratory."

three to 10 hours per page, depending on the content.* The time required to make revisions on existing documents ranges from one to four hours per page, depending on the extent of the revisions. Using these time ranges as a guide, it would take between three hundred and a thousand man hours (7.5–25 weeks) to draft one hundred pages of new text. One hundred to four hundred man hours (2.5–10 weeks) of time would be required to revise those same one hundred pages of text. These are man hours that are taken away from casework or productive management activities, unless the laboratory has an individual dedicated to this task as part of his assigned duties.

Drafting laboratory reports and writing policy and procedure manuals are two different skill sets that are not necessarily exchangeable. An examiner's technical ability to develop or administer an analytical technique does not necessarily provide the ability to articulate that knowledge into a coherent written procedure. The procedure must be written in such a way as to allow an individual unfamiliar with the technique to perform it simple by reading the written method.

There is a community of freelance technical writers that specialize in the preparation of operational and technical manuals. Their expertise lies in their ability to articulate complicated procedures in an easily understandable fashion that removes ambiguity. Tapping into this resource can be a cost effective way to prepare and maintain the laboratory's quality documents.

Outsourcing the writing of these documents is simply contracting a professional writer to provide a service the laboratory does not have the time, resources, or expertise to perform. The laboratory's management maintains complete editorial control over the content of the policies and procedures. The writer is only a tool that is used to place the information in a coherent document. Laboratories routinely contract the installation and maintenance of scientific equipment they utilize on a daily basis. Contracting a professional writer to write and maintain the operational and technical manuals that guide a laboratory's daily operation is an extension of that principle.

The laboratory's administrative policies and procedures and the quality assurance manual define how policies, procedures, and technical methods are developed, evaluated, approved, and implemented. Outsourcing this function is possible if the laboratory's policies and procedures make a provision for it.

Audits

The laboratory accreditation process (ASCLD/LAB and ISO 17025) is the ultimate outsourcing of laboratory quality systems auditing. The laboratory pays an outside entity to evaluate and compare its quality systems to a set of accepted standard criteria. The approach ASCLD/LAB and ISO take to the accreditation inspection/evaluation process differs slightly. However, the concept of an entity outside the laboratory evaluating its quality systems is the same.

ASCLD/LAB accreditation requires the laboratory to contract with ASCLD/LAB to perform the inspection, using ASCLD/LAB inspectors, many of which are laboratory directors or managers themselves. The value of forensic laboratory directors policing themselves can be debated. However, the ASCLD/LAB program has dramatically improved the quality

* www.writingassist.com/pdfs/EstimatingWritingProjects.pdf

and reliability of the analytic results produced by forensic laboratories in the United States since it inception in 1981.

ISO 17025 accreditation requires the laboratory's quality systems to be evaluated by an independent group of inspectors. These inspectors have received training concerning the 17025 standards and are authorized by the ISO to conduct inspections on its behalf. It can be debated that this method results a more objective evaluation.

Both accreditation systems require a periodic review of the laboratory's quality systems. ASCLD/LAB accreditation requires a participating laboratory to annually conduct an audit of its quality system* and report its findings to ASCLD/LAB.† ISO 17025 also has requirements to annually audit the quality systems of the laboratory seeking accreditation.‡,§ Neither body requires the audit to be conducted by employees of the laboratory or the laboratory system. In the case of the ISO requirements, Section 4.13¶ appears to encourage outsourcing quality system audits.

If it is accepted that the accreditation inspections performed by the accrediting body are an outsourced audit of the laboratory's quality systems, then it is reasonable to conclude that the annual quality system can be outsourced as well. Both situations perform the same function, an objective evaluation of the laboratory's quality systems. There should be no difference in scrutiny utilized during the evaluations.

Outsourcing the laboratory's annual audit would be the preferred option if an objective review of the quality systems is the goal. Though annual internal audits by laboratory managers satisfy the accreditation requirement, the managers bring in preconceived notions about laboratory's quality programs. They cannot objectively evaluate how the quality systems are working because they are exposed to it on a daily basis. True objectivity can only be obtained from an independent review by an outside entity.

Proficiency Testing

Proficiency testing is another component of a quality assurance program. Additionally, it is an essential part of a laboratory's ability to instill confidence in its clients. It is one thing to have the theoretical knowledge of, and access to modern instrumentation. It is a different thing to be able to practically apply that knowledge, utilize the appropriate

* ASCLD/LAB criteria 1.4.2.4. "Does the laboratory conduct and document an annual review of its quality system?" *2003 Manual*, American Society of Crime Laboratory Directors, Laboratory Accreditation Board.

† ASCLD/LAB criteria 1.4.2.3. "Did the laboratory conduct and document an annual audit of its operations and submit an annual accreditation audit report to ASCLD/LAB by the required deadline?" *2003 Manual*, American Society of Crime Laboratory Directors, Laboratory Accreditation Board.

‡ ISO 17025 Section 4.13.1. "The laboratory shall periodically, and in accordance with a predetermined schedule and procedure, conduct internal audits of its activities to verify that its operations continue to comply with the requirements of the quality system and this International Standard. The internal audit program shall address all elements of the quality system, including the testing and/or calibration activities. It is the responsibility of the quality manager to plan and organize audits as required by the schedule and requested by management. Such audits shall be carried out by trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited."

§ ASCLD/LAB criteria 4.14.1. "In accordance with a predetermined schedule and procedure, the laboratory's executive management shall periodically conduct a review of the laboratory's quality system and testing and/or calibration activities to ensure their continuing suitability and effectiveness, and to introduce necessary changes or improvements."

¶ ISO 17025 Section 4.13. "Such audits shall be carried out by trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited."

instrumentation, and achieve the correct results. Proficiency testing is the vehicle used to demonstrate that an examiner can walk the walk as well as talk the talk.

Laboratories have outsourced portions of their proficiency testing program for years. By nature, blind tests need to be provided by a source outside the system to ensure the results are not compromised prior to the conclusion of the test. External proficiency testing (i.e., outsourcing the function) is mandated by ASCLD/LAB.*

The ISO 17025 standards do not directly address the use of proficiency testing. A relevant standard places the burden on management to ensure their personnel have the knowledge, skills and demonstrable abilities to conduct the examination they are tasked to perform.† However, ISO has established proficiency testing guidelines.‡, §

Benefits

Outsourcing quality system services can be advantageous for many reasons. It provides a mechanism to acquire qualified temporary personnel, to provide cost savings, and to offer impartiality and resource management. The creation of a quality assurance program can be daunting and preparation for routine accreditation can be time consuming and difficult. Outsourcing a portion of these services to qualified individuals, affords an expeditious road to accreditation or reaccreditation with the fewest delays in the process. Few, if any, inspections will result in no findings to remediate, but hiring professionals to perform this duty will ensure the least amount possible.

Cost Effective

As demonstrated above, a significant number of man hours can be dedicated to quality assurance document preparation and maintenance, as well as other quality assurance program activities. This number must be doubled to fully appreciate the effect on the laboratory's manpower allocation. Not only does a lab have to account for the man hours dedicated to the task, the hours required to backfill the void left by the examiner or manager perform associated quality assurance task must also be accounted for. In essence, for every hour an examiner or manager spends on quality assurance related tasks, they loose two hours of examination or management productivity. With highly qualified personnel performing these duties externally, they can be done much more quickly than if they are performed by personnel within the laboratory, putting these funds to better use. Additionally, grant money can often be used for these functions, thus not putting undue strain on the laboratories internal budget.

* ASCLD/LAB criteria 1.4.3.1. "Does the laboratory participate in proficiency testing programs conducted by approved test providers, where available?"

† ISO 17025 Section 5.2.1. "The laboratory management shall ensure the competence of all who operate specific equipment, perform tests and/or calibrations, evaluate results, and sign test reports and calibration certificates. … Personnel performing specific tasks shall be qualified on the basis of appropriate education, training, experience and/or demonstrated skills, as required."

‡ ISO/IEC Guide 43-1: Proficiency testing by interlaboratory comparisons-Part 1: Development and operation of proficiency testing schemes.

§ ISO/IEC Guide 43-2: Proficiency testing by interlaboratory comparisons-Part 2: Selection and use of proficiency testing schemes by laboratory accreditation bodies.

Resource Management

Outsourcing quality systems services frees laboratory personnel to do the business of the forensic laboratory, examining physical evidence. Hundreds of man hours are dedicated managing a facility's quality systems. Every hour spent on this task is one less hour spent examining evidence. Outsourcing these services provides the ability to focus a facility's finite manpower resources on combating a constantly increasing examination backlog.

Forensic laboratories have a finite set of resources at their disposal. The senior management is constantly trying to balance finances and personnel allocations to combat an ever increasing backlog. Outsourcing all, or a portion, of the laboratory's quality assurance functions is a method in which the senior management can optimize its limited resources.

Maximizing the bench time of technical personnel is a priority in the battle to reduce laboratory backlogs. Every hour an examiner is away from the bench is an hour casework is not being performed. Court and professional development activities are instances where an examiner is unavoidably removed from the bench. Quality control steps with the examination process reduce case productivity, but do ensure the quality of the examination's results. However, some of the administrative activities related to quality assurance programs, such as quality document preparation and administrative audits, are situations where the laboratory's limited resources are not focused on the primary function, the examination of physical evidence. In most organizational charts, the quality assurance manager is a staff function, reporting directly to the laboratory director.

Objectivity

Internal audits are used to identify issues before they become a problem. Unfortunately, internal audits cannot always provide the objectivity necessary to identify issues that may become a potential problem if not addressed. The forest-and-trees concept effects objectivity of an internal auditor. Evaluators who work in the environment they evaluate may believe things to be acceptable that someone from the outside may have an issue with. Additionally, personal relationships can get in the way of objectivity in many cases. Working day in and day out with staff members while trying to enforce new regulations and requirements is daunting for even the most personable quality manger.

Paying for professional services demonstrates objectivity. Performing service in-house can be perceived as the system is attempting to hide something. Using colleagues can give the impression of cronyism. Paid professional service providers offer the needed objectivity.

Government forensic laboratories are routinely accused of being lackeys of the police who manipulate the evidence to fit the investigators theory. The same perception could be perpetuated when laboratory directors from different systems exchange annual auditing services. A "you pass my lab and I will pass yours" accusation, however unwarranted, can be avoided simply by contracting an impartial professional service to perform the annual audit. The outside audits would of course need to be held confidential.

Continuity

The management of a laboratory's quality assurance services requirements may only require sporadic attention and not be enough to justify a full time employee. However, program continuity suggests that they should be performed or coordinated by a single individual

or group. Outsourcing a quality assurance function or the entire program provides the laboratory's management a tool in which to ensure the style and content of the quality assurance services is uniformly implemented and administered.

The preparation and maintenance of an analytical section's procedure manuals is an example of how outsourcing this component of the system can provide a sense of continuity. It would not be uncommon for a procedure manual to be thrown together by one individual to meet the criteria for an initial accreditation inspection. Five years later, in a mad dash, a different individual is tasked with updating the procedure manual. Without formatting standards the differences in writing styles can lead to the disjointed presentation of information lacking continuity. The misunderstandings that may arise could potentially affect the quality of the examinations performed due to a lack of clarity.

Another example would be the variation in style and content of the different methods manuals of different analytical sections within a laboratory. Each section is required to maintain a manual describing the analytical techniques used as well as the supporting quality assurance procedures. This requirement should extend to the format of the manuals themselves. The consistency in formatting will simplify the transition of an examiner from one analytical section to another. The transitioning examiner will know exactly where to look in the manual to fine specific types of information. This holds true for the QAM as well, when they are performing their annual audits of each analytical section.

Trained Professionals

Professional technical writers are skilled in the craft of writing procedures manuals that are easy to read and understand. Performing an examination and writing the procedure explaining how to perform it are two different skill sets. Professional technical writers are trained to wordsmith documents into easy-to-read and easy–to-understand documents that leave little ambiguity.

Laboratory quality system evaluations can be outsourced to senior forensic professionals with experience and training in the evaluation of forensic laboratories. The consultant(s) used should have experience in evaluating the client facility's specific systems.

Laboratory managers rely on trained professionals with specific skills and training to perform laboratory examinations. That same reasoning can be extended to the evaluation of the administrative, quality, and technical systems that are used in the facility's daily operation.

Program Control

There is an adage "you have to give up control to take control." Quality assurance may not be a 12-step program, but they do share the control issue. The laboratory director gains more control of the resources available to him by giving control of all or a part of the control of the quality assurance program to an outsourced entity. He takes control by assigning quality assurance tasks to professionals with experience in quality assurance matters. The laboratory director takes control of his resources by allowing his examiners to examine physical evidence and his managers to manage.

Third-party audits and evaluations are based on the needs the participating laboratory. The participating laboratory maintains total control over the services provided. The laboratory provides access to the facility and related documents and the service provider gives

an objective review concerning their compliance with accreditation standards. A detailed report is generated which describes the consultant's opinion of the facility's administrative, quality, and technical systems as related to accreditation criteria.

Outsourcing the preparation and maintenance of a laboratory's operational manuals based on the information provided by the participating laboratory. The participating laboratory has total control over the content. The laboratory provides the content and service provider places it into a useable form. Draft manuals are provided for review and comment before final version is sent to print. This ensures that each manual's content is accurate and unambiguous. The job is not completed until the participating laboratory is satisfied.

Conclusion

Establishing and maintaining a quality assurance program is a key element of laboratory accreditation. More importantly, it is an essential element of good science and critical to instill confidence in the reliability of examination which effect a person's liberty.

The managers of forensic facilities are continually balancing their resources in an effort to efficiently provide objective examinations. Outsourcing all or a portion of a laboratory's quality systems services can be a cost effective way to ensure the examinations are performed in an objective way and accreditation criteria are satisfied.

Policy Manual Development

III

Content and Format 6

Manual Types

Policy and procedure manuals have a myriad of names. General Orders (GO), Standard Operating Procedures (SOP), Administrative Regulations, Policies and Procedures, and Technical Methods are just a few of the variations. Some organizations spend an inordinate amount of time devising acronyms to uniquely identify the set of documents that define their operation.

A manual by any other name is still a manual. No matter what they are called, all manuals have the same purpose. They either document what needs to be done and how to do it, act as a reference, or support the implementation of a policy or procedure.

Manual Categories

There are two general categories of manuals exist in the realm of laboratory. Each group has similar components. The only difference is the target audience the manual is directed.

Operational and *technical* are the terms that can be used to categorize the types of manuals used in a laboratory. Operational manuals contain policies and procedures that apply to all factions of the laboratory's operation. Technical manuals focus on the issues specific to an analytical discipline. There may appear to be some redundancy in both manuals addressing the same topic. However, the focus the topics covered and their specificity define which category the guideline falls under.

Quality assurance manuals are a good example of this redundancy. The laboratory will have an organization-wide quality assurance policy concerning a particular topic. For example, the operational manual may have the following generic statement than can be applied to all laboratory sections: "The laboratory shall perform routine calibration checks on the instruments used to perform examinations of physical evidence," which has universal application. A specific statement, such as "The laboratory shall perform routine calibration checks on the gas chromatograph," has relevance in drug analysis or forensic chemistry, but has no application in forensic biology or DNA examination. This type of statement would be found in the technical methods manual of the chemistry section and not the biology section.

Operational Manuals

Operational manuals are one or more groups of policies, procedures, and associated documents that are directed at all factions of the laboratory. They apply equally to clerical personnel and to those in professional roles. Technical employees apply these rules and regulations in the same manner as administrative workers.

Many organizations refer to operational manuals as their GO. They group all of the policies and procedures that effect the "general" operation of the organization into a manual with one or more subdivisions. These directives have general application, although individual policies may affect one group of employees more than another.

This chapter will discuss four basic categories of operational manuals. The title of each may vary from organization to organization. Some institutions may debate that some of the groupings should be included under the umbrella organization's operational manual. Other institutions may want to expand this list to include other topics. However, this book will utilize the categories of administrative, quality assurance, health and safety, and sample control.

Technical Manuals

Technical manuals address the specific operational needs of the analytical section. They are the analytical section's operational bible. A technical manual is the cookbook used to prepare the reagents used to perform the examinations, ensure the equipment is operating properly, and guarantee the analytical results are reproducible.

A technical manual may be equated to the operational manual's procedure manual. The operational manual acts as the general policy. The operational manual statement, "The laboratory shall perform routine calibration checks on the instruments used to perform examinations of physical evidence," provides the "Thou shall" guidance of a policy. The corresponding technical manual policy and procedures serve as the procedure used to implement the policy. The technical manual statement "The laboratory shall perform routine calibration checks on the gas chromatogram by…" serves as the "how to" guidance of a procedure.

A comprehensive technical manual is a soup-to-nuts compendium of policies, procedures, and supporting documents used to guide the examiner though their stint in an analytical section. The technical manual is used to ensure uniformity and consistency in the laboratory's examination process and ultimate analytical result. The technical manual should do the following:

- Define the training every examiner should receive
- Describe how the reagents should be prepared
- Illustrate how every examination should be performed
- Characterize how analytical data should be evaluated
- Define acceptable report wording terminology that should be used to ensure consistency

Manual Components

All manuals are created equal in a generic sense. Their purpose is to provide guidance concerning the operation of the laboratory as a whole or function of a specific component. As such every manual or submanual has three basic components. These components are policies, procedures, and supporting documents.

The number of each component and their relationship with other components will vary from manual to manual. For example, some policies stand alone and do not require

a procedure to define its implementation. Other policies may have numerous corresponding implementation procedures. The applicable procedure will depend upon the circumstances surrounding the implementation of the policy. Some procedures may require the use of static forms to ensure consistency in documentation or simplification of recording events. Other procedures simply require an individual to perform a series of tasks in a specific order.

Policy

Policies and procedures can be equated to the laboratories goals and objectives. Policies are the goals. Procedures are the objectives.

A manual policy can be equated to a program goal. It is a generic statement defining a concept. Without supporting information a policy does not provide guidance in how to achieve the desired outcome. However, it provides the underlying basis for all related procedures and supporting documents.

Policies are "Thou shall" statements. They are commandments of sorts, using the Bible analogy for a manual's raison d'être. They define things that must be done. They do not generally define how the task should be accomplished, only that it needs to be done.

Having a documented set of policies and procedures has numerous benefits. Accreditation programs require that a laboratory have a comprehensive set of polices and procedures. Some uninformed managers think the only purpose of a current set of policies and procedures is to meet accreditation requirements. They do not understand how an up-to-date set of polices and procedures increases the efficiency and productivity of their operation.

Documenting the why and how a laboratory addresses a particular operational or technical issue much more than checking off a box in a list of accreditation criteria. It is simply good laboratory practice. It is an essential component of a laboratory's quality assurance program, which should exist whether the laboratory seeks accreditation or not. Remember, accreditation follows quality. Quality does not follow accreditation.

Procedure

Procedures are the other half of the policy and procedure duet. As the policy acts as a goal, the procedure serves as an objective. Each can stand alone, but they have more meaning as a complimentary pair. Policies give procedures a reason for being. Procedures provide a vehicle for implementing a policy.

Documented procedures are a quality assurance tool used to ensure reproducibility. Correctly implementing a procedure should produce the same result every time the procedure is performed. The accuracy of the result is a different issue. The primary focus of a procedure is reproducibility. The accuracy of the result is the responsibility of the validation procedures of the quality assurance program.

Support Documents

Support documents are sources of information. Generally, they do not provide guidance in what should be done (policy) or how it should be accomplished (procedure). They simply provide resources to that facilitate the implementation of the policies and procedures. In

some instances, supporting documents serve as the foundation of a policy or procedure by referring to an administrative regulation of the laboratory's parent organization or local or national governing body.

Static Documents

Static documents are informational texts that provide information supporting the implementation of a policy or a procedure. The content of these documents is outside of the laboratory's control, thus, unchanging or static. However, the laboratory's operation relies on them, even though it does not have control of their content.

The policies and procedures of the laboratory's parent organization are an example of static documents. Most laboratories are a component of a larger organization. The laboratory is obligated to adhere to the policies and procedures of the parent organization, just as an analytical section is obligated to adhere to laboratory's GO.

The mechanism for hiring personnel is an example. The laboratory has a policy that requires qualified candidates fill all positions. The parent organization has a specific procedure for the selection of employees based upon their qualifications. The laboratory's selection policy would defer to the parent organization's current procedure for selecting employees. The parent organization's employee selection procedure would be one of the laboratory's static documents, because the laboratory cannot change the content of the document and is obligated to implement its content as written.

Analytical sections of a laboratory can have static documents as well. Laboratories involved in environmental testing would be an example of analytical sections that would utilize static documents. These laboratories are required to utilize methods sanctioned by the Environmental Protection Agency (EPA) when performing certain types of examinations. These methods do not allow for variation, to ensure consistency and reproducibility. The laboratory cannot change or modify the method, so it is a static document and outside the document control requirements of the quality assurance program.

Forms

Forms, worksheets, and questionnaires—no matter what they are called, all have essentially the same purpose. They provide a vehicle to collect information. More important, they collect the same information under the same set of circumstances. This ensures all of the relevant information is collected in a format that is conducive for analysis and comparison at a later time.

Figure 6.1 is an example of a form developed for a firearms database program. Certain pieces of information must be collected concerning the firearm entered into the database. The form provides a mechanism for the technician or examiner to quickly and efficiently record the information. The form's format allows for the efficient entry of the information into the database by clerical personnel at a later time.

Quality programs are implemented to ensure consistency and reproducibility. Forms and their variations are incorporated into the laboratory's operating and analytical procedures to ensure that all of the relevant information is gathered in a reproducible format. This simplifies data entry and facilitates efficient data analysis.

A laboratory's standardized forms are subject to document-control policies in the same fashion as any policy and procedure. This is to ensure the most recent revision of a form is in circulation. This, in turn, ensures all of the required information is gathered under the current demands of the policy, procedure, or analytical method that the form supports.

Date		Record Number

Firearm Test Fire Worksheet Form

Owner

Owner Name			Identification Number
Address			
City		Postal Code	Phone
☐ Business	☐ Civilian	☐ Military	☐ Police

Weapon Information

Manufacturer		Model	
Caliber/Gauge	Barrel Length	Serial Number	

Type	☐ Rifle	☐ Pistol	☐ Revolver	☐ Shotgun
Action	☐ Single Shot	☐ Single Shot	☐ Single Action	☐ Single Shot
	☐ Semi Auto	☐ Semi Auto	☐ Double Action	☐ Semi Auto
	☐ Full Auto	☐ Full Auto	☐ Pin Type	☐ Full Auto
	☐ Bolt Action	☐ Blow Back	☐ Break Open	☐ Bolt Action
	☐ Lever Action	☐ Recoil	☐ Swing Out	☐ Lever Action
	☐ Pump Action	☐ Gas		☐ Pump Action
	☐ Other	☐ Other		☐ Other

Operation

Safety Functioned	☐ YES	☐ NO	☐ NONE
Function as Designed	☐ YES	☐ NO	☐ N/A
Trigger Pull	Single Action		Double Action
Comments			

Test Fire Ammunition

Manufacture	Projectile Type	Projectile Size	Lot#
3 Projectiles Collected	☐ YES	☐ NO	☐ N/A
3 Cartridge Cases Collected	☐ YES	☐ NO	☐ N/A

Examiner _____ Date _____

Figure 6.1 Example of a worksheet.

It is not uncommon for laboratory examiners to create some type of form to assist in their analytical duties. Many laboratory examinations involve repetitive tasks that generate large amounts of data that needs to be collected and evaluated. Examiners create forms to ensure that all the information is collected in a format that they personally can evaluate at a later date. These forms extremely useful, but are not the subject of this discussion.

Once the examiner's analysis form or worksheet crosses the line from personal use to mandatory use by all examiners, then it becomes part of the quality process. Quality control ensures consistency and reproducibility. As such examination worksheets should reflect consistency in form and content. This ensures that all of the relevant information is gathered. Additionally, it streamlines the review process by providing standardized placement of the technical information used to compare the data to the results.

Organization Charts

Organization charts provide an overview of the laboratory's relationship with the parent organization. It also provides a visual representation of the interrelationships of the functional components within the laboratory itself. These charts are required by accreditation bodies. However, beyond use for administrative functions and establishing workflow, these charts have minimal effect on the quality of the work at the examiner level.

The level of detail of a laboratory's organizational chart can be as detailed as the laboratory management desires. A single chart like the one depicted in Figure 6.2 provides an overview of the laboratory's general organizational structure and satisfies the criteria requiring an organizational chart. However, it does not provide detail concerning staffing levels, and that can be used in strategic planning.

Each branch of the main organizational chart can have a separate chart describing the functions within the branch. Figure 6.3 is the forensic chemistry branch of Figure 6.2 and provides significantly more detail. At a glance, the observer can determine staffing levels, the chain of command, and the interrelationship between analytical sections.

Organization charts are living documents that require maintenance to ensure their information is current. They are also considered controlled documents. As such, each revision is subject to the laboratory's document control policy.

Content

Manuals come in all shapes, sizes, and formats. There is no correct or incorrect method of writing a manual. The format use is generally up to the discretion of the author or the senior managers who are involved in the approval process.

The format of the manual may be immaterial for many of the people reading this book. It has been predetermined years before their arrival. These individuals are only responsible for updating the content and providing information that may be lacking.

At the other end of the spectrum, the person drafting the manual is creating the document from the ground up. He has the latitude to select the format that is used as well as the flow of the information presented. This person must not only consider the content of what he is writing, but how it relates to other components of the manual.

Somewhere in the middle is the operational laboratory that is changing administrative direction for some reason. Many of these operations have chosen to consolidate the

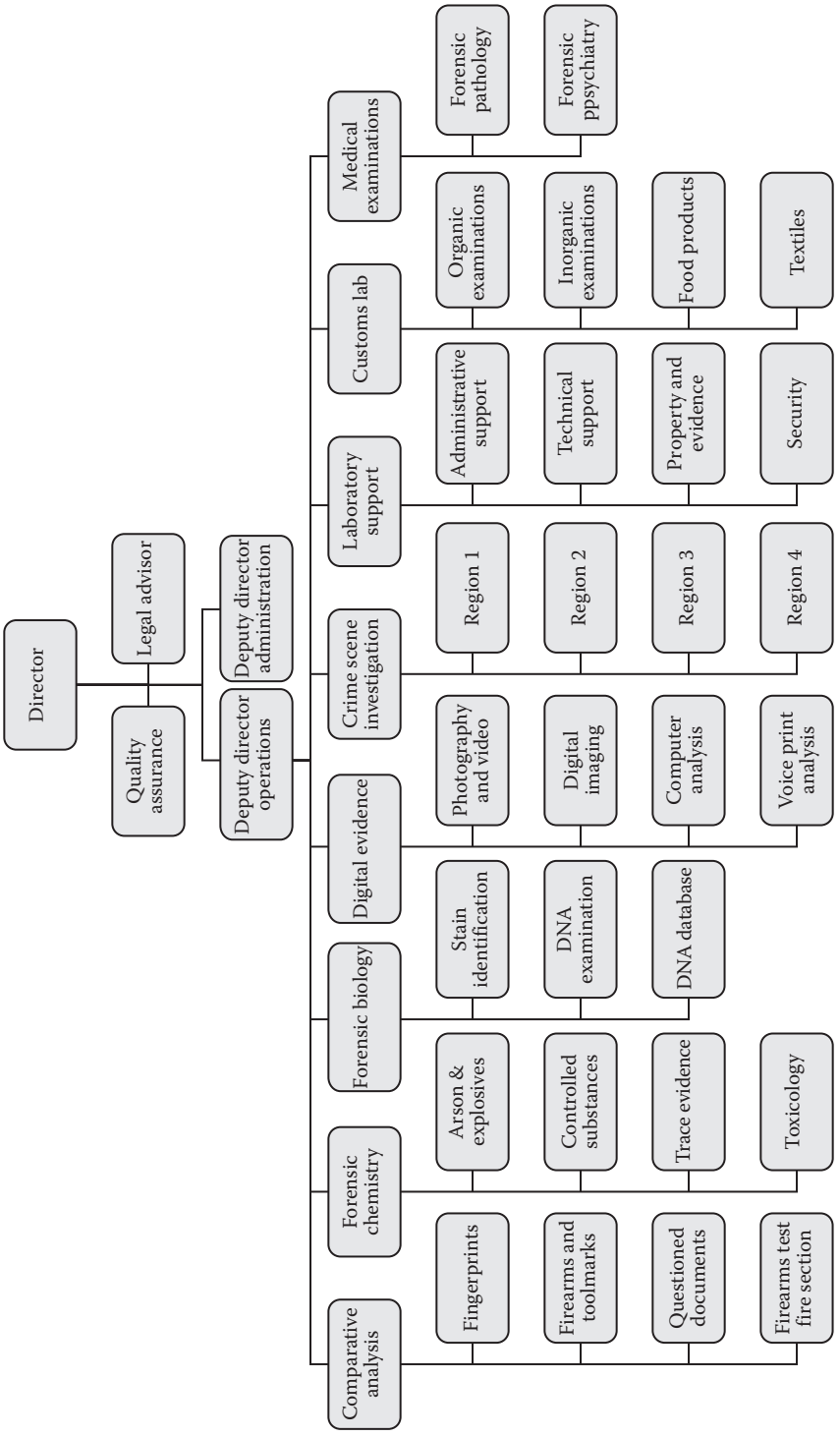

Figure 6.2 Example of a general organization chart.

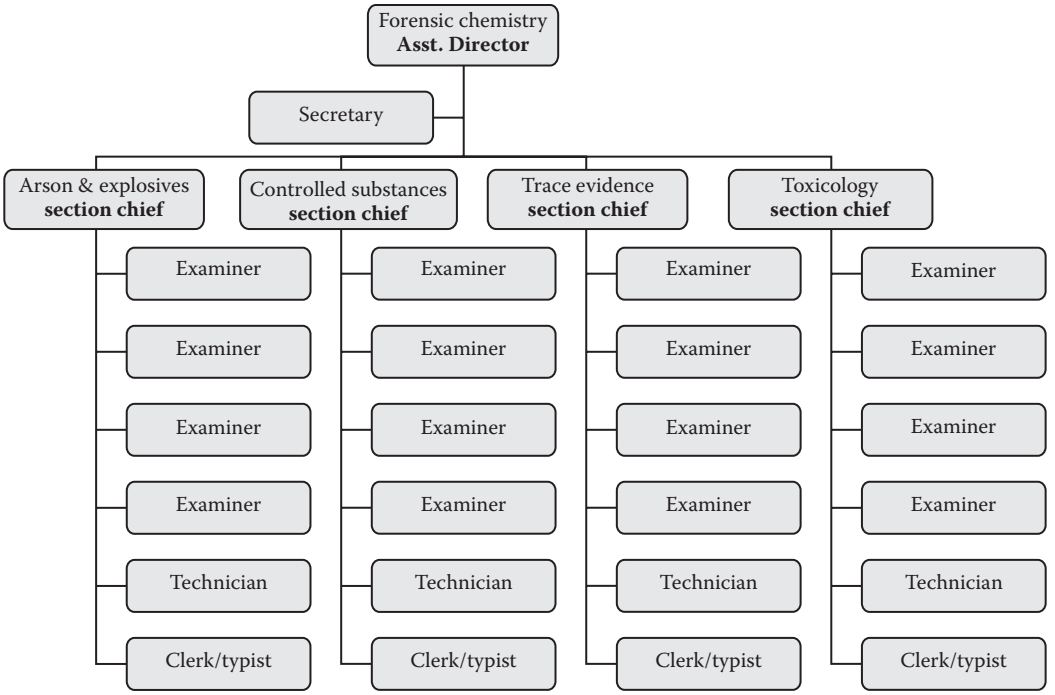

Figure 6.3 Example of a unit-specific organization chart.

hodge-podge of manuals with assorted styles into a single format. The reasons for the desire to change manual style range from a change in management to a desire to seek accreditation.

Manuals used to guide a laboratory's daily operation can be divided into two basic types. Each type has a function and format. The manual types are operational and technical.

Operational

Operational manuals are used to guide the laboratory's day-to-day operation. They have impact on all factions of the laboratory's operation. They affect clerical personnel as well as technical examiners. How an individual policy or procedure affects a given employee category may differ slightly. However, they do apply to each category in some way.

An operational can be divided into four basic sections. The laboratory type will determine the relevance of each section to its specific operation. However, each section has an application to one degree of another. These are the four basic sections of an operational manual:

- Administrative functions
- Quality assurance functions
- Health and safety functions
- Sample control functions

Administrative Functions

The administrative functions section of the operational manual has the most relevance to the greatest number of personnel. This section includes everything from the laboratory's mission statement and goals and objectives, to personnel issues, to the document control policy. All of the policies and procedures that affect the administrative operations of the laboratory should be encompassed within this section. Topics covered in the administrative manual should include the following:

- Management and organization
- Physical plant
- Personnel
- Case management
- Document control
- Security
- Forms

Quality Assurance Functions

The operational manual's quality assurance section outlines the laboratory's generic quality assurance program. It defines the quality assurance measures that universally apply to all factions of the laboratory. The policies and procedures contained in the various technical manuals will define how each analytical section will implement the generic policy.

For example, the operational quality assurance policy may read, "All instruments used in laboratory examinations will be calibrated monthly." There is no procedure associated with this policy. However, the forensic chemistry technical manual may read, "All gas chromatographs used in laboratory examinations will be calibrated monthly." This policy would have an associated procedure within the technical manual.

The generic topics covered within the operational manual's quality assurance section include the following:

- Quality assurance program overview
- Audits, inspections, and reviews
- Document control
- Equipment and chemicals
- Personnel
- Sample control
- Laboratory information management systems
- Issue management
- Forms

Health and Safety Functions

Policies and procedures concerning health and safety issues affect every employee within the laboratory. Some policies and procedures affect technical personnel more than clerical. However, as a whole, the section has universal application.

- Safety responsibility and authority
- Safe practices and procedures

- Occupant emergency plan
- Personal protective equipment
- Blood-borne pathogens
- Chemical hygiene plan
- Hazardous waste disposal
- Spill control and containment
- Laboratory fume hoods
- Ergonomics and office safety
- Forms and static documents

Sample Control Functions

Every laboratory has a mechanism in place to ensure the integrity of the samples they examine. What the sample is called varies from laboratory to laboratory. Whether it is called evidence or a specimen, a sample or an exhibit, is immaterial. The location and condition of samples must be tracked from the moment they enter the laboratory until the time they are properly disposed of. Therefore, sample integrity is every employee's responsibility.

Forensic laboratories may call it property and evidence. Clinical or quality assurance laboratories may call it sample control. No mater what name is used, this section of the administrative manual contains the following sections:

- Administrative issues
- Facilities
- Staffing scheduling and responsibilities
- Packaging and labeling
- Storage
- Evidence control
- Disposition and purging
- Forms and static documents

Technical

Operational manuals provide the generic guidance concerning what needs to be accomplished. The technical manuals provide the practical guidance concerning how each section of the laboratory is to implement the general policies outlined by the operational manual.

Each section of the laboratory has a mission and tasks that are specific to its operation. Generically, they may be similar to other sections within the laboratory. However, the specifics will differ or be unique to a specific section. Therefore, each section of the laboratory should be issued a technical manual that describes the specifics of how the employees of that section will implement the various policies and procedures within their sphere of responsibility.

The specific content of each section within a technical manual will differ from section to section. However, the topics that need to be addressed will remain the same. These topics include the following:

- Training
- Analytical methods

- Quality assurance
- Equipment and chemicals
- Reference material
- Literature references
- Forms

Training

Every employee within the laboratory requires some type of training to effectively perform their assigned tasks. Many laboratory accreditation programs only focus on the training of the technical staff. These individuals perform tasks directly related to the examination of the samples. However, the tasks performed by the balance of the staff are equally important when considering the quality of the laboratory's overall operation.

The performance of the support staff directly affects the productivity of the technical staff. If they are not adequately trained, the performance of the technical staff will be adversely impacted. Therefore, support staff training should be documented as well.

The training section of each technical manual should document all of the elements an employee is required to address before being allowed to participate in the examination of samples. The training section should list the reference material that is required reading. An outline of the training's learning objectives as well as the practical exercises should always be included.

One or more written exams should be incorporated into the training program to document the employee understands the information that has been presented. However, the content of these exams does not have to be incorporated into the technical manual's training section. Examination content should be reserved for a separate lesson plan, which should be developed for each analytical section.

There should be three training tracts for new examiners. One training track should be devoted to new section employees with no professional experience. The second track would address new employees with professional experience in the section's examination discipline. The final track would encompass employees with professional experience who transfer in from another section of the laboratory and have no practical experience in the analytical section's topic area. Each type of new employees has different training requirements.

Analytical Methods

The analytical methods section of the technical manual is the section most people associate with the "technical methods" manual. It provides detailed explanations concerning the steps required to conduct any of the authorized analytical procedures the analytical section performs. This is only one component of a comprehensive manual. The other sections of the technical methods manual provide supporting information that are equally as important to the performance of a given examination technique.

Each analytical method should include all the information necessary to conduct the analysis. The information can be in the form of a step-by-step set of instructions that walk the examiner through the process. The information can reference another procedure that describes the preparation of reagents used in the analysis. Or the information can reference a static document that contains information concerning the nationally or internationally accepted standardized analytical method. Each method should also contain some reference regarding the origin of the method and its validation with the laboratory.

There are two schools of thought concerning the level of detail that the analytical section should contain. One school of thought dictates that an analytical procedure should provide a detailed description of each step of the analytical procedure in an effort to ensure consistency. The other school of thought provides a generic description of the analytical requirements of the procedure and relies on the experience and training of the examiner to correctly implement the procedure using generally accepted methodology.

There is no right or wrong way to write an analytical procedure. Reality dictates that the procedures that are the most useful to the examiner in his daily work lay somewhere between the two extremes describe above. The procedure need to be detailed enough to guide an inexperienced examiner through the analytical process and achieve a reproducible result. The procedure also has to be generic enough and provide an experienced examiner the latitude to adapt the analytical scheme to correspond to nonstandard sample conditions.

Quality Assurance

Each analytical section has quality assurance requirements that are specific to that section. The quality assurance section of the operational manual outlines the generic quality assurance procedures that should be implemented. The quality assurance section of the technical manual defines the specifics steps of the process.

Equipment and Chemicals

Each analytical section utilizes a unique set of equipment and chemicals. The technical manual should contain a list of all of the chemicals and equipment used by the section to make identifications and comparisons. The chemical list should contain the following information for each chemical that is utilized:

- Name.
- Common name (if applicable).
- Manufacturer.
- Lot number.
- Date received.
- Expiration date (if applicable).
- Location. (Where in the laboratory is the item located?)
    - Form QAM-F013 is an example of a chemical inventory form that can be used to inventory laboratory chemicals.

The equipment list should contain the following information for each piece of equipment that is utilized:

- Instrument.
- Manufacturer.
- Model number.
- Serial number.
- Location (if applicable).
    - Form QAM-F010 is an example of an equipment inventory form that can be used to track the location of the laboratory's equipment and instrumentation.

The equipment and chemical information can be place into a form and should be updated on a regular basis. Additionally, a master list of reference material should be maintained by the laboratory's quality assurance manager.

Reference Material

Each analytical section utilizes a unique set of reference material. The technical manual should contain a list of all of the traceable reference material that is used by the section to make identifications and comparisons. The list should contain the following information for each item that is utilized as a reference standard:

- Name.
- Common name (if applicable).
- Manufacturer.
- Lot number.
- Date received.
- Expiration date (if applicable).
- Location. (Where in the laboratory is the item located?)
    - Form QAM-F014 is an example of an reference standard inventory form that can be used to track the location of the laboratory's reference standards.

This information can be place into a form and should be updated on a regular basis. Additionally, a master list of reference material should be maintained by the laboratory's quality assurance manager.

Literature References

Each analytical section utilizes literature references as a factual basis for the examination they perform. These literature citations are also utilized as part of the employees' training. Incorporating the copies of the text of the most significant literature references provides the technical manual users with a ready reference to the reference information they would most commonly require access to.

Forms

Forms that are sanctioned by the laboratory for general use are considered controlled documents. As such, the most current revision should be used by the laboratory's employees. All other revisions should be removed from circulation. Copies of outdated versions should be achieved for historical reference purposes.

Each analytical section utilizes forms that are unique to that analytical section. The section's technical manual should contain the most current revision of the form it uses in the normal course of business.

It is not uncommon for laboratory examiners to create some type of form to assist in their analytical duties. Many laboratory examinations involve repetitive tasks that generate large amounts of data that need to be collected and evaluated. Examiners create forms to ensure that all the information is collected in a format that they personally can evaluate at a later date. These forms extremely useful, but are not the subject of this discussion.

Once the examiner's analysis form or worksheet crosses the line from personal use to mandatory use by all examiners, then it becomes part of the quality process. Quality control ensures consistency and reproducibility. As such examination worksheets should reflect consistency in form and content. This ensures that all of the relevant information is gathered. Additionally, it streamlines the review process by providing standardized placement of the technical information used to compare the data to the results.

Format

There are no hard fast rules that define a manual's format. There are as many variations of manual formats as there are individuals who draft them.

The one underlying quality they all have is some semblance of organization and continuity. Some manuals are well thought out. Concepts are grouped in an intuitive fashion, allowing the reader quickly and easily navigate to the topics of his choice. Continuity of visual style allows the reader to transition from section to section without realizing he has changed topics.

The organizational style of other manuals defies description. Font and layout styles change from section to section. Some sections appear to be thoughtfully organized. Other sections look like a kindergarten cut-and-paste conglomeration of polices, procedures, and analytical method from a variety of sources. The content may be factually correct and serve a useful purpose. However, its visual appeal and lack of continuity and organizational flow reduce the manual's credibility before the reader has a chance to explore the content.

Single Document versus Multiple Documents

A single document or multiple documents are the two basic manual styles that are used in laboratories. Each has its strengths and weaknesses. Ultimately, the choice of which style to use is left to the discretion of the individual tasked with developing the manuals or to the approving authority.

Single Document

The single-document format is a compilation of the laboratory's policies and procedures. It has a narrative format and resembles a book of legal statutes.

Each manual is divided into chapters that address individual topics. Chapters are divided into sections. Sections are divided into subsections. Each component and subcomponent of the manual contains a section of text that discusses the topic at hand in the appropriate level of detail.

An outline format is used throughout the manual to aid in locating information. Figure 6.4 is one generic example of an outline format that can be used. Any of the other commonly accepted outline formats can be substituted for the one used in Figure 6.5. Every manual produced by the laboratory should use the same single-document format if this format is chosen.

Multiple Documents

The multiple-document format resembles the single-document format in that the manual is divided into chapters, sections, subsections, and so forth. The difference lies in how the

MANUAL TITLE

Chapter X (Descriptive Title)

1 SECTION NAME

Text

1.1 SUBSECTION NAME

Text

1.1.1 SUB-SUBSECTION

Text

2 SECTION NAME

Text

2.1 SUBSECTION NAME

Text

2.1.1 SUB-SUBSECTION

Text

Chapter Y (Descriptive Title)

1 SECTION NAME

Text

1.1 SUBSECTION NAME

Text

1.1.1 SUB-SUBSECTION

Text

2 SECTION NAME

Text

2.1 SUBSECTION NAME

Text

Chapter Z (Descriptive Title)

3 SECTION NAME

Text

Figure 6.4 Single-document manual format.

ADMINITRATIVE POLICIES AND PROCEDURES

(Revision 01)

TABLE OF CONTENTS

Page

Figure 6.5 Example single-document manual table of contents.

text of the policies and procedures is presented. The text of each policy and procedure is addressed as an individual document in the multiple-document formats.

Multiple-document-formatted manuals have additional information imbedded into each document that the single-document manuals do not. Each document contains statements concerning why the document exists (the purpose) and who it applies to (the scope) and defines terms that may have a specific meaning within the context of the document. Additionally, there is an endorsement section that specifically details the date and under whose authority the specific policy or procedure was approved. Figures 6.6 and 6.7 are

TITLE (CATEGORY)

Subtitle (Descriptive Title)

1 PURPOSE

A statement concerning why this policy exists.

2 SCOPE

A statement concerning who and what is affected by the policy.

3 DEFINITIONS

Specifically defines certain terms or phrases used within the policy.

4 POLICY

Statements used to define the actual policy.

5 PROCEDURE

Statements used to define how the policy is implemented.

6 APPROVAL

The signatures of the approving authority defined in the document approval policy.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

Figure 6.6 Operational policy format.

examples of the multiple-document formats that can be utilized in operational and technical manuals, respectively. Figures 6.8, 6.9 and 6.10 are examples of outline formats that can be utilized in either the individual or multiple document formats.

Document Maintenance

Controlled document maintenance should be considered when selecting a manual format. The single-document and the multiple-document formats have different maintenance

TITLE (CATEGORY)

Subtitle (Descriptive Title)

1 PURPOSE

A statement concerning why this policy exists.

2 SCOPE

A statement concerning who and what is affected by the policy.

3 RELATED PROCEDURES

A list of the policies, procedures or analytical methods that are related to this procedure or analytical method:

- XXX P00a
- YYY M00a

4 SAFETY CONSIDERATIONS

Statements concerning the hazards involved with the procedure and the precautions taken to abate them.

5 INSTRUMENTATION

A list of the instrumentation required.

6 STANDARDS AND CONTROLS

A list of the reference standards and procedural controls required for a successful analysis.

7 PROCEDURE OR ANALYSIS

Statements that describe the sequence of events required to properly conduct the analysis.

8 REPORT WORDING

Suggest or approved verbiage used to describe analytic results in reports issued by the laboratory.

9 REFERENCES

List of literature citations used to validate the procedure.

10 APPROVAL

The signatures of the approving authority defined in the document approval policy.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

Figure 6.7 Technical policy format.

Numeric Outline Style

Style A

1. Section
Text

1.1. Subsection
Text

1.1.1. Sub-Subsection
Text

Style B
1 Section
Text

1.1 Subsection
Text

1.1.1 Sub-Subsection
Text

Style C
1 Section
Text

1.1 Subsection
Text

1.1.1 Sub-Subsection
Text

Figure 6.8 Numeric outline numbering styles.

and dissemination requirements. These requirements directly affect the quality assurance manager's workload. The approach taken also directly impacts the ability to disseminate changes quickly and efficiently.

When a controlled document is modified the entire document is required to be reissued. This would technically require the reissuance of a multipage document if a single word were changed. This can be problematic for a large manual that is a dynamic living document or if employee manuals are printed versions.

There are methods to reduce or eliminate the need to issue changes in the single-document manual that avoid reissuing the entire document or to reduce the need to reprint multiple copies of the entire to address minor changes in grammar or content. Issuing change notice memoranda that address the modifications that have been made and their effective date is one method. The changes would be incorporated into the next regularly scheduled printing and distribution of the effected manual.

Another alternative is to provide all employees access to an electronic version of all manuals. This can be done by providing employees access to an Internet or intranet site

Non-Numeric Outline Style

Style A
1) Section
Text

a) Subsection
Text
i) Sub-Subsection
Text

Style B

1) Section
Text

a) Subsection
Text

i) Sub-Subsection
Text

Style C

Article I. Descriptive Title
Text
Section 1.01 Descriptive Title
Text
(a) Descriptive Title
Text
(i)

Figure 6.9 Non-numeric numbering styles.

that contains the current revision all of the laboratory's controlled documents. Another option would be to e-mail each employee an electronic copy of the revised manual when the revisions have been approved.

The use of a multiple-document format presents different issues but has similar resolutions. The entire document is generally reissued when a manual modification is made using a multiple-document format. The document is distributed as soon as the approval process has been completed. No follow-up documentation or notifications are required.

Multiple Document Template

A multiple-document format manual has two main sections. Each section has multiple components that should be incorporated into all documents. This consistency can be used to create a generalized template that can be used when preparing controlled documents. The document template outlines the information required for each document type. All that is required of the author is the specific details concerning the policy, procedure, or supporting document under development.

TITLE (CATEGORY)

Subtitle (Descriptive Title)

1 SECTION NAME

Text

1.1 SUBSECTION NAME

Text

1.1.1 SUB-SUBSECTION

Text

1.1.1.1 SUB-SUB-SUBSECTION

Text

Figure 6.10 Administrative policy layout.

Administrative Information

All controlled documents are required to contain certain pieces of administrative information. This information is used to identify the document and ensure a complete and current revision is in use. The administrative information is also used to preserve a historical record of the document and enables it to be used when reconstructing past events based upon the policies and procedures that were in effect at the time.

The location of the administrative information is left to the author's discretion. It is immaterial that the information is contained in the document's header or the footer. It does not matter if it occurs once or on every page. The important fact is that the information is in the document in a location that can be easily deciphered by the reader.

The administrative information each document should contain includes the following:

- Organization's name
- Category
- Descriptive title
- Document number
- Revision number
- Effective date
- Revision date
- Page numbers
- End-of-document statement

Organization's Name Including the name of the organization on every controlled document may seem to be unnecessary. Without this piece of identifying information, the controlled document in question may as well belong to "Joe's Crab Shack." The verbiage may be verbatim from one of Joe's documents. However, this label is essential in identifying

the policy, procedure, or supporting document as one that is officially accepted by the laboratory.

Category Each manual is divided into pieces, regardless of the format used. Components are divided into subcomponents. Sections are divided into subsections. Chapters are divided into sections, sections into paragraphs, paragraphs into subparagraphs. All this division and subdivision is done in an effort to allow the reader to find specific information at some point in the future.

Categories, chapters, or sections are all terms that can be used interchangeably to describe the major groups of an individual manual. The titles of these individual groups are left to the discretion of the manual's author or approving authority. The only requirement is that title adequately represents the topic of the subcomponents it contains.

This information is required to be placed only on the first page of the document. However, it is common practice to include the group name in the footer information of all pages of the document.

Descriptive Title The subtitle or descriptive title provides the readers information they require to quickly identify the central idea of the policy, procedure, or supporting document. Like the category or title, the descriptive tile is also used for organizational purposes.

Document Number Every controlled document should have a unique document number that distinguishes it from all other controlled documents. It should appear on every page, usually in the document's footer. It is used to associate every page of the document.

The age of electronic file cabinet has simplified the assignment of document numbers. Document numbers can be generally associated with the file name that the document is stored under. This filing system allows for quick retrieval and modification when required. This number should not change.

Document numbers are unique to a specific document. These numbers are never reused or reassigned to a different document. If a document in no longer relevant in the laboratory's operational environment, the document number is retired and noted as such.

Revision Number Each controlled document should have a unique document number. However, each document will have multiple revision numbers over the course of the document's life. Assigning a unique revision number is done to ensure the current revision of the controlled document is in circulation. Each time a controlled document is revised, it should be assigned a new revision number. The revision number should be located in the vicinity of the document number so the reader can quickly and easily identify the revision of the document under review.

The revision number should reflect if a document has been retired and is no longer in use or circulation. A notation such as "Retired" or "Inactive" should be placed in the section reserved for revision number when a controlled document has been removed from circulation.

Effective Date The effective date of the document is a piece of administrative information that identifies whether the controlled document was in relevant at a given point in time. The effective date is first date the information in the document is effective. Generally, this date coincides with the date of the signature of the approving authority but can be at some point in the future.

Revision Date Every controlled document has a built in sunset clause. This is the date when the document is reviewed to establish its relevance and applicability in the laboratory's current operating environment. This date is placed on the document as a reminder to the reader that a more recent revision of the document may exist.

Page Numbers The page number and total number of pages are traditionally included to ensure that all pages of the document are accounted for. Additionally, if a page is separated from the group, it can be easily replaced in the proper location.

End-of-Document Statement The end-of-document statement informs the reader that the document contains no information beyond that point.

Content

The content of policy and procedure documents is the reason they were created. It should be short and concise and focus on a single topic. The verbiage should be such that the reader can easily understand the information that the document is attempting to relay.

Documents should be written in plain language. Technical jargon should be avoided. At times, the use of jargon is unavoidable. In these circumstances, jargon and other document specific terms should be defined within the document itself or in a glossary of terms.

Documents should be understandable. Ambiguity should be avoided. The purpose of these documents is to define how and why things are to be done. This specificity is the core of the laboratory's quality assurance program. Vagueness in a procedure leads to variation, which in turn can lead to lack of precision.

The content of policy and procedure documents is divided into a number of sections. Each section has a specific function concerning how and why the document exists. Some technical procedure documents have more sections than operational documents because of the nature and purpose of the procedure. Other than that they can utilize the author can utilize the same format template.

Operational Figure 6.6 is an example of a simple template that can be developed for use for all operational policies and procedures. It provides the administrative information in the header and footer sections. The body of the document is reserved for the "who, what, when, where, and why" details of the document. Operational documents should contain the following types of information:

- Title/subtitle
- Purpose
- Scope
- Definition of terms
- Policy
- Procedure
- Approval
- Document identification information

Title/Subtitle The title and subtitle provide the reader information concerning the topics that the document will address. The title is generally associated with the topic's category. The subtitle is generally a descriptive title of the document's contents. For document

control purposes, these should be the same as the administrative information's category and subcategory.

Purpose The purpose is a brief statement concerning why this policy exists. It informs the reader why the policy or procedure was written. It can be as long and detailed or short and concise as the author or approving authority desires. However, shorter is better, since it is not the point of the document.

The following is an example of a purpose statement:

The purpose of this document is to establish the AGENCY NAME's Mission Statement.

Scope The scope is a brief statement concerning who and what is affected by the policy. It informs the reader who or what the focus of the subsequent information is. It is usually only a single sentence in length.

The following is an example of a scope statement:

This document applies to all factions of the AGENCY NAME.

Definitions The definition section defines terms that may be unfamiliar to the reader. Professional jargon is commonly utilized in a laboratory setting. Other terms may have multiple meanings depending on the context in which they are used. This section specifically defines certain terms or phrases used within the policy.

There are two basic methods to address defining terms within a controlled document. One method involves establishing a master glossary that every controlled document refers to. The other method defines specific terms within the document itself. Each has its merits and its drawbacks. These methods are described in more detail in Chapter 7.

Policy The policy statement is one of the reasons a document exists. It is a statement or series of statements used to define the laboratory's policy concerning a specific topic. It is the "Thou shall" decree that formulates one of the bricks the quality assurance program is built from.

Policy statements should be short, concise and not be ambiguous. Multiple statements may be required if the policy has situational conditions that must be addressed.

Policy statements do not address implementation. They simply focus on the fact that a specific task should be done. How it is implemented is either specifically defined in a procedure statement within the policy or in a separate procedure document. There are situations when it is immaterial how the policy is implemented. In those instances a statement to that effect is placed into the policy document.

Procedure The procedure section is a series of statements used to define how the policy is implemented. It is the "Do it this way" decree that supports the "Thou shall" policy statement.

Procedure statements can be simple one- or two-line directives that outline how a procedure is to be implemented. They can also be a multipage guide outlining the implementation of a policy under a variety of circumstances. A statement that leaves it to the individual's judgment on to implement a policy can be considered a procedure statement in itself.

Simple procedures can be embedded into the policy document. More-detailed procedures may require a separate procedure document. This style format is left to the discretion of the author or approving authority.

Approval The approval section provides the reader information concerning who approved the document and when it was approved. The number of approving individuals is defined in the laboratory's document control policy. There can be as few or as many individuals as desired. However, there must be at least one.

The location of this section is left to the discretion of the author or approving authority. One philosophy is that it is important that the document's approval to be the first thing the reader sees. The other philosophy places less importance on the document's approval and places the approval section at the end of the document. Both philosophies satisfy the requirement of an approval section to advise the reader that the document has been approved and when the approval occurred.

Document Identification Information The document identification information correlates to the information in the laboratory's document control program. The location of this information on the document (header/footer) is irrelevant. The only requirement is that it is on every page, because it is used to ensure the most recent revision of the procedure is in circulation.

The document identification information should include the following:

- Title and subtitle
- Document number
- Revision number
- Effective date
- Revision due date
- Page number and total number of pages

Technical Methods In many situations, the templates utilized to create operational manual policy and procedure documents can be used to create technical manual policy and procedure documents. However, analytical methods and procedures contained in technical manuals require additional information that is either immaterial to the implementation of an operational policy or procedure. Therefore, a separate template should be developed to include the additional sections required by analytical methods or technical procedures.

Title/Subtitle The same guidelines used to develop the title and subtitle of operational documents can be used to develop this section of a technical method.

Purpose The same guidelines used to develop the purpose section of operational documents can be used to develop this section of a technical method.

Scope The same guidelines used to develop the scope of operational documents can be used to develop this section of a technical method.

Related Procedures The execution of a technical procedure or analytical method is affected by one or more other technical procedures. Everything from the way chemical reagents are prepared to how instruments are operated or calibrated will in some way affect how a procedure is conducted. As such, the method's reader should be aware of these methods and procedures.

The information in this section can be a simple list of the related items. The list should be constructed in such a way as to allow the reader to quickly and easily identify the relevant

method. Therefore, each reference should minimally contain the document's document number and descriptive title. The procedure's manual location can be substituted for the document number for printed copy references.

Safety Considerations Safety considerations are statements concerning the hazards involved with the procedure and the precautions taken to abate them. This can be boilerplate language that can be utilized in numerous procedures and methods since it can be applied equally to a variety of laboratory situations. The addition of specific hazards and their abatement should be added as required.

Instrumentation This section should list the instrumentation required to perform the procedure or method.

Standards and Controls This section should contain a list of the reference standards and procedural controls required for a successful analysis.

Procedure or Analysis This section describes the sequence of events required to properly conduct the analysis. It is the "Thou shall" decree that defines how the analysis is conducted. The procedure statements can be simple one- or two-line directives that outline how a procedure is to be implemented. It can also be a multipage guide outlining the specific steps that are required under a variety of circumstances. Additionally, this statement can refer to a static document that contains a standardized method that must be utilized under a specific set of circumstances. A statement that leaves the examination method to the examiner's judgment can be considered a procedure statement in itself.

Report Wording This section should contain suggested or approved verbiage used to describe analytic results in reports issued by the laboratory.

References This section should contain a list of literature citations used to validate the procedure.

Approval The same guidelines used to develop the approval section of operational documents can be used to develop this section of a technical method.

Document Identification Information The information in this section is the same type of information that is included in the documentation identification information section of the operational manual.

Operational Manuals 7

Operational manuals consist of one or more groups of policies, procedures, and supporting documents that are directed at all factions of the laboratory. They apply equally to clerical personnel and those in professional roles. Technical employees apply these rules and regulations in the same manner as administrative workers.

Many organizations refer to operational manuals as their general orders. They group all of the policies and procedures that effect the "general" operation of the organization into a manual with one or more subdivisions. These directives have general application, although individual policies may affect one group of employees more than another.

This discussion will focus on four basic categories of operational manuals. The title of each may vary from organization to organization. Some institutions may debate whether some of the groupings should be included under the umbrella of an operational manual. Other institutions may want to expand this list to include other topics. However, this book will utilize the following categories:

- Administrative
- Quality assurance
- Health and safety
- Sample control

This chapter will discuss each of these sections. The comments will be generic in nature. The format discussed and associated document templates will focus on the multiple-document manual style. However, the comments are equally applicable to the single-document format. Additionally, the numerous individual document templates can be modified and merged into a single document.

Definitions

Overview

One of the keys to effective communication is understanding the terms that are used in a discussion or a document. Too many times, misunderstandings have occurred or mistakes have been made because one of the parties had a different understanding of some of the terms that were used.

Professional jargon is commonly utilized in a laboratory setting. Personnel banter about acronyms and catch phrases, assuming everyone understands the meaning or the context in which they are used. New employees often smile and nod with understanding when these words and phrases are first encountered, not wanting to show their ignorance. The sooner the new employee understands the meaning of the local language, the sooner they can be productive.

Other terms may have multiple meanings depending on the context in which they are used. Look at any thesaurus. Words have conditional meanings. Therefore, it is imperative for the reader to understand the meaning of terms that have a double entendre.

A laboratory's policies and procedures are the law of the land. As such, there should be no misunderstanding of the content of the written documents that define them. Therefore, it is imperative that the author of theses documents remove any ambiguity during their preparation. Defining ambiguous terms or expressions with dual meanings is an essential part of the development process.

The process of defining terms can be accomplished in two manners. Each controlled document can have a section dedicated to defining terms that may have ambiguous meanings within the specific document. Creating a separate document that contains all of the questionable terms that appear throughout all of the laboratory's manuals is another method to address the issue.

Both systems have their pros and cons. Which system is implemented is a matter of personal choice on the part of the author or the approving official. The only requirement in this component of any manual is that a definition of terms can be found somewhere in the document.

Definitions Template

Appendix A can be utilized as a guide to define the terms that appear in operational and technical manuals. These definitions should be modified as required to meet the organization's specific needs. This is not an all-inclusive list, and some definitions may not be appropriate for some organizations. However, in total they represent the basic topic area that should be incorporated into an organization's operational and technical manual.

Template #	Description
Appendix A	Definition of Terms

Administrative Manual

Overview

The administrative section of the operational manual has the most relevance to the greatest number of personnel. This section includes everything from the laboratories mission statement and goals and objectives, to personnel issues, to the document control policy. All of the policies and procedures that affect the administrative operations of the laboratory should be encompassed within this section.

Management and Organization

The management and organization section of the administrative manual provides a look at the engine that drives a laboratory's operation. It legitimizes its existence and defines its purpose. It provides an overview of the laboratory's operational and organizational structures. This section also delineates laboratory's planning process and explains how it deals with current as well as future needs.

These topics should be included in the management and organization section:

- Organizational role
  - Mission statement
  - Goals and objectives
  - Legal direction
- Organization
  - Structure
  - Authority
  - Supervision
  - Organization of laboratories
  - Work content
- Directing
  - General
  - Delegation of authority
  - Communication
  - Documentation
- Planning
  - Services and functions
  - Budget
  - Policy and procedure development distribution
  - Long-range planning

Physical Plant

If the management and organization section is the laboratory's engine, then the physical plant is the body. It is the shell in which the engine operates.

The physical plant section defines the infrastructure that houses the laboratory. It establishes the space requirements and provides design guidance. The physical plant section also outlines the security policies and procedures used to ensure examination integrity.

The physical plant section may also include policies, procedures, and supporting documents concerning the equipment utilized by the laboratory. This section would concentrate on the laboratory's master equipment list and would include office and clerical equipment as well as the equipment and instrumentation involved in the examination process.

Topics that should be in the physical plant section include, but are not limited to, the following:

- Space
- Design
- Security
  - General
  - Access
  - Entry log
    - Key control
  - Intrusion security
- Equipment inventory

Personnel

If management is the laboratory's engine and the physical plan is the body, then the personnel is the fuel that drives the laboratory bus. As with any engine, the quality of the fuel directly affects the performance. Therefore, the strength of the laboratory's personnel policies directly affects its performance.

The personnel policies and procedures encompass who should be selected (i.e., the job descriptions and minimum qualifications) to how they are selected (i.e., the selection process). Employee development and maintenance are also addressed in this section through professional development and evaluation components. Any administrative issue associated with the laboratory's employees falls under the umbrella of the personnel section.

Topics that should be in the personnel section include, but are not limited to, the following:

- Job descriptions and minimum qualifications
  - Management positions
  - Professional staff
  - Technical staff
  - Administrative staff
- Selection and promotion
  - New employee selection
  - Promotion
- Performance measures and evaluations
  - Employee evaluations
  - Code of conduct
    - Agency code of conduct
    - Laboratory code of conduct
- Statements of qualifications
- Grievance procedure
- Time and attendance
  - Duty hours
  - Overtime
  - Sick leave
  - Vacation leave
- Professional development
  - Training programs
  - Employee development
  - Literature resources
  - Periodical circulation
  - Training records

Case Management

The general operation of every laboratory is fundamentally the same. The operation of a forensic laboratory is generically the same as the quality control lab at a pharmaceutical company. A hospital laboratory operates using the same principles as a water quality laboratory. The analytical procedures may differ but the operating principle is the same: accept, examine, report, and return the samples as quickly and efficiently as possible.

Case management is the key to a successful laboratory operation. The management systems and principle may be cutting edge. The physical plant can be state-of-the-art. The personnel can all be world class. However, all these components are ineffective if a mechanism to move the samples through the analytical system does not exist.

The laboratory's case management system is the road map used to drive samples on their trip through the laboratory. The route a sample takes is laboratory-specific. However, every laboratory has a detailed route each sample must take to get from the beginning to the end. All personnel should be provided a copy of the map if the management expects then to arrive at the same place.

The purpose of the laboratory may differ, but all laboratories must be able to account for samples. Whether it is a forensic laboratory providing service to the criminal justice community or an analytical laboratory offering services for profit, all laboratories assign each submission a case or job number. Whether it is a laboratory in a hospital or a quality assurance lab in a manufacturing facility, every sample has a unique sample identifier. All laboratories must account for receiving and returning samples. All laboratories must have a mechanism to prioritize their work stream and distribute their work load equitably. Finally, all laboratories should have a method of analyzing the statistical information. That is the function of the laboratory's case management system.

Topics that should be in the personnel section include, but are not limited to, the following:

- Case numbering
- Sample submissions
  - Sample submission policy
  - Sample log-in procedure
  - Nonsample property submissions
  - Chain of custody
- Sample returns
  - Storage policy
  - Sample returns
  - Nonsample property returns
  - Chain of custody
- Assignment and distribution
  - Priorities
  - Distribution process
- Laboratory information management system (LIMS)

Document Control

All laboratories have numerous controlled documents whose content needs to be monitored. Each laboratory must establish policies and procedures to ensure the content of these controlled documents is current and correct.

The access to certain controlled documents is on a need-to-know basis. For example, examination reports are the client's property and not for public dissemination. Even information that can be considered "public record" should have some control on its distribution through an associated dissemination procedure.

The document control section defines which documents are controlled, how they are filed, and to whom they can be disseminated. It establishes how polices, procedures, and

technical methods are developed, approved, and disseminated. Additionally, procedures concerning the review of controlled documents for content and their relevance are contained within this section.

Topics that should be in the document control section include, but are not limited to, the following:

- Document retention
  - Examination reports
  - Administrative information
  - Internal communications
  - External communications
  - Procurement records
- Filing
  - Property and evidence records
  - Examination reports
  - Administrative information
  - Internal communications
  - External communications
  - Procurement records
- Report dissemination
  - Law enforcement
  - Non–law enforcement
  - Case file dissemination
  - Manual dissemination
  - Freedom of Information Act requests
- Policy development and review
- Policy development procedure
- Policy review procedure
- Policy approval procedure
- Policy dissemination procedure
- Policy numbering procedure
- Policy retirement procedure

Security

Every laboratory requires some type of security. Sample integrity is one reason. Client confidentiality is another. Whatever the reason, security measures are utilized to guarantee privacy and will vary from laboratory to laboratory. Since they do exist in some form, they should be documented as official policies and procedures.

The security section of the administrative manual contains the policies and procedures used to establish a mechanism that meets the laboratory's security needs. Who has access to the laboratory and what areas they have access to need to be defined. Hours of operation need to be identified, not only for public access but to include after-hours access by laboratory personnel. The type of alarm systems and their locations should be included in this section. Finally, the procedures that should be followed if a breach of the security system is detected should be incorporated.

Topics that should be in the security section include, but are not limited to, the following:

- Authorized personnel
  - General access
  - Specific area access
  - Escort policy
  - Access control
  - Documentation
- Access hours
  - Hours of operation
  - After-hours access
- Key control
  - General access
  - Limited access
- Alarms
  - Intrusion alarms
  - Video surveillance
  - Fire and smoke alarms
  - Duress alarms
  - Documentation
- Security and safety
  - Security breach
  - Safety violation
  - Documentation

Forms and Static Documents

Forms and static documents are documents that the laboratory relies on to conduct business. Forms are documents utilized to ensure all of the information concerning a specific topic is gather and disseminated. These documents come in all shapes and sizes. The forms that are specific to the operation of the administrative section should be incorporated into this section.

Static documents are documents that the laboratory does not have control over their content. Examples of administrative static documents are the laboratory's parent organization policies and procedures. The laboratory cannot change them but is expected to adhere to them. Therefore, these documents must be incorporated into the laboratory's operational manual.

Administrative Templates

The following is a list of templates that can be utilized as a guide to develop the policies, procedures, and supporting documents terms that appear in administrative manuals. The text of these documents can be located in Appendix B. These documents should be modified as required to meet the organization's specific needs. This is not an all-inclusive list, and some documents may not be appropriate for some organizations. However, in total they represent the basic topic areas that should be incorporated into an organization's administrative manual.

Management and Organization

Template #	Description
APP-P102	Legal Authority
APP-P103	Mission Statement
APP-P104	Goals and Objectives
APP-P105	Services and Functions
APP-P106	Budget
APP-P107	Policy and Procedure Development and Distribution
APP-P108	Policy and Procedure Understanding
APP-P109	Long Range Planning
APP-P110	Organizational Structure
APP-P111	Work Content
APP-P112	Delegation of Authority
APP-P113	Supervision
APP-P114	Communication
APP-P115	Quality Assurance Program

Physical Plant

Template #	Description
APP-P201	Space
APP-P202	Design
APP-P203	Construction
APP-P204	Access Control
APP-P205	Key Control
APP-P206	Alarms
APP-P207	Housekeeping

Personnel

Template #	Description
APP-P301	Job Descriptions
APP-P302	Selection and Promotion
APP-P303	Evaluations
APP-P304	Code of Conduct
APP-P305	Statement of Qualifications
APP-P306	Grievances and Complaints
APP-P307	Duty Hours
APP-P308	Overtime
APP-P309	Sick Leave
APP-P310	Annual Leave
APP-P311	Training
APP-P312	Professional Development
APP-P313	Literature Resources
APP-P314	Periodical Circulation
APP-P315	Training Records
APP-P316	Dress Code
APP-P317	Signature/Initial Exemplars
APP-P318	Outside Work Permits

Case Management

Template #	Description
APP-P401	Case Numbering
APP-P402	Sample Submission
APP-P402	Sample Return
APP-P404	Sample Database
APP-P405	Case Assignment
APP-P406	Backlog Management
APP-P407	Laboratory Information Management System (LIMS)

Document Control

Template #	Description
APP-P501	Document Retention
APP-P502	Document Disposal
APP-P503	Document Inventory
APP-P504	Document Approval
APP-P505	Document Format
APP-P506	Document Numbering
APP-P507	Document Filing
APP-P508	Report Dissemination
APP-P509	Manual Dissemination
APP-P510	Freedom of Information Act Requests
APP-P511	Document Retirement
APP-P512	Document Review
APP-P513	File Removal
APP-P514	Electronic File Security

Security

Template #	Description
APP-P601	Authorized Access
APP-P602	Escort Policy
APP-P603	Facility Entry Log
APP-P604	Hours of Operations
APP-P605	Alarms
APP-P606	Security Staff
APP-P607	Security Breach
APP-P608	Safety Violations

Forms

Template #	Description
APP-F001	Document Inventory Form
APP-F002	Operational Manual Distribution Log
APP-F003	Technical Manual Distribution Log
APP-F004	Administrative Policy Orientation Log
APP-F005	Acting Authority Roster

APP-F006	Key Control Log
APP-F007	Employee Evaluation Form
APP-F008	Manager Evaluation Form
APP-F009	Security Equipment Inspection Form
APP-F010	Statement of Qualifications
APP-F011	Grievance Report Form
APP-F012	Grievance Report Record Form
APP-F013	Training Record Log Form
APP-F014	Training Record Critique Form
APP-F015	Case Log
APP-F016	Examiner Case Log
APP-F017	Section Case Log
APP-F018	Visitor Entry Log
APP-F019	Vehicle Entry Log
APP-F020	Security Status Check Form
APP-F021	File Removal Log Form
APP-F022	ASCLD/LAB Criteria File Form
APP-F023	ISO 17025 Criteria File Form
APP-F024	DNA Quality Audit Criteria File Form
APP-F025	Policy and Procedure Association Chart

Quality Manual

Overview

The operational manual's quality assurance section outlines the laboratory's generic quality assurance program. It defines the quality assurance measures that universally apply to all factions of the laboratory. The policies and procedures contained in the quality assurance section of various technical manuals will define how each analytical section will implement the generic policy.

For example, the operational quality assurance policy may read, "All instruments used in laboratory examinations will be calibrated monthly." There is no procedure associated with this policy. However, the forensic chemistry technical manual may read, "All gas chromatographs used in laboratory examinations will be calibrated monthly." This policy would have an associated procedure within the technical manual.

Having an operational and numerous technical quality assurance manuals may seem redundant. However, it is necessary to establish standardization and uniformity throughout the organization. The operational quality assurance program establishes the laboratory's quality assurance program standards. The analytical requirements of each technical section can vary significantly and it is impractical if not unrealistic to impose the exact same quality assurance procedures on two completely different analytical techniques.

The concept may be easier to understand taken in a different light. The redundancy disappears if one considers the operational quality assurance manual the "policies" and the quality assurance section of the technical manuals the "procedures." The operational quality manual commands, "Thou shall." It is left to the discretion of each technical section to

establish a quality assurance procedure that describes how to implement the "Thou shall" of the operational manual.

Quality Program Overview

The overview section provides information concerning the quality program's organizational structure. It defines how the laboratory's quality program in the same way the administrative manuals management and organization section define its reason for being.

To be effective the quality program must articulate why it exists. The overview section defines the quality program and establishes the goals and objectives by which its success is measured. Additionally, this section should contain statements concerning the management's commitment to quality as well the employee's dedication to implementing the program's policies and procedures.

Laboratory accreditation requires the laboratory to establish a quality manager position. A convenient place to define the quality manager's duties is within the overview section. This places most of the quality program's administrative details neatly within a single manual section.

Traditionally a section that defines all the terms specific to the quality manual can be located within the overview section. There are a couple of alternatives to a specific section of definitions. One would be to refer definitions to a single definition of terms section, as was discussed earlier in this chapter. A second alternative is to establish a definition of terms section specific to the quality program within the overview section. A third option is to define terms as needed within specific policies, procedures, and supporting document. As with defining terms in the administrative section, the location of the definitions is left to the discretion of the manual's author or approving authority.

Topics that should be in the quality program overview section include, but are not limited to, the following:

- Program objectives
- Program definition
- Quality assurance manager
  - Job description
  - Auxiliary staffing
- Definitions (optional)

Audits, Inspections, and Reviews

A common laboratory mission statement contains this phrase: "dedication to continual self improvement of its analytical and management systems." A program of internal and external evaluation is an essential component of self improvement. Ineffective systems cannot be improved if the management does not know they are ineffective. Broken system cannot be fixed if the management does not know what is not working correctly.

A system of audits, inspections, and reviews is a crucial element of an effective quality program. It is also an essential element of laboratory accreditation programs. However, that should not be the driving force behind implementing an objective assessment system. A commitment to quality examinations and dedication to continual self improvement is the only motivation that will positively influence a quality program.

The audit, inspection, and review section of the quality manual defines the policies, procedures, and supporting documents used by the laboratory to evaluate it performance. Audits assess how well the laboratory is adhering to its own polices and procedures. Inspections are used to evaluate how well specific laboratory mechanisms are functioning. Reviews simply judge whether policies, procedures, and supporting documents are still appropriate or require modification.

Documentation is a key component of the evaluation process. This section outlines and specifically defines the record-keeping systems used by the laboratory to document the results of the various audits, evaluations, and reviews that are conducted by the laboratory.

Topics that should be in the audits, inspections, and reviews section include, but are not limited to, the following:

- Quality system audit
  - Purpose
  - Scope
  - Auditors
  - Documentation
- Laboratory inspections
- Recordkeeping reviews
  - Documentation
  - Reviews
- Accreditation

Document Control

Documents are a laboratory's lifeblood. There is a document associated with almost every action and reaction that occurs. Policy documents define what should be done. Procedure documents provide guidance on how a task should be done. Files contain the reports, forms and associated paperwork that are used to document that the tasks mandated by policies have been conducted in accordance to the procedures.

Document control is a key component of a laboratory's quality program. It ensures that the most recent policies, procedures, and supporting documents are in circulation. Document control is used to standardize the information produced and used by the laboratory in its daily operation. It is used to ensure the information contained in the documents is as accurate as possible and meets the guideline established by the approving authority. Document control is used as a mechanism to store and retrieve information. It is also used a method to secure documents from unauthorized dissemination.

The document control portion of the quality manual contains three main sections that focus on the documents related to the examination process. However, these principles can be extrapolated to other types of documents. These sections are manual types, manual development, and case documentation.

The manual type section defines the types of manuals or manuals topics that come under the control of the quality assurance program. Each topic is further subdivided into topic areas that detail what information each section should contain.

The document development section contains bulk of the policies and procedures concerning document control. It provides a cradle-to-grave description of the life of a controlled document. It describes how the need for a policy or a procedure is established and carried through the development process. It then details the approval and dissemination process.

Controlled documents should grow and evolve to meet the changing needs of the laboratory. As such, a mechanism is required to modify these documents to meet the current laboratory needs. The controlled document section offers guidance on this mechanism.

The laboratory will have policies, procedures, or support documents that out live their usefulness. Therefore, a mechanism to retire and archive these documents must be established for historical purposes. This section defines that mechanism.

Controlled documents extend beyond policies and procedures. Examination reports and the notes that support the conclusions they contain are considered controlled documents. Therefore, their must be policies and procedures established to address their format and content as review and dissemination.

Topics that should be in the document control section include, but are not limited to, the following:

- Policies and procedures manuals
  - Administrative policies and procedures manuals
  - Analytical methods manuals
  - Evidence control manuals
  - Health and safety manuals
  - Quality assurance manuals
  - Training manuals
- Manual development, maintenance, and control
  - Operational policies
    - Development procedures
    - Review procedures
    - Approval procedures
    - Dissemination procedures
    - Revision of procedures
    - Retirement of procedures
  - Technical methods
    - Development procedures
    - Validation procedures
    - Review procedures
    - Approval procedures
    - Dissemination procedures
    - Deviation from approved procedures
    - Revision of procedures
    - Retirement of procedures
- Documentation
  - Case notes
    - Format
    - Content
    - Corrections
    - Dissemination
  - Case reports
    - Format
    - Content

  - Reviews
  - Corrections
  - Dissemination
  - Storage
- Property and evidence

Equipment and Chemicals

Equipment and chemicals are the tools examiners rely on to perform their analysis. The purpose of the equipment and chemical portion of the quality manual is to outline the policies procedures and supporting documents that ensure the tools the examiners are using at functioning as designed and rendering reliable information. This section is composed of four components: weights and measures, equipment, chemicals, and reference materials.

The weights and measures section defines the units of measurement that the laboratory will utilize during the normal course of business. Whether the laboratory uses the metric or the English system is immaterial. The significant lies in the definition of which units are to be used and the condition that allows deviation from their usage.

The equipment section mandates an inventory of the equipment used for analytical purposes and establishes how often it should be updated. This section contains the general policies and procedures concerning the calibration and maintenance of equipment. (Specific policies and procedures are relegated to the technical manuals of the analytical sections the equipment is utilized.) Finally, the equipment segment contains the laboratory's policy concerning the use of external resources (i.e., equipment does not belong to the laboratory).

The chemical sections mandates and inventory of the chemicals utilized for analytical purposes as well. These inventories are used to ensure the freshness and reliability of the chemicals used for examinations. Additionally, this section contains generic policies and procedures concerning the preparation and validation of test reagents. As with the equipment, the procedures concerning specific reagents are relegated to the technical manuals of the analytical section they are used in.

The final module of the equipment and chemical section has to do with reference material. This component contains the generic policies and procedures concerning the acquisition and use of reference materials. As with the equipment and chemicals, the policies and procedures concerning specific reference materials are relegated to the technical manuals of the analytical section they are used in.

Topics that should be in the equipment and chemicals section include, but are not limited to, the following:

- Weights and measures
- Equipment
  - Inventories
  - Calibration logs
  - Maintenance logs
  - Use of external resources
- Chemicals
  - Inventories
  - Reagent preparation logs
- Reference standards
  - Inventory

- Traceability log
- Validation log

Personnel

The most valuable resource a laboratory has is its personnel. As such, the personnel section of the laboratory's quality manual is one of the most important. The level of the laboratory equipment's technology is irrelevant, the quality of the chemicals is immaterial, and the condition of the facility in inconsequential if the personnel is substandard. Every part of every examination has a human factor. Therefore, the quality of the personnel must be specifically addressed.

The right person for the right job is a basic tenet of personnel management. The minimum qualification section of the quality manual establishes policies that mandate personnel have minimum qualifications for the positions they hold. This is generically addressed in the personnel section of the administrative policies and procedures and more specifically in the technical manuals of the individual analytical sections. However, identifying and selecting the proper personnel is only the beginning.

The old saying, "There is the right way, the wrong way, and the Army way," is applicable in the realm of laboratory personnel. Personnel need to be taught what is acceptable and what is unacceptable. Personnel with no or minimal experience need to be provided basic instruction concerning the analytical techniques used by the laboratory. Experienced personnel who are new to the examination techniques need a different type of instruction. New employees with experience in the examination area will need remedial training to familiarize themselves with the techniques that are authorized for use by the laboratory. All this falls under the heading of training.

Qualifications and training are only two parts of the personnel puzzle. After a person with the minimum qualifications is trained, his performance must be evaluated to ensure the quality of his work. Just as the performance of the equipment is monitored through calibration logs, a mechanism to continually evaluate the performance of the laboratory's personnel must be established and implemented. This is accomplished through a proficiency testing program.

Professional development is a component of personnel management that is often overlooked. Laboratories have a huge investment in their professional staff. A laboratory can easily invest thousands of dollars in time and money in developing a examiner prior to their performing a single examination. The personnel section outlines the laboratory's professional development policies and procedures used to keep their employees abreast of the current trends and analytical methods. It is the personnel version of equipment maintenance.

Topics that should be in the personnel section include, but are not limited to, the following:

- Minimum qualifications
- Training
  - New employee
  - Basic technical training
  - In-service technical training
  - Remedial training
  - Documentation

- Proficiency testing
  - Definitions
  - Frequency
  - Procedure
  - Documentation
- Court monitoring
  - Policy
  - Rating criteria
  - Documentation
- Professional development
  - Professional association affiliation
  - Professional meeting attendance
  - Professional training
  - Continuing education
  - Professional certification
- Peer groups and technical leaders

Sample Integrity

Sample integrity is another essential element of a quality program. The laboratory can have a state of the art facility. The equipment can be operating at peak performance. The examiners can be thoroughly trained and proficient. All this makes no difference if the integrity of the samples is compromised in some way.

The sample integrity section addresses generic policies and procedures that relate to ensuring the samples have not been mishandled or altered while under the laboratory's control. These policies and procedures can encompass the entire scope of sample handling within the laboratory's operating parameter. However, if the scope of sample handling is sufficiently large, a separate manual may be additionally required to adequately address all of the issues related to sample integrity, as is discussed elsewhere in this chapter.

The sample integrity section utilizes a holistic approach in defining the policies and procedures used to ensure that the sample the client submits to the laboratory is the sample that is analyzed. Everything from the way samples are to be packaged and labeled to the numbering system used for identification is outlined in one of the policies and procedures in this section. Even the subject of cross contamination is addressed in this section.

Topics that should be in the sample integrity section include, but are not limited to, the following:

- Sample submission procedures
  - Sample log-in procedure
  - Case numbering
  - Sample packaging
  - Marking and sealing
  - Special handling procedures
- Processing and returning of samples
  - Loss, cross-transfer, and contamination of samples
  - Creation of items or subitems
  - Intralaboratory transfers
  - Return of sample

- Release of sample
  - To law enforcement
  - To non-law enforcement

Laboratory Information Management Systems

Accreditation bodies find it highly desirable for a laboratory to have a LIMS. However, the accreditation criterion never defines what constitutes a LIMS. What one region of the world considers a LIMS is different from another region. It is commonly held in the United States that a LIMS is a computer-based database that can sort volumes of information and generate statistical reports that can be used by the senior managers to focus resources where they are most needed. In developing nations, a series of bound log books serves the same purpose.

Is the computer-based system more efficient? Definitely. Is the computer-based system better than the log book system? Not necessarily.

As you can see, there is a large crevice between the extremes of LIMS technology. Even with this extreme, there is commonality. Both systems need policies, procedures, and supporting documents to ensure LIMS is utilized properly and the information derived from it is reliable, representative, and accurate.

As with sample integrity, generic LIMS polices and procedures can be addressed in a section of the quality manual. However, as the size and scope of the LIMS grows, so does the number policies, procedures, and supporting documents. Ultimately, there will be a point of time when a separate manual specifically to address LIMS issues will be required.

Issue Management

Every laboratory encounters situations that affect the quality of the work it does. How the laboratory deals with these circumstances will affect the quality of its work and ultimately its reputation among its peers and clients. Taking prompt action to address the topic is the most effective way to tackle the situation before it becomes a problem.

Issue management, or corrective actions, is a form of self-improvement to identify situations, implement solutions, and follow up on their effect. Cursory observations of laboratory operations, such as audits and inspections, will identify "issues" that are currently impacting quality. A deeper reflection will discover "risks" that have the potential of affecting quality at some time in the future. Both situations must be addressed. The only difference is in the priority placed upon the implementation of the corrective action required to resolve the problem.

No one likes their baby called ugly, and many managers take it personally. This is especially true when it will take time and money and resources to make an ugly situation pretty. The barer of the ugly "truth" is frequently looked on with disdain. This is why the quality assurance manager is one on the most disliked people in the laboratory, simply because his job is to identify deficiencies that affect quality. In essence, his job is to call the baby ugly.

The relationship between senior managers and their laboratory's operation is no different than a parent and their children. Both may be within dysfunctional situations and will have a tendency to deny, overlook, or ignore problems. Their reasoning may be different, but the result is the same. They do not implemented the corrective action required to change an unacceptable situation in hopes that it will go away on its own accord or that no one will notice. Unfortunately, the situation never goes away and someone eventually notices.

An issue management program is implemented for the same reasons a laboratory implements a quality program. It is essential in identifying, correcting, and monitoring the effects of the correct action taken to resolve issues that affect the quality of the laboratory's work. It detects the risk or issue. It defines the steps that are required to correct the address the problem or predicament that has been identified. Finally, the program monitors the effects of the resolution to ensure the desired effects have been achieved.

Issue management is a requirement for most accreditation programs. However, as with a quality program, it should not be the driving force that influences its implementation. The need to identify and resolve problems as quickly and efficiently as possible should take precedence, whether the laboratory is accredited or not. This is a function of the senior management or the quality assurance manager.

The issue management section of the quality manual establishes the policies, procedures and supporting documents necessary to take corrective action when risks or issues are identified. The implementation of this section applies equally to all sections of the laboratory, as opposed to other quality manual sections where the implementation is driven by the polices of the individual analytical sections. Additionally, this section takes away the discretionary power of the laboratory director to address a problem once a risk or issue has been documented.

Topics that should be in the issue management section include, but are not limited to, the following:

- Risk identification
  - Employee suggestion
  - Peer groups
  - User groups
  - Safety
  - Audits
  - Employee performance
    - Proficiency tests
    - Case review
    - Testimony monitoring
- Issue resolution
  - Employee suggestions
  - Peer groups
  - User groups
  - Safety
  - Audits
  - Employee performance
    - Proficiency tests
    - Case review
    - Testimony monitoring
- Corrective reports actions

Forms

The laboratory's administrative program has forms and static documents that it relies on to conduct business. The laboratory's quality manual has its own. The forms and documents are utilized to ensure all of the information concerning the quality program is gathered, collected,

filed, and disseminated. These documents come in all shapes and sizes. The forms that are specific to the operation of the quality program should be incorporated into this section.

The quality program's static documents are those that the laboratory does not have control over their content. Examples of quality program static documents are the requirements established by the accreditation programs the laboratory participates in. The laboratory cannot change them but is expected to adhere to them. Therefore, these documents must be incorporated into the laboratory's operational manual.

Quality Manual Templates

The following is a list of templates that can be utilized as a guide to develop the policies, procedures, and supporting documents terms that appear in quality manuals. The text of these documents can be located in Appendix C. These documents should be modified as required to meet the organization's specific needs. This is not an all-inclusive list, and some documents may not be appropriate for some organizations. However, in total they represent the basic topic areas that should be incorporated into an organization's quality manual.

Quality Assurance Program Overview

Template #	Description
QAM-P101	Legal Authority
QAM-P102	Mission Statement
QAM-P103	Program Objectives
QAM-P104	Program Definition
QAM-P105	Quality Manager
QAM-P106	Accreditation
QAM-P107	Commitment to Quality
QAM-P108	Change Management
QAM-P109	References
QAM-P110	Customer Service

Audits, Inspections, and Reviews

Template #	Description
QAM-P201	Quality System Audits
QAM-P202	Inspections
QAM-P203	Audit Documentation
QAM-P204	Audit Reviews
QAM-P205	Technical Procedure Deviation
QAM-P206	Control of Nonconforming Work

Document Control

Template #	Description
QAM-P301	Manuals
QAM-P302	Operational Document Development
QAM-P303	Operational Document Dissemination
QAM-P304	Operational Document Retirement

QAM-P305	Technical Document Development
QAM-P306	Technical Document Dissemination
QAM-P307	Technical Document Retirement
QAM-P308	Controlled Document Review
QAM-P309	Examination Documentation
QAM-P310	Examination Notes
QAM-P311	Examination Note Corrections
QAM-P312	Examination Note Dissemination
QAM-P313	Examination Reports
QAM-P314	Examination Report Review
QAM-P315	Examination Report Corrections
QAM-P316	Examination Report Dissemination
QAM-P317	Examination Report Storage
QAM-P318	Technical Procedure Acceptance

Equipment and Chemicals

Template #	Description
QAM-P401	Weights and Measures
QAM-P402	Measuring Device Calibration
QAM-P403	Instrument Calibration
QAM-P404	Instrument Calibration Logs
QAM-P405	Equipment Inventories
QAM-P406	Equipment Maintenance Logs
QAM-P407	External Equipment Use
QAM-P408	Chemical Inventories
QAM-P409	Expired Chemical Usage
QAM-P410	External Chemical Usage
QAM-P411	Chemical Procurement
QAM-P412	Chemical Receipt
QAM-P413	Reference Standard and Material Inventory
QAM-P414	Reference Standard and Material Validation
QAM-P415	Reagent Preparation Logs
QAM-P416	Equipment Procurement
QAM-P417	Equipment Receipt
QAM-P418	Reference Standard and Material Procurement
QAM-P419	Reference Standard and Material Receipt
QAM-P420	Equipment Use

Personnel

Template #	Description
QAM-P501	Minimum Qualifications
QAM-P502	Training
QAM-P503	Proficiency Test Evaluation

QAM-P504	Proficiency Test Documentation
QAM-P505	Testimony Review
QAM-P507	Professional Association Affiliation
QAM-P408	Professional Meeting Attendance
QAM-P509	Professional Training
QAM-P510	Continuing Education
QAM-P511	Professional Certification
QAM-P512	Technical Leaders
QAM-P513	Peer Group
QAM-P514	Conflict of Interest
QAM-P515	Proficiency Test Program
QAM-P516	Contract Labor
QAM-P517	Quality Roles of Personnel

Sample Control

Template #	Description
QAM-P601	Sample Submission
QAM-P601	Sample Transfers
QAM-P603	Loss, Cross–transfer, and Contamination
QAM-P604	Item and Subitem Creation
QAM-P605	Intralaboratory Transfer Documentation
QAM-P606	Sample Return
QAM-P607	Sample Release
QAM-P608	Individual Characteristic Database Samples
QAM-P609	Sample Control Manual

Laboratory Information Management Systems

Template #	Description
QAM-P701	Laboratory Information Management Systems

Issue Management

Template #	Description
QAM-P801	Risk Identification
QAM-P802	Issue Identification
QAM-P803	Corrective Action Reports
QAM-P804	Corrective Actions

Examination Methods

Template #	Description
QAM-P901	Examination Method Selection
QAM-P902	Examination Requests

QAM-P903	Contract Examinations Services
QAM-P904	Environmental Factors
QAM-P905	Examination Procedure Validation
QAM-P906	Examination Procedure Uncertainty
QAM-P907	Sampling

Forms

Template #	Description
QAM-F001	Quality Assurance Orientation Checklist
QAM-F002	Customer Survey
QAM-F003	Corrective Action Report Form
QAM-F004	Operational Manual Distribution Log
QAM-F005	Technical Manual Distribution Log
QAM-F006	Document Inventory
QAM-F007	ASCLD/LAB Audit Worksheet
QAM-F008	ISO 17025 Audit Worksheet
QAM-F009	DNA Audit Worksheet
QAM-F010	Equipment Inventory Log
QAM-F011	Equipment Calibration Log
QAM-F012	Equipment Maintenance Log
QAM-F013	Chemical Inventories
QAM-F014	Reference Standard and Material Inventory
QAM-F015	Reference Standard Validation Log
QAM-F016	Training Record Log
QAM-F017	Proficiency Test Database Form
QAM-F018	Proficiency Test Report
QAM-F019	Testimony Review Form
QAM-F020	Corrective Action Report Form
QAM-F021	Corrective Action Report Log
QAM-F022	Item Creation and Transfer Form
QAM-F023	Examination Satisfaction Survey
QAM-F024	Reagent Preparation Log

Health and Safety Manual

Overview

Policies and procedures concerning health and safety issues affect every employee within the laboratory. Some policies and procedures affect technical personnel more than clerical. However, as a whole the section has universal application.

Safety Responsibility and Authority

The health and safety section of the operational manual defines how the laboratory addresses issues that affect the health and welfare of its employees and other individuals that may

come in contact with the facility. This initial section outlines the scope of the health and safety program as well as the responsibilities of specific individuals and the employees collectively.

Laboratory safety is everyone's responsibility. Personal responsibility is essential when it comes to implementing safe work practices and in maintaining a safe work environment. However, the laboratory is responsible for defining the parameters of what acceptable work practices are and how the organization plans to abate or mitigate health and safety issues that are outside of its direct control.

There are numerous components of a health and safety plan. Not every employee will be affected by every component. The safety responsibility and authority section outlines and defines the responsibilities of the various individuals who play key roles in them implementation of the laboratory's health and safety plan. These individuals include the following:

- Assistant director
- Section chiefs
- Unit chiefs
- Supervisors
- Health and safety program manager
- Unit health and safety coordinator
- Employees

Safe Practices and Procedures

This will sound redundant, but the point cannot be overstated. Laboratory safety is everyone's responsibility. Personal responsibility is essential when it comes to implementing safe work practices and maintaining a safe work environment. However, the laboratory is responsible for defining the parameters of what acceptable work practices are and how the organization plans to abate or mitigate health and safety issues that are outside of its direct control.

The safe work practices section defines the laboratory's expectations concerning safe work practices within the laboratory. In some instances, these directives will appear simplistic and be common knowledge for anyone with laboratory experience. Both of these assumptions are valid. However, from a liability point of view, an employee cannot be held accountable for utilizing acceptable work practices unless they are defined, documented, and presented to an employee. It is irrelevant if the work practices are common knowledge. If they are not defined, documented, and presented to the employee, the employee cannot be held accountable.

Work practices in this section do not have to be documented in great detail. Generic statements concerning what is and is not an acceptable work practice is all that is required. The key is that a list of documented work practices exists.

Generic work practice topics include the following:

- Awareness
- Eating and drinking
- Personal hygiene
- Personal protective equipment (PPE)
- Biological safety
- Chemical safety
- Housekeeping

- Fire prevention
- Emergency procedures
- Waste disposal
- Miscellaneous

Occupant Emergency Plan

The laboratory environment presents an environment that is more conducive to experience an accident or emergency of some type. The chemical involved in the examination process have a variety of health and safety issues associated with their use. Chemical spills happen. Fires occur. Explosions take place. These occurrences may be rare, but their potential must be addressed.

Accident and emergency situations in the laboratory may be rare. However, a plan must be in place for the rare instance that they occur. Emergency situations create confusion and chaos. If a plan is not in place, and its execution practiced, the confusion may lead to more problems that the original situation presented. Therefore, the laboratory needs to establish a documented emergency plan.

The occupant emergency plan (OEP) provides all employees what to do in case an emergency evacuation of the building is require. The protocol is used to ensure that all employees are accounted for and no one is left in the building if an emergency evacuation is required do to a chemical spill, fire, explosion, or other issue that requires the evacuation of the facility.

Topics in the OEP include the following:

- General guidelines
- Emergency coordinators
- Emergency evacuation procedures

Personal Protective Equipment

The nature of laboratory work presents employees a variety of health and safety issues due to exposure to a variety of chemicals and biological and physical hazards. The hazards associated to these can be abated or mitigated through the use of PPE.

The U.S. Occupational Safety and Health Administration (OSHA) requires that employers provide their employees PPE if they have the potential to be exposed to a variety of health and safety issues. Employers are also required to provide training concerning the use and maintenance of the PPE it issues to its employees. Additionally, OSHA has established specific regulations concerning PPE specifications and the circumstances under which they should be used.

The PPE component of the health and safety section documents the laboratory's efforts to comply with the OSHA regulations concerning the use and maintenance of PPE. Topics in this section include the following:

- Background
- Eye and face protection
- Protective clothing
- Hand protection
- Foot protection
- Head protection
- Hearing protection
- Respiratory protection

Blood-Borne Pathogens

Blood-borne pathogens are one of two groups of tetra-ethyl nasties that pose health hazards to laboratory personnel performing laboratory duties. Blood-borne pathogens encompass all infectious diseases that are found in biological fluids. The diseases include, but are not limited to, HIV, hepatitis, and tuberculosis. These diseases can be found in biological fluids such as blood, semen, and vaginal secretions.

The laboratory can effectively protect its employees from blood-borne pathogens by implementing a documented prevention program. This component of the health and safety section defines the policies and procedures the labor has implemented to protect its employees from infections from exposure to blood-borne pathogens.

The topics in the blood-borne pathogen section include the following:

- Background
- Scope and application
- Definitions
- Universal precautions
- Engineering controls
- PPE
- Safe work practices
- Cleaning and disinfecting
- Biohazard spills
- Infectious waste disposal
- Communication of hazard
- Hepatitis B vaccination
- Postexposure evaluation and follow-up
- Training
- Record keeping

Chemical Hygiene Plan

Chemicals are the other group of tetra-ethyl nasties that pose a health hazard to laboratory personnel performing laboratory duties. Chemicals pose a broader hazard risk because all examination sections have a potential exposure to some type of chemical as part of their regularly assigned duties. This is opposed to blood-borne pathogen exposure that only occurs to personnel working with blood or body fluids.

The laboratory can effectively protect its employees from chemical-related hazards by implementing a documented prevention program. This component of the health and safety section defines the policies and procedures the laboratory has implemented to protect its employees from infections from exposure to chemical hazards.

The chemical hygiene plan addresses the same issues the blood-borne pathogen program addresses. It documents the policies and procedures concerning how laboratory employees handle the chemicals they encounter during the normal course of business. The same principles of documentation found in the blood-borne pathogen program apply to the chemical hygiene plan.

Topics addressed in the chemical hygiene plan include the following:

- Background
- Scope

- Hazards
- Identifying hazards
- Measures to reduce exposures
- Emergency equipment
- Procurement and receiving of chemicals
- Chemical storage
- Transporting chemicals
- Employee information and training
- Exposure/injury notifications
- Medical consultation and follow-up

Hazardous Waste Disposal

The generation of hazardous waste is an unavoidable by-product of laboratory examinations. No laboratory is immune form this reality. The type and amount of waste that is generated will vary and depend on the nature of the examinations that are performed. But every laboratory will generate some type of hazardous waste.

The hazardous waste generated by the laboratory must be dealt with in a responsible manner. Gone are the days of the solution to pollution is dilution. Pouring waste products down the drain is not an option. Neither is depositing containers of various types of hazardous waste in the trash for disposal in the local landfill.

The disposal of hazardous waste is serious business. Improper handling can lead to detrimental health and safety issues. Additionally, there are legal ramifications, some with significant financial penalties attached, for the improper handling of hazardous waste. Therefore, it is in the laboratory's best interest to implement policies concerning the proper handling of hazardous waste.

The documentation of the policies and procedures related to the handling of hazardous waste has the same purposes as the documenting any other policy or procedure. This documentation ensures there is a uniform method utilized to dispose of the hazardous waste generated by the laboratory and that the method is consistent with the relevant statutes.

Topics addressed in the hazardous waste disposal section include the following:

- Background
- Characterization of hazardous waste
- Hazardous waste handling and disposal procedures
- Disposal of empty containers
- Nonhazardous chemicals
- Regular trash
- Radioactive waste
- Biological waste
- Waste minimization

Spill Control and Containment

The nature of laboratory spills differs from spills in other environments. The ramifications of spilling a cup of coffee differ significantly from spilling an equal volume of sulfuric acid. Mercury spills need to be addressed in a different manner than volatile organic solvents.

Accidents and spills happen. Laboratories try to minimize them but they still occur. Therefore, the laboratory must establish policies and procedures to address the physical and chemical properties of the substances that potentially would be spilled.

The topics contained in the spill control and containment section include the following:

- Spill control policy
- Spill control and containment guidelines

Laboratory Fume Hoods

Laboratory fume hoods minimize employee's exposure to the hazards associated with examination they perform. Their proper operation is essential in ensuring the health and welfare of the examiners who utilize them.

The function and design of laboratory fume hood vary to address the properties of the materials the examiner is working with. Each has different operating conditions. Each has different maintenance requirements. Therefore, policies and procedures should be established to describe the optimum operating conditions and maintenance requirements for each type of laboratory fume hood.

The topics that should be addressed in the laboratory fume hood section include the following:

- Background
- Fume hood use guidelines
- Storage in fume hoods
- Ductless fume hoods
- Biological safety cabinets
- Glove boxes

Ergonomics and Office Safety

Health and safety issues extend outside the confines of the laboratory. An office environment has its own unique set of health and safety issues. They may not have the immediate impact as those in a laboratory environment. However, they can and do affect the health and welfare of the laboratory's staff. Therefore, policies and procedures that address the nonlaboratory environments should be included in the health and safety section.

The topics addressed in the ergonomics and office safety section should include the following:

- Ergonomics
- Laboratory environment
- Office environment
- Office safety

Forms and Static Documents

The laboratory's health and safety program has forms and static documents are documents that it relies on to conduct business. The forms are documents are utilized to ensure all of the information concerning the health and safety program is gathered, collected, filed, and

disseminated. These documents come in all shapes and sizes. The forms that are specific to the operation of the quality program should be incorporated into this section.

The health and safety program's static documents are those that the laboratory does not have control over their content. Examples of health and safety static documents are the requirements established by OSHA. The laboratory cannot change them but is expected to adhere to them. Therefore, these documents must be incorporated into the laboratory's operational manual.

Health and Safety Manual Templates

The following is a list of templates that can be utilized as a guide to develop the policies, procedures, and supporting documents terms that appear in health and safety manuals. The text of these documents can be located in Appendix D. These documents should be modified as required to meet the organization's specific needs. This is not an all-inclusive list, and some documents may not be appropriate for some organizations. However, in total they represent the basic topic area that should be incorporated into an organization's administrative manual.

Safety Responsibility and Authority

Template #	Description
HAS-P101	Responsibility
HAS-P102	Authority

Safe Practices and Procedures

Template #	Description
HAS-P201	Awareness
HAS-P202	Eating and Drinking
HAS-P203	Personal Hygiene
HAS-P204	Personal Protective Equipment
HAS-P205	Biological Safety
HAS-P206	Chemical Safety
HAS-P207	House Keeping
HAS-P208	Fire Protection
HAS-P209	Emergency Procedures
HAS-P210	Waste Disposal
HAS-P211	Miscellaneous

Occupant Emergency Plan

Template #	Description
HAS-P301	Guidelines
HAS-P302	Emergency Coordinators
HAS-P303	Emergency Evacuation Procedure

Personal Protective Equipment

Template #	Description
HAS-P401	General Guidelines
HAS-P402	Eye and Face Protection
HAS-P403	Protective Clothing
HAS-P404	Hand Protection
HAS-P405	Foot Protection
HAS-P406	Head Protection
HAS-P407	Hearing Protection
HAS-P408	Respiratory Protection

Blood-Borne Pathogens

Template #	Description
HAS-P501	General Guidelines
HAS-P502	Universal Precaution Guideline
HAS-P503	Engineering Controls
HAS-P504	Personal Protective Equipment
HAS-P505	Safe Work Practices
HAS-P506	Cleaning and Disinfecting
HAS-P507	Biohazards
HAS-P508	Infectious Waste Disposal
HAS-P509	Hazard Communication
HAS-P510	Hepatitis Vaccinations
HAS-P511	Postexposure Evaluations
HAS-P512	Training
HAS-P513	Record Keeping

Chemical Hygiene Plan

Template #	Description
HAS-P601	General Guide
HAS-P602	Flammable Materials
HAS-P603	Corrosive Materials
HAS-P604	Oxidizing Material
HAS-P605	Reactive Materials
HAS-P606	Explosive Materials
HAS-P607	Peroxide Forming Materials
HAS-P608	Compressed Gases
HAS-P609	Carcinogens
HAS-P610	Reproductive Toxins
HAS-P611	Chemical Labeling
HAS-P612	Material Safety Data Sheets
HAS-P613	Exposure Reduction
HAS-P614	Emergency Equipment
HAS-P615	Chemical Procurement and Receipt

HAS-P616	Chemical Storage
HAS-P617	Chemical Transportation
HAS-P618	Information and Training
HAS-P619	Exposure and Injury Notification
HAS-P620	Medical Consultation and Follow-Up

Hazardous Waste Disposal

Template #	Description
HAS-P701	Program Overview
HAS-P702	Waste Characterization
HAS-P703	Handling and Disposal
HAS-P704	Empty Container Disposal
HAS-P705	Nonhazardous Chemical Disposal
HAS-P706	Regular Trash Disposal
HAS-P707	Radioactive Chemical Disposal
HAS-P708	Biological Waste Disposal
HAS-P709	Waste Minimization

Spill Control and Containment

Template #	Description
HAS-P801	General Policy
HAS-P802	Containment Procedures

Laboratory Fume Hoods

Template #	Description
HAS-P901	General Policy
HAS-P902	General Procedures
HAS-P903	Fume Hood Storage
HAS-P904	Ductless Fume Hoods
HAS-P905	Biological Safety Cabinets
HAS-P906	Glove Boxes

Ergonomics and Office Safety

Template #	Description
HAS-P1001	Ergonomics
HAS-P1002	Laboratory Environment
HAS-P1003	Office Environment
HAS-P1004	Office Safety

Forms and Static Documents

Template #	Description
HAS-F001	Emergency Equipment Inspection
HAS-F002	Health and Safety Manual Orientation
HAS-F003	Health and Safety Manual Review
HAS-F004	Waste Disposal Log
HAS-F005	Waste Stream Information Form

Sample Control Manual

Overview

Not all laboratories have a property and evidence section. This is mainly a focus of forensic laboratories. However, all laboratories must address issues concerning sample integrity. The principles are the same, even if the terminology is different.

Every laboratory has a mechanism in place to ensure the integrity of the samples they examine. What the sample is called varies from laboratory to laboratory. Whether it is called evidence or a specimen, a sample or an exhibit, is immaterial. Their location and condition must me tracked from the moment they enter the laboratory until the time they are properly disposed of. Therefore, sample integrity is every employee's responsibility.

Forensic laboratories may call it property and evidence. Clinical or quality assurance laboratories may call it sample control. No matter what name is used, this section of the administrative manual contains the following subsections:

- Administrative issues
- Facilities
- Staffing
- Packaging and labeling
- Storage
- Evidence control
- Disposition and purging

Administrative Issues

The property and evidence section of a forensic laboratory is a microcosm within the laboratory itself. As such it has policies and procedures that address needs specific to its operation. The administrative section addresses the organizational needs of the property section. Some of these issues may not be applicable to non-forensic laboratories. However, many do have generic applications in all laboratory environments.

The organizational placement of the property and evidence section is addressed in the administrative section. Ideally, the property and evidence section is outside of the direct administrative control of the laboratory's examination sections. This independence is used to ensure sample integrity by removing the undue influence of examination section managers on the administration of the property room activities.

The administrative section defines the need for a policy manual that addresses the specific functions related to the management of the samples submitted to the laboratory for examination. This section outlines the topics that the manual should include.

Maintaining the chain of custody of samples submitted to the laboratory is one of the principle functions of the sample control section. As such, establishing a sound documentation policy is essential in sustaining sample integrity for the duration of the samples tenure in the laboratory. The documentation component of the administrative section codifies the documentation needs of the specific documentation requirements of the sample control section.

The sample control section functions as a warehouse. It store samples prior to analysis and subsequent to their return to the individual or agency that submitted them for analysis. This function requires the personnel to discern the location of a sample at any given time. As such, establishing a mechanism to maintain an inventory of all of the samples submitted to the laboratory is mandatory.

The inventory component of the sample control manual's administrative section details how the section will maintain sample inventories. Additionally, this section defines the need to perform routine and unscheduled checks on the inventories of the sample storage facilities. This function is done as a quality systems check to demonstrate sample integrity has been maintained.

Audits of the sample control section are used to assess how well the section is adhering to its own polices and procedures. It serves the same quality assurance purpose as audits of the laboratory's operational systems. The only difference is that property and evidence audit focuses specifically on issues related to the storage of samples submitted to the laboratory for examinations.

The training component of the administrative section addresses the training needs of sample control personnel. As with other components, having a separate training section for the sample control section may seem redundant. However, as will be demonstrated in the laboratory's analytical sections, the property and evidence section has training requirements that are specific to its operation. As such, a component of the administrative section is dedicated to addressing these specific needs.

Topics addressed in the sample control manual's administrative section should include the following:

- Organizational placement
- Policy manual
- Documentation
  - Forms
  - Valuables and firearms
- Inventories
- Audits
- Training

Facilities

The purpose of the sample control section is to provide a secure storage environment for the samples submitted to the laboratory for analysis. This mission requires the section to establish criteria concerning the facilities it utilizes. The design and construction of the facilities call for standards beyond those of the general laboratory.

The security requirements of the sample control section also require enhancement beyond those implemented by the laboratory in general. The volume of samples stored within the sample control section increases potential for sample tampering. Augmenting the security systems of the sample control section reduces the potential of sample tampering. The security component of the facilities section defines the enhanced security requirements of the sample control section.

Topics addressed in the sample control manual's facilities section should include the following:

- Construction
- Layout
- Security
  - General
  - Access
    - Entry log
  - Key control
  - Intrusion security
  - Security breaches

Staffing Scheduling and Responsibilities

As a semiautonomous division of the laboratory, the sample control section has different personnel requirements. The personnel in this section do not have examination responsibilities and should not be required to have a technical background required by the analytical sections. If the sample control section is under a different administrative section of the parent organization, the different personnel policies and procedures for this component must be addressed in a documented format and incorporated into policies and procedures of the laboratory.

Topics addressed in the staffing section should include the following:

- Staffing
  - Staffing levels
  - Minimum qualifications and selection
- Scheduling
- Responsibilities

Packaging and Labeling

The sample control section is a weigh station for a sample on its journey from client to laboratory and back. Establishing a safe haven for samples that maintain their integrity is a primary function of the sample control section. Regulating how samples are packaged and labeled plays a significant roll in preserving sample integrity. Instituting policies and procedures concerning the packaging and labeling of samples submitted to property and evidence section provides a system of regulation that will augment other security measures implemented to promote sample integrity.

The sample control section is the link between the customer or recipient of laboratory services and the examination process. The sample control section must ensure the samples received by the examiners are in the same condition that the customer submitted them.

This is accomplished through instituting packaging requirements for samples submitted to the sample control section for examination by the laboratory.

Packaging and labeling requirements apply equally to samples that are returned from the laboratory after the analysis has been completed. The client should receive the samples from the sample control section in substantially the same condition that it was submitted. The laboratory examiners are held to the same packaging and labeling standards upon returning the samples after examination, that the client is upon submittal.

Packaging and labeling guidelines can be established that generically apply to most samples that are submitted for examination. Each laboratory establishes its own variations of industry specific guidelines for sample packaging and labeling. The complete guide covers from the packaging and labeling requirements of individual samples through the requirements of sample containers that are submitted to the sample control room.

There are a number of different types of forensic evidence samples. As a group, they have the same packaging requirement. However, each has subtle nuances that must be addressed to ensure the integrity of the sample, preserve the physical characteristics that require examination, or prevent theft. These special circumstances should be addressed to ensure the information is codified and disseminated.

Topics addressed in the packaging and labeling section should include the following:

- General circumstances
  - Individual items
  - Case submissions
  - Package labeling
  - Package seals
  - Package documentation
- Special circumstances
  - Currency
  - Firearms
  - Contraband drugs
  - Biological evidence
  - Hazardous materials
  - Nonevidentiary items
    - Found property
    - Safe keeping

Storage

Warehousing samples submitted to the laboratory for analysis is the primary function of the sample control section. As such it must provide a safe and secure storage environment. This must be done in a fashion that is conducive to knowing where a sample or group of samples is at any giving time during its tenure with the laboratory.

The ability to account for a sample's whereabouts is essential when in the area of forensic examinations. Any break in the chain of custody will preclude the use of any subsequent analytical results produced by the laboratory. Therefore, establishing a storage system that will provide accountability is vital.

The length of time a sample resides with the sample control section will depend upon the section's function in within the laboratory's parent organization. In some instances,

the sample control section only provides short-term storage. It acts as a weigh station for samples waiting for analysis or return to the client.

In some instances the laboratory's parent organization is the end user. The property and evidence section is the final destination for samples. The sample control section is required to maintain their possession until disposal is required.

Temporary storage is a storage scenario that is commonly over looked. Temporary storage is the situation in which samples are briefly left unattended. This usually occurs in a situation in which the samples are brought to the sample control section outside the normal hours of operation. In this situation, the laboratory must establish policies and procedures to ensure the integrity of the samples during the time it is unattended.

General sample storage is a simple warehousing function. The sample control section establishes systems that allow its personnel to know where any sample is at any time during its term in the storage facility. The system is irrelevant for purposes of this discussion. The relevant points are that the system exists and it is documented.

Some samples have storage requirements. This is true with forensic evidence. Biological samples have storage requirements that will protect the physical properties of the biological fluids that are submitted for analysis. Forearms, contraband drugs, and currency and other valuables require additional security measures that will prevent theft. Samples that contain hazardous materials must be stored in a manner that will minimize the hazardous and protect the health and welfare of the property and evidence personnel.

Topics addressed in the storage section should include the following:

- Temporary
- Short-term
- Long-term
- Storage areas
  - Currency
  - Firearms
  - Contraband drugs
  - Biological evidence
  - Hazardous materials
- Storage system

Sample Control

Sample integrity is a cradle-to-grave proposition. It begins from the moment the property and evidence section takes possession of the samples from the client. It does not end until the samples are returned to the client or are disposed if in an authorized manner. Transfers to and from the laboratory must be controlled in the same strict manner. Therefore, the sample control section must establish policies and procedures that will control the intake, return, and internal distribution of samples placed in their charge.

What happens to a sample once it leaves the control of the sample control section and is given to laboratory personnel for examination is outside the control of the sample control section. However, the intralaboratory exchanges that happen during the examination process have the same impact on the sample's chain of custody as the sample's intake and return to storage. Therefore, policies and procedures must be put into place to address these exchanges.

Larger organizations have satellite facilities that serve as a sample collection points for clients geographically removed from the laboratory facility. The transfer of the samples from the satellite facility to the main storage facility is an important link in the chain of custody. In some instances, it may be the weakest link in that it deals with temporary storage as well as transportation over a distance. Therefore, it is critical that these transfers have documented policies and procedures.

Topics addressed in the storage section should include the following:

- Submission procedures
  - Intake
  - Return
- Laboratory distribution procedures
  - Distribution
  - Return
- Intralaboratory exchange procedures
- Database information
- Sample collection facility transfer

Disposition and Purging

The sample control section must have a mechanism to remove samples from their custody once the laboratory examination has been completed. This process is accomplished through a variety of methods, which include purging, destruction, or diversion.

Purging is the process that is used for samples involved in situations in which the property and evidence section is not responsible for sample long-term storage. The client is notified at the conclusion of the examination process and requested to retrieve their samples. If the samples have not been retrieved in a specified amount of time, an alternative method of removing the samples from the sample control system is employed.

Destruction is a process that is used in situations in which the property and evidence section is responsible for the long-term storage of the samples. At some point in time, the retention of the samples is unnecessary and they can be removed from the storage area and destroyed in a prescribed fashion.

The uniqueness of some samples provides them a potential for use as laboratory exemplars. These samples can be diverted to the laboratory for use as reference material once the examination has been completed and the need to retain samples in storage has expired. The policies and procedures for this mechanism must be documented in the same manner as those used to purge or destroy samples whose storage is no longer required.

Topics addressed in the disposition and purging section should include the following:

- Purging
  - Purging procedure
- Destruction
  - Destruction criteria
  - Destruction procedure
- Diversion
  - Diversion procedure

Sample Control Templates

The following is a list of templates that can be utilized as a guide to develop the policies, procedures, and supporting documents terms that appear in property and evidence manuals. The text of these documents can be located in Appendix E. These documents should be modified as required to meet the organization's specific needs. This is not an all-inclusive list, and some documents may not be appropriate for some organizations. However, in total they represent the basic topic area that should be incorporated into an organization's property and evidence manual.

Administrative Issues

Template #	Description
SCM-P101	Organizational Placement
SCM-P102	Sample Control Manual
SCM-P103	Transaction Documentation
SCM-P104	Forms
SCM-P105	Inventories
SCM-P106	Audits

Facilities

Template #	Description
SCM-P201	Storage Facility Requirements
SCM-P202	Regional Collection Centers
SCM-P203	Facility Construction
SCM-P204	Facility Design
SCM-P205	Security—Access
SCM-P206	Key Control
SCM-P207	Intrusion Security

Staffing Scheduling and Responsibilities

Template #	Description
SCM-P301	Staffing
SCM-P302	Training
SCM-P303	Scheduling
SCM-P304	Responsibilities

Packaging and Labeling

Template #	Description
SCM-P401	General Packaging
SCM-P402	Individual Item Packaging
SCM-P403	Case Packaging
SCM-P404	Package Labeling
SCM-P405	Package Sealing
SCM-P406	Currency
SCM-P407	Firearms

SCM-P408	Contraband Drugs
SCM-P409	Biological Materials
SCM-P410	Hazardous Materials
SCM-P411	Nonevidence Items
SCM-P412	Found Property
SCM-P413	Safe Keeping

Storage

Template #	Description
SCM-P501	Temporary Storage
SCM-P502	Short-Term Storage
SCM-P503	Long-Term Storage
SCM-P504	General Storage Areas
SCM-P505	Currency Storage
SCM-P506	Biological Evidence Storage
SCM-P507	Hazardous Materials Storage
SCM-P508	Storage System

Sample Control

Template #	Description
SCM-P601	Database Information
SCM-P602	Submission Procedure
SCM-P603	Return Procedure
SCM-P604	Laboratory Distribution
SCM-P605	Intralaboratory Exchange
SCM-P606	Regional Facility Transfer

Disposition and Purging

Template #	Description
SCM-P701	Purging
SCM-P702	Destruction
SCM-P703	Diversion

Forms

Template #	Description
SCM-F001	Sample Control Orientation
SCM-F002	Examination Submission Form
SCM-F003	Examination Submission Form (Continuation)
SCM-F004	Nonexamination Inventory Form
SCM-F005	Nonexamination Inventory Form (Continuation)
SCM-F006	Chain of Custody Continuation
SCM-F007	Currency Inventory
SCM-F008	Firearms Inventory
SCM-F009	Sample Control Database

SCM-F010	Sample Destruction
SCM-F011	Examination Completion Notification
SCM-F012	Storage Area Entry Log
SCM-F013	Temperature Record Log
SCM-F014	Sample Control Section Audit Packet
SCM-F015	Security Breach Form
SCM-F016	Sample Control Manual Inventory

Technical Methods Manuals

8

The technical methods manual is a group of manuals used by an analytical section. The operational manuals provide the laboratory's generic operational. The analytical section's technical methods manuals define the specific requirements of individual examination areas. Too many times, a laboratory will discount the need for each analytical section to have a comprehensive set of technical methods because of the misguided belief that many of the issues are covered in the laboratory's general polices and procedures manuals.

Each analytical section has a separate and distinct function that aids the laboratory in its quest to fulfill its mission and the goals and objectives of the laboratory as a whole. These duties vary from section to section. Some analytical sections have nothing in common from an analytical standpoint. (Questioned document examination and DNA analysis is an example.) It is obvious that due to the differences in sample substrates, instrumentation, and analytical methods each section should have its own technical methods manual.

Some sections, however, share examination techniques but differ in their detection limits and sample substrates. (Contraband drugs and toxicology is an example.) Their generic methodology is similar. In this instance, each section still requires a separate technical methods manual to address the subtle differences and situations that are unique to the examination section.

The need for technical methods manuals extends beyond the analytical sections of the laboratory. Administrative and technical support sections within the laboratory have their own function, whose tasks need to be defined and documented. The continuity of the operation of these sections is just as important to the quality of the laboratory's work product as any of the analytical sections. Therefore, a technical methods manual documenting how the administrative and technical support operations are conducted is equally important to the successful operation of a laboratory.

The quality of the laboratory's technical methods manuals is just as important as the quality of the laboratory's operational manuals. If one had to choose, one could logically deduce that the technical methods manuals should be given the time and attention in an effort to be the more comprehensive set of documents, for the technical methods manuals drive the laboratory's operational machine. Unfortunately, this is not that case in many situations. The need for a quality set of operational and technical manuals is equally important.

Many times, there is a disconnect between the senior management's understanding for the need of technical methods manuals. This commonly occurs when the senior management places the quest for accreditation before the need for quality. They do not understand that accreditation is a result of a quality operation and, conversely, that a quality operation is does not result from accreditation. This philosophy leads to the development of a pretty operational manual that looks good and meets the accreditation criteria. The technical manuals are thrown together in an effort to check off a line on the accreditation inspection as opposed to developing a manual that can be used as the analytical section's technical bible.

The technical methods manuals of laboratories that have multiple analytical sections should have the same format. This continuity in format eases simplifies the preparation of technical methods manuals by establishing an approved format. The content of the manual

is just as important as its format continuity. This format continuity allows the quality assurance manager to easily audit the variety of technical methods manuals. This ease of review can be extended to the accreditation auditors. (Again, develop for quality purposes, effect on accreditation compliance naturally follows.)

It is not uncommon for laboratories without a dedicated quality assurance staff to have each analytical section prepare their own technical methods manuals. This is usually done because the quality assurance staff generally does not have the knowledge to adequately address all of the issues involved in drafting a technical methods manual, or does not have the time, or both. Therefore, the preparation of these documents is delegated to one of more individuals within the section.

Each person has different approach to writing. This results in an eclectic collection of writing styles that meet the laboratory's need for a technical methods manual, but is not easy to audit nor as user-friendly as it could be. Differences in writing styles can easily be accounted for by implementing a standardized format.

A technical methods manual should contain all of the information relevant to the operation of the analytical or support section it supports. It should define all of the routine tasks specifically relegated the section's personnel. The technical methods manual should define the educational and training requirements of the section's personnel, the methods used by the personnel to perform the tasks they are assigned, the quality assurance methods specific to their section, and an inventory of the tools used to perform their assigned tasks.

Each laboratory has its own unique technical requirements. This is opposed to operational manuals that have generic application relevant to any type of laboratory. The format and content of technical methods manuals is subject to more customization than operational manuals. Therefore, this book does not provide suggested policy and procedure wording.

Technical methods manuals do contain certain similar components. These similarities exist regardless of the format, style, or the detail of the content. The topics each technical methods manual should include but not be limited to the following:

- Training manual (TM)
- Analytical procedures manual
- Quality assurance manual
- Documentation requirements
- Inventories

Training Manuals (TMs)

The common theme of all quality assurance programs is continuity. Continuity provides an element of consistency that is needed to effectively ensure the reliability of the laboratory's results. Program continuity should be initiated from the beginning. Therefore, continuity in the selection and training of personnel is the foundation of every section of the laboratory.

The examiner's education and training serve as the foundation of each analytical section. The selection and training of the analytical section's examiners is the cornerstone the quality programs that ensure the accuracy and precision of the laboratory's examination results. Therefore, the continuity of these programs is essential.

Minimum Qualifications (MQs)

Establishing a common thread of education and professional experience in the selection process provides the basis of a successful training program. Trainees who possess the basic knowledge, skills and abilities required to master the analytical section's examination skills are far more likely produce accomplished examiners than trainees who do not possess this basic knowledge.

The operational methods manual establish the generic minimum requirements for examiners employed by the laboratory. Each analytical section can place additional educational or professional experience requirements on prospective examiners in an effort to enhance the continuity effect of examiner screening process. However, the section must document the additional minimum requirements if the section institutes selection criteria beyond those outlined in the operational methods manual. This documentation is used to ensure the continuity of the personnel selected as trainees who eventually become the section's examiners.

The training manual's minimum requirements section has no established format. The section can be a simple statement referring to the laboratory's basic minimum qualification (MQ) policy if there are no requirements beyond those defined in the operational manual. It can be as simple as a few bullet points in a brief narrative outlining the requirements beyond those defined in the operational manual. The section can be a comprehensive position description reiterating the minimum requirements from the operational manual with the addition of the section specific requirements. Or the section can be something in between. The only specific requirement is that the additional minimum requirements are documented.

Training Program

The training program is another instance that is not adequately covered in the laboratory's general policies and procedures. At best, the general policy will read something to the effect, "Each analytical section will establish a comprehensive training program, to include competency testing, to ensure the quality and reliability of the examination results issued by the laboratory," or "Each examiner will be provided comprehensive training and successfully complete a competency examination prior to performing unsupervised examinations." These statements may address the accreditation requirement for having a training policy. However, they fall short on the detail of how these functions should be performed.

The purpose of the laboratory's training program is to teach the trainee the examination techniques that are outlined in the technical methods manual. Laboratory training programs should not be used to teach trainees the basic skills trainees should have acquired through a university education. Training programs should be designed teach the trainee how to apply that knowledge to the examinations that the analytical section is responsible for. The continuity in MQs is used to ensure the trainees or prospective trainees have the basic knowledge required understand and apply the analytical techniques employed by the section.

Continuity in training is an essential element in establishing precision in the analytical process. Trainees should all be provided the same foundational reading material. They should all be presented with the same lecture material and practical exercises. They should all be subjected to the same rigorous oral and written examination process to ensure the

lessons have been learned. This continuity in training is done ensure the information is uniformly distributed and properly applied.

Documentation is used to ensure the continuity of the examination section's training program. It is used to ensure that the trainees who were trained last year receive the same information (with allowances for updates and modifications in analytical methods) as the trainees who will be trained next year or in five years. The trainees assigned to the central laboratory should receive the same basic training as the trainees assigned to a regional facility. There should be certain allowances for regional differences. However, the basic skeleton of the training should be consistent through out the system.

Documenting the analytical section's training program is also a component of the laboratory's quality program. It is a method to demonstrate the information that all trainees are provided and the practical experience that the trainee receives prior to being allowed to perform unassisted examinations. Additionally, documented testing protocols provide tangible proof that the trainee has absorbed the information and mastered the examination techniques employed by the analytical section.

TM topics should include, but not be limited to, the following:

- Background
- Training program mechanics
- Individual training modules
- Written quiz
- Written final exam
- Practical final
- Moot court
- Supervised casework
- Unsupervised casework

Background

The background module of the TM should be a brief summary of the history surrounding the analytical section, its prominence within the laboratory, and the section's role in assisting the laboratory to meet its mission responsibilities. This module does not have to be a detailed narrative but should provide enough information to familiarize the reader about the analytical section's capabilities.

Training Program Mechanics

The training program mechanics section provides a summary of methods used to prepare an examiner to play an effective role in the analytical sections activities. This section gives a synopsis of the different types of training and educational exercises that new examiners participate in. Different types of examiners require different level of training.

The term *new examiners* has a broad meaning in this context. New examiner means new to the laboratory, not just new to the profession. Examiners new to the profession must be trained to use the knowledge, skills and abilities they acquired through education and training to perform the examinations the analytical section is responsible for. This is done to ensure the new examiners understand the theory and practical applications of the analytical techniques that are analytical section employs.

Experienced examiners who are new to the laboratory must be trained to use the knowledge, skills and abilities they have acquired at another laboratory to perform the

examinations according to the methodology used by the laboratory. This is done to ensure the new examiners understand the theory and practical applications of the specific analytical techniques that are analytical section employs. There may be subtle differences in the analytical techniques that experienced examiners used in their previous laboratory and the techniques employed by this analytical section.

Training Modules

The bulk of the TM content is comprised of the training modules that define the activities used to transfer the information to the new examiner. These documented modules have two general purposes. The first is to ensure the "all" of the information is provided to new examiners in a "consistent" fashion.

As previously stated, continuity is the key to a successful training program. All examiners should be given the same information. All examiners should be provided the same training. This continuity enables both management and examiners to manage the expectations of the other. Continuity in training provides examiners the knowledge of what is expected in a complete examination. Management's expectations of the examiner's work product make technical and administrative reviews more effective.

The training needs of examiners new to the profession and experienced examiners new to the laboratory are different. However, the continuity principle should remain in effect. It is perfectly acceptable to have two training tracks: one for new examiners and one for experienced examiners. If there was no allowance for experience, there would be no savings in time and effort by hiring an experienced examiner, and thus, no advantage to hiring an experienced examiner. Therefore, a defined group of training modules to meet the transitional needs of the experienced examiner should be incorporated into the analytical sections TM.

The second purpose of documenting an analytical section's TMs surrounds litigation. At some point in time, a laboratory will find itself in court defending the examinations that it performed. The examiner's training, and by extension the TMs, is often part of the discovery process. The laboratory must defend the training that they provided and demonstrate that it contained adequate information for the examiner to successfully perform the examination(s) involved in the litigation. By the same token, the examiner must be able to demonstrate that he was (or was not) provided adequate training to perform the examination under discussion.

In either case, documentation is the key. The old legal adage that "if it is not written down, it does not exist" is very much in play. Without supporting documentation, litigation quickly becomes a game of he said/she said in which no one wins. A documented training program that is administered in a consistent manner will minimize the issues surrounding litigation involving the training of laboratory personnel.

All training programs contain the same modules. How they are grouped will depend upon the laboratory policy and the specifics of the training program. The general modules in all training programs include the following:

- Objectives
- Required reading
- Suggested reading
- Study and discussion exercises
- Practical exercises

Objectives Each training module should list the module's learning objectives. This defines the purpose of the training module and lays the foundation and expectations of what the module will accomplish.

Learning objectives detail the issues that the training module will address. They can be one of more simple statements defining the general information the trainee will be provided. Statements such as "At the completion of this training module, the trainee will be able to …" are common.

There are some schools of thought that require a performance measure should be incorporated into the learning objective. Statements such as "At the completion of this training module, the trainee will be able to correctly identify nine of ten …" are common. This establishes a competency expectation within the learning object and is used as part of the evaluation process.

Testing of some type is required to establish competency. However, where the competency level should be defined and how it should be established is subject to debate. Ultimately, this decision is made by the individual laboratory and should be documented in the analytical section's training and quality assurance manuals as well as the laboratory's general quality assurance manual.

Required Reading A standard baseline of knowledge must be established. This baseline is the foundation of all subsequent training exercises. As such a standard set of reading material should be required to ensure that all examiners have the same informational foundation.

The required reading list should include a broad spectrum on information concerning the analysis. Topics should include, but not be limited to, the following:

- The historical origins of the examination technique to enable the new examiner to understand the evolution of the techniques.
- Theoretical and practical application of the general examination technique.
- Theoretical and practical application of the specific instrumentation and equipment used in the examination technique.
- Information concerning the reliability of the examination techniques employed by the analytical section.
  - These reading should include information concerning error rates and uncertainty limits.
  - Readings that discuss the unreliability of an examination technique are just as, or more, important as readings that discuss the reliability of the examination technique.
- Information concerning sampling and statistical probability of results, when relevant.

This list of required reading documents should be a dynamic document. As such, it should be reviewed and updated on a regular basis. Relevant articles should be added. Outdated articles should be removed. However, the composition of topics covered should remain the same.

Suggested Reading Every examination technique has volumes of treaties written concerning some aspect of the examination. With the advent of computers, word processing programs, and the electronic age of the Internet, the volume of information has increased

exponentially. It is unrealistic to incorporate all of these writings into the required reading list of a training program. Thus, the foundational required reading list was established and modified as required.

The fact that an article is not on the required reading list does not negate or diminish its informational value. These articles serve as supplemental and supporting documents provide corroboration to the information provided in the required reading. Additionally, they may provide information concerning alternative techniques that are used by other laboratories but not part of the analytical sections approved methods.

Study and Discussion Exercises Reading articles only provides a single dimensional approach to training. It does not allow for the explanation or the interpretation of the documents or how they relate to the methodology employed by the analytical section. Therefore, study and discussion exercises should be incorporated into the training. As with other components of the TM, how these activities are implemented is not as important as that they are put into practice.

Study and discussion exercises are used to reinforce the information presented in the reading. Discussions and lectures provide the trainee's mentor the opportunity explain how the analytical section incorporates the information in the required and suggested reading material into the approved methodology. They also allow the trainee the ability to demonstrate understanding of concepts through the participating in practical exercises.

The study and discussion section of the technical methods manual would contain an outline of the topics covered in the lecture material. A separate instructor's guide that supplements the study and discussion section would be beneficial. This document would contain the outlines trainee mentors use for lectures and practical exercises.

Practical Exercises Effective training has a mantra used to describe its principles. The chant "see it, hear it, say it, do it" resonates in the minds of training course developers as they design training programs that not only transfer information from instructor to student but enable the students to apply the knowledge.

"See it." People retain approximately 55% of the things they see. "Hear it" adds another 10% of the information provided in an instructional setting. "Say it" provides repetition to reinforce the principles learned through the instructor's presentation, at the same time allowing the trainee to take possession of the concept by repeating the information himself.

"Do it" is probably the most effective part of the instructional process. Incorporating practical exercises into instructional models has proven to increase the understanding and retention of information by orders of magnitude in some cases. Placing abstract concepts into tangible scenarios allows the trainee to see that the lecture has some basis in reality. Practical exercises also provide the trainee the opportunity to apply the concepts in a situation that he would encounter. Therefore, practical exercises are an essential part of a successful training program.

The continuity of the practical exercises trainees perform is as important as the reading material and lectures they are exposed to. Each trainee should perform the same practical exercises at the completion of an instructional module. This allows the trainee to visually reinforce, in a tangible way, the abstract concepts he heard in lectures or reading. Additionally, the instructor has the opportunity to observe the trainee applying the techniques and correct any deficiencies he may observe.

As with many manual components, the format is not as important as the content, and the content is not as important as the fact that the information is documented. Documenting

that the trainee will participate in a defined set of activities at the end of an instructional period will provide continuity in the training process. Incorporating whether or not the details of how the practical exercise should be conducted is left to the discretion of the manuals approving authority.

Testing

Having a training program is a desirable thing. Having a documented training program that all examiners must participate in prior to performing unsupervised examinations is better. Having a mandatory documented training program with a documented testing component is the ultimate goal.

Testing is an essential component of an effective training program. Testing ensures the information that has been disseminated has been absorbed by the trainee. A documented testing program stands as proof that the trainee has retained the theoretical information he has been provided and can apply it in a practical situation. This proof may be required at some point in the future if the credibility of the examiner is brought into question as part of litigation.

Program evaluation is a reason for testing that is often overlooked. Too often, the trainee performance is the focus of the test results. The competence of the instructor or the quality of the training material is usually never brought into question. Unfortunately, bad instructors and poor training materials or programs as a whole are to blame for poor trainee performance.

Just as with any corrective action, a root cause determination must be made before effective corrective action can be taken. Therefore, the section chief, technical leader and quality assurance manager must work together to evaluate the root cause of poor training program test performance before taking corrective action.

The training testing process consists of the following:

- Written quizzes
- Final examination
- Practical exercises
- Competency testing
- Moot court

Written Quiz Periodic written quizzes are used to gauge how much of the information from the recent training module the trainee has retained. The results from these quizzes are used to identify areas in which remedial training is required to ensure that the trainee has mastered the module prior to moving to the next module.

The content of these quizzes should not be part of the TM that is disseminated as part of the technical methods manual. These quizzes should be maintained as part of the instructor's guide. This restriction on the dissemination of the quizzes is done to ensure the integrity of the quiz and its usefulness are an instructional tool.

Written Final Exam A comprehensive final written examination is a mean of documenting the level of understanding of the theoretical aspects of the training the trainee has achieved. The results of this examination should be maintained as an objective method of documenting the trainee's comprehension of topics covered during the training process. How the results are recorded is left to the discretion of the approving authority. The important issue is that they are documented.

As with the quizzes, the final examination document should be a part of the instructor's guide and should not be incorporated into the TM that is generally disseminated.

Practical Exercises Practical exercises should have an evaluation component so the instructor can appraise how well the trainee has grasped the practical application component of the training. As with quizzes, these tests are performed for informational purposes to identify weaknesses in the trainee's knowledge base so remedial action can be taken if required. The retention of the results of these trials may or may not be placed into the trainee's training file follows the same logical path as the retention of quiz results.

Competency Testing The successful completion of a competency test is the only test that is required by many laboratory accrediting bodies. However, that should be the guiding reason for their use. The accuracy and quality of the laboratory's examination results should be the motivating factor. Once this is obtained, accreditation will naturally follow.

It is one thing to know the theory of an examination technique and be able to recite it chapter and verse in a written or oral examination. It is a completely different skill set to be able to apply that knowledge in a practical situation, properly implement the examination technique, and obtain the correct answer. At the end of the day, the client does not care if the examiner understands the theory of the examination techniques used. All the client cares about is that the results of the examination are accurate. Therefore, competency testing prior to unsupervised casework is essential, if not mandatory.

Moot Court The examiners in certain types of laboratories must present the results of their examinations in court. These laboratories usually incorporate a moot court exercise into the training to prepare the examiner for trials and tribulations of the testimony process. During the moot court, the examiner presents and defends his examination through questioning by individuals acting as a prosecutor and a defense attorney. The exercise is designed to mirror the activities that occur during the examination and cross examination of experts during the litigation process.

All laboratories should consider incorporating a moot court of some type into their training process. Questioning an examiner's analysis through adversarial questioning allows the examiner to build confidence in his abilities. The knowledge that every aspect of his examination will be subject to public peer review will effect the way the examiner approaches his examination.

The moot court section of the TM should outline the moot court process. It should provide the generic type of questions the trainee will be subjected to, but not the questions themselves. Providing the moot court questions allows the trainee to mold his analysis to fit the moot court question, as opposed to molding the analysis to meet the needs of the sample and information requested by the client.

Supervised Casework

Participating in the training program, passing the written exams, successfully completing the competency testing, and enduring the moot court process do not automatically create an expert examiner ready to solo at his laboratory work station. A period of supervised casework is required to ensure the examination principles learned during the training process are deeply engrained into the examiner's work habits.

The supervised casework section of the TM should define the parameters of the examination types the new examiner will be allowed to par take in initially. It should establish a continuum of examination complexity for the new examiner as well as generic time frames for they should spend at each level. Additionally, there should be an evaluation system built into the process to allow the mentoring examiner to critique the progress of his apprentice.

Unsupervised Casework

At some point in time, the new examiner will have demonstrated his ability to satisfactorily perform the gamut of examination types the analytical section performs. The unsupervised casework section defines the criteria used to establish that the new examiner has mastered the examination techniques used by the analytical section. There should also be an evaluation mechanism that can document that the new examiner has achieved a level of understanding of the practical application of the methods that will allow him to perform examinations that do not neatly conform to the sterile situation encountered in training or during his supervised casework.

Analytical Procedures

It is becoming apparent that the technical methods manual encompasses more than a recipe for the examiners in an analytical section to follow when they perform the testing procedures they are responsible for conducting. Ensuring the examiners selected for the positions have a relevant educational foundation is important. Training in the examiners in the methodology that is accepted by the laboratory is essential. These criteria are critical and should be a documented part of the technical methods manual if continuity in an analytical is to be established.

The analytical procedure section is the driving force behind every other section of the technical methods manual. The testing methods described in this section are used to establish the educational requirements for the examiners who will be performing the testing. The training program reflects the examinations that are carried out. The analytical procedures determine what chemicals, equipment, and reference materials are required. The specificity of the tests conducted influences the wording of client reports. Without the analytical procedures the balance of the technical methods manual cannot exist.

The analytical procedures section is the recipe section of the technical methods manual. It provides the directions the examiners use to conduct the examinations the analytical section is responsible for. They should be detailed enough to allow an examiner with a basic understanding of the theory and application of the testing process to correctly perform all of the tasks associated with the examination. In some instances, the procedure does not allow the examiner to deviate from the documented procedure. In other instances, the procedure would provide the examiner acceptable methods to apply at his discretion.

As with other policy and procedure sections, there is no correct or incorrect method of documenting the analytical procedures which are utilized by the analytical section. The only requirement is that they are documented utilizing the laboratory's document

control procedure. However, analytical procedures have common elements that should be addressed. These elements include, but are not limited to, the following:

- Sampling scheme
- Reagent preparation
- Examination protocol

Sampling Scheme

The reliability, accuracy, and precision of analytical results are based upon the following three basic principles: sample preparation, sample preparation, sample preparation. If the wrong sample is selected, the results will be incorrect. If the sampling is not representative of the population, the results will be statistically invalid. If the sample is contaminated, the results will be skewed. The sample preparation technique used in some instances will affect the resulting instrumental data. If the examination result is *x,* then the examiner's next step would be *y,* and so on.

Continuity and consistency of the analytical results produced by an analytical section is the main purpose behind documenting the analytical procedures. Sampling is the most crucial element of the analytical process. Therefore, a documented sampling scheme is an essential component of the analytical procedure.

Every analytical section has different sampling requirements. Some require a single representative sample for a larger bulk submission. Others require a statistically representative number of samples from a submission of multiple individual items. Some laboratories are required to leave sufficient sample for reexamination if necessary. The common thread in the sampling scheme section of every analytical section is that it must be documented, regardless of the sampling scheme incorporated.

Reagent Preparation

Reagents are a combination of chemicals used to perform an analytical procedure. The generic composition of common reagents used by the examiners is part of their basic body of knowledge. However, it would be difficult for most examiners to quickly and accurately establish the exact ratios of chemicals used to prepare a specific reagent.

A generic example would be a one normal solution of sodium hydroxide (1 N NaOH). Conceptually, all chemists know what that is. However, most would be hard pressed to recite the amount of sodium hydride required to produce a one normal solution in 100 milliliters of water without some assistance. Therefore, a documented reagent preparation method provides examiners a reference to use to consistently prepare the testing reagents according to approved chemical ratios.

Establishing a reagent preparation section simplifies reagent preparation focusing all of the reagent recipes in one location. The examiner or technician responsible for preparing a new batch of reagent can simply go the reagent preparation section to find the ratios of chemicals required to prepare the reagent of choice. Some manuals bury this information into the specific analytical procedure, making it difficult to quickly identify the location of the recipe.

Each reagent preparation method should consist of two components: the recipe and a quality control procedure. The recipe is used to ensure every batch of the reagent is prepared using the same ratios. The quality control component is used to ensure the reagent functions as designed before it is distributed for general use.

Examination Protocol

Examination protocol describe the methods used by the examiner during the analytical process. Thee method can be test specific, detailing how a specific test is conducted. The method can be sample specific, detaining all of the sequence of individual tests that a sample would be subjected to. Or the examination method can be a combination of the two.

Test Specific

Test-specific methods details how a particular test is conducted. This information does not need to be included in every instance the test is employed. Many analytical sections apply a specific test to different sample scenarios. A test specific methods section provides a single location for the examiner to locate the protocol for a specific test method.

A test-specific method simplifies the document control process. The documentation concerning the test method must be modified in every instance it occurs. Having a single location that contains the complete procedure will require only a single document or location to be modified if the method is changed. If the test method is detailed in every sample-specific method it is used, a modification every document or occurrence will be required when the method is modified.

Test-specific methods have the option of including a results section. A test method may have different results for different applications. For example, a chemical color test may provide a different color reaction depending upon the class of compounds the reagent chemical reacts with. This information may be included in this section, placed into the sample-specific section or be contained in both sections.

Sample Specific

Many samples require a series of individual tests incorporated into a sample-specific method. A sample-specific method can be simplified by simply referencing specific test methods. This reference may or may not include a suggested or mandatory sequence the testing must be conducted. However, all of the tests required by a specific sample type must be listed.

The detail in which individual tests are addressed in the sample-specific area is left to the discretion of the approving authority. Simply listing the required tests provides a simplified document that requires minimal changes if specific tests are modified in the future. However, an examiner unfamiliar with the protocols of a specific test will have to refer back to a different section of the manual to perform the test.

Test-specific results should be listed in sample-specific format. The examiner should be able to quickly identify a positive or negative result for a specific test.

Format

The format of technical methods should mimic that used by administrative and quality manuals when practical. As discussed in Chapter 6, the format the manual is presented in is not as important as the content. The form is irrelevant, as long as the manual contains all of the pertinent information.

That being said, manual format does play a role in establishing the laboratory's level of professionalism. A laboratory that implements a standardized format for the technical methods manuals for all analytical sections to use gives the perception of a well organized unified institution with attention to detail. A laboratory in which the technical methods manuals

of each analytical section have their own style and format brings into question the unity of the analytical sections and may call in question the senior managements leadership. Both situations adequately address the need to document all of the analytical section's technical information. Both situations can effectively meet the analytical section's needs for an operational manual. However, one scenario gives the perception of unity and cohesiveness among the laboratory's analytical sections. The other scenario provides the perception of multiple analytical sections operating autonomously under the umbrella of the laboratory's name.

Continuity is important. All analytical procedures should contain the same information. Regardless of the format type used to present it, continuity in the information provided is important. All analytical procedures should contain the following information:

- Descriptive information
- Document identification information
- Purpose statement
- Scope statement
- Related procedure list
- Safety considerations
- Instrumentation
- Standards and controls
- Analytical procedure
- Report writing
- References
- Approval

A description of the contents each of these sections should contain can be found in Chapter 6: Content and Format.

Quality Assurance Procedures

Section-Specific QA Program

The documentation of an analytical section's quality assurance procedures is an often forgotten or ignored component of the technical methods manuals. It is not unusual for a laboratory to assume that the documentation of a laboratory wide quality assurance manual will ensure quality. Unfortunately, the generic "Thou shall" statements contained in the laboratory-wide quality assurance manual do not provide the detail required for analytical section personnel to implement the program. Additionally, without the detail, there is no way to perform an independent audit of the program to evaluate if the quality assurance program is functioning as designed.

There are similarities in the quality assurance procedures between analytical sections. However, there are some distinct differences that must be addressed. The quality requirements and procedures in a chemistry lab are different than those in a biology lab. Therefore, the specific quality program needs of each analytical section should be in their own technical methods manual.

Where the analytical section's quality assurance procures are located is another issue that is left to the discretion of the approving authority. Some quality assurance procedures

apply only to a specific examination and may be best documented within the examination procedure. Some quality assurance procedures have a broad application and may more efficiently be located within a separate quality assurance section. The location of the procedure may be optional, but their existence is not.

Error Rates and Confidence Limits

Another component of a quality assurance program is establishing and documenting the error rate and confidence limits of the examinations performed. Section 5.4.6 of ISO/IEC 17025 is the accreditation criterion that addresses the estimation of uncertainty of measurement. The existence of an accreditation criterion that addresses uncertainty should not be the driving force for each analytical section to identify issues that would contribute to the uncertainty of the examination results. Examiners should know the answer to questions concerning the error rates and confidence limits of their examinations when the question is asked by a client in reference to one of his samples or an attorney during a legal preceding that involves an examination that was performed by the laboratory.

Each analytical section must establish its own uncertainly and confidence levels. Every analytical section has different variables that contribute to the error rate. Sample type and matrix differ from section to section. The number of individual pieces within a sample that require examination will vary.

Six Sigma calculations can be used to establish acceptable confidence limits in this section. When placed into perspective, what may on the surface be an acceptable confidence limit in one context takes on a different meaning when looked at in another situation. The examples in Chapter 4 will help put how confidence limits can put things in perspective.

Documentation Requirements

Just as the testing procedures and instrumentation used differ from analytical section to analytical section, so does the documentation necessary to demonstrate the examination was conducted. Therefore, the technical methods manual of each analytical section should contain a section that outlines the documentation requirements.

Documentation is the key component of any analytical procedure. The guiding principle of manual policy and procedure preparation, "if it is not written down, it does not exist," can be extended to the examinations conducted by an analytical section. The examiner must be able to prove beyond a reasonable doubt what test was done, when the test was conducted, where the tests were performed, why certain methods were used, and how the tests were actually carried out. Once the answers to these questions have been addressed, the examiner can consider how they will document the results.

A documentation policy also assists in streamlining the technical review process. The technical review process is simplified if every examiner within an analytical section utilizes the same format for taking examination note, documenting instrumental results, and utilizes approved wording for reporting results. The technical reviewer instinctively knows where to look for the information that is required to form a conclusion and what wording that is acceptable in reports that are disseminated to the client. Additionally, a standardized format allows the administrative reviewer to quickly identify whether or not all of the administrative information has been included and tasks have been completed.

Forms and Worksheets

Forms and worksheet are the ultimate in standardizations. The continuity in form and content in documenting the examination process is extremely useful as a quality assurance tool as well as an aid in the examination process. They provide the examiner an outline of the examination that is to be conducted as well as a place to document analytical results or observations.

Forms and worksheets are equally as useful for the technical and administrative reviewer. The technical reviewer knows where to look for the technical information used to form the examiners conclusion and compare it to the results presented on the laboratory report. The administrative reviewer has their own sections to review to ensure the administrative tasks have been completed and information documented.

Forms and worksheets have a unique distinction in the controlled document community. Personal forms and worksheets that are created by individual examiners to simplify their examination documentation process are not subject to the laboratory's document control requirements. Forms and worksheets that the analytical section requires to be used to document the examination process are generally considered official laboratory documents and subject to the document control requirements established in the relevant operational or quality policy and procedure.

The status of the document may change when an examiner places his personal forms or worksheets on laboratory letterhead. Placing personal forms and worksheets on laboratory letterhead or affixing the laboratory's seal or logo to these documents gives the perception that they are official documents whose use is sanctioned by the laboratory. The use of laboratory letterhead, seals, or logos on personal forms and worksheets should be addressed in an operational or quality policy to eliminate any issues that may arise from such use.

Examination Notes

The laboratory's quality manual should have one or more policies concerning examination notes. The policy states "Thou shall" maintain examination notes to document the analytical process with some basic guidelines concerning what the examination notes should contain. This broad statement can be used as part of any technical methods manual without modification but has minimal effect on the actual quality control process.

Each examination section has distinct analytical requirements used as a foundation for the reports that are provided to the client. Each analytical step must be documented in such a manner as to allow the technical reviewer to understand the thought process the examiner used to derive his conclusion. Having analytical section specific criteria and formats for examination notes provides the continuity in the examination process.

Establishing section specific examination notes criteria simplifies the analytical process. It provides the examiner a road map to the examination process and defines what analytical steps are required to complete the examination as well as the documentation required to justify his conclusion.

Implementing section specific examination notes standards streamlines the technical review process. The technical reviewer knows what information is required and the format presentation. The review can quickly identify if the required examinations were performed, if the analytical information is present and determine if the data justifies the conclusion articulated in the report.

Examination Reports

Each analytical section reports the results of a specific set of examinations. As such each analytical section has specific information that will be disseminated in their laboratory reports. The information disseminated in these reports should be standardized for the same reasons the examination notes should be documented.

The reporting of the results of some examinations is simple. "The sample contained 253 grams of 'stuff.'" This objective reporting of analytical data leave little for the reader to interpret or misconstrue. Therefore, the reporting criterion of this type of information in the technical methods manual is relatively straightforward.

However, the requirements changed when the reports contain opinions that are subject to interpretation. In these instances, the criteria for each for reporting each opinion type should be established as well as acceptable verbiage. This helps ensure the consistency of the reports in areas which the results may be subject to interpretation.

Establishing acceptable language for reporting analytical results has the same rational as implementing examination note requirements. Implementing reporting criteria: established continuity in the reporting of results, provides the examiners guidelines for reporting analytical results and simplifies the technical review process.

Establishing reporting criteria and continuity in important in the reporting of subjective examinations in which "expert opinions" are involved. Establishing acceptable wording for reports that involve an expert opinion there can be a battle between the expert's ego and the laboratory's reputation. Experts come and go, and their reporting can be adapted to meet the laboratory's accepted reporting criteria. The laboratory is an institution whose examination results should have consistency in verbiage and meaning, even in examination areas whose results are subject to interpretation. The laboratory's name and reputation are on the letterhead, and should take precedence to the examiner's ego.

Establishing section-specific examination report criteria simplifies the reporting process. It provides the examiner a road map to the examination process and defines what analytical criteria are required to justify an analytical result or examiner's conclusion. Additionally, establishing acceptable verbiage eliminated personal interpretation within the laboratory.

Implementing section-specific examination report standards streamlines the technical review process. The technical reviewer knows what information is required and the verbiage that is acceptable. The reviewer can quickly identify if the required examinations were performed and determine if the data justifies the conclusion and if the wording is consistent with the accepted reporting policy.

Inventories

Each analytical section has "stuff" that is specific to the types of examination they perform. The technical methods manual should identify what this stuff is and where it can be found. Therefore, the technical methods manual should have a "stuff" section so people will know where to find the stuff when they need to.

The previous paragraph is a parody of a classic comedy routine, but it does have relevance in the world of technical methods manuals. All analytical sections have chemicals, equipment, and reference material used to perform the examinations the section is

responsible for. The examiners and auditors need to know where to find these items when the need arises. The examiners need to know where they are so they can utilize them to perform their analytical activities. The auditors need to know where they are to verify they exist and are in proper working order.

Inventories of the following groups of items should be documented in the inventory section of the technical method manual:

- Chemical inventories
  - Bulk chemicals
  - Bulk prepared reagent solutions
- Equipment inventories
  - Analytical instruments
  - Spare parts
  - Maintenance and calibration logs
- Reference inventories
  - Reference standards
  - Reference material
  - Reference literature, to include books and technical journals
  - Calibration standards

Criteria Files

9

Every accrediting body has a list of requirements used to establish compliance with their standards of accreditation. This list of *criteria* is the road map down the accreditation path.

The American Society of Crime Laboratory Directors Laboratory Accreditation Board (ASCLD/LAB) in their 2005 Legacy Program accreditation criteria categories include: essential, important, and desirable. Simply put, essential elements are "must have" criteria that require 100% compliance. Important criteria are "should have" elements that require 75% compliance. Finally, desirable criteria are "nice to have" factors that require only 50% compliance.

By contrast, other accrediting bodies require total compliance with every criterion. The International Standards Organization (ISO) is such a body. ISO Standard 17025 for Testing and Calibration Laboratories requires 100% compliance with all applicable criteria.

A criteria file is a document that is used to associate accreditation criterion to the policies, procedures, or other documents that address it. It is a document management tool. Just as important, it is an instrument used during the accreditation inspection process.

The existence of a criteria file is not in itself listed on the criteria for laboratory accreditation. It is one of those "nice to have" items listed in the documents that come with the accreditation packet. Even though it is in the 50% category, it is better to have a criteria file than not to.

The criteria file is a policy management tool. It provides the quality assurance manager insight as to which criteria require a policy, procedure, or associated document to be drafted to address the issues covered by the specific criterion. Additionally, a criteria file provides a method to index and cross-reference all the policies, procedures, and associated documents related to a specific topic.

As previously stated, obtaining accreditation should not be the reason for creating policy and procedure manuals but the end result of having them. That does not mean that accreditation criteria should not be used in developing the laboratory's manuals. Accreditation criteria are based on sound principles of quality assurance that should be part of the laboratory's standard operating procedures. Incorporating criteria files into the manual preparation process provides insight into what policies and procedures should be established to improve the quality of the laboratory's analytical results.

The road to accreditation ultimately must be traveled by the inspection team. Anything that will ease their journey through the quagmire of your documents will simplify the process. The more an inspection resembles a guided tour through a laboratory's policies, procedures, and associated documents, and less like a scavenger hunt, the happier the inspectors will be.

As politically incorrect as this may sound, happy inspectors write happy reports. Anything a laboratory can do to make a happy inspector will increase the likelihood of achieving accreditation. There is nothing that makes an inspector happier than to see a criteria file.

ISO 17025 has approximately 200 individual criteria that need to be addressed. All need 100% compliance. ASCLD/LAB (2005) Legacy Program has up to 150 individual criteria that need to be address. Each criterion may have one or more policies, procedures, and associated documents to address it. It is not unreasonable for a laboratory to have in excess of 300 policies and procedures. If the inspectors are not provided a map to guide them through the document maze, they will not be happy. The criteria file provides the map needed to make the inspector's job easier, thus happier.

The laboratory's operational and quality manual format will drive the format used to create the criteria file format. If the laboratory chooses to have its quality manual format mimic that of the accreditation criteria, ISO 17025 for example, a criteria file may not be required. However, if the laboratory requires accreditation under multiple disciplines, one or more criteria files will be required.

A criteria file is nothing more than a cross-reference index that links a specific accreditation criterion to one or more of the laboratory's official policies or procedures. Appendix K and Appendix L are examples of criteria files for ISO 17025 and ASCLD/LAB Legacy as they relate to the policy and procedure templates presented in this book. Forms APP-F011 and APP-F012 are templates that can be used to build your own criteria files for the ASCLD/LAB Legacy and ISO 17025 programs, respectively.

Two other forms that help manage a laboratory's policies and procedures are the document inventory template (APP-F001) and the policy and procedure association form (APP-F025). The document inventory provides the reader information on the status of each controlled document. The policy and procedure association form provide the reader a quick reference to the identity of documents that have some relationship to the document under investigation. Both of the forms are helpful in managing the laboratory's controlled documents as well as providing auditors information concerning how those documents fit into the laboratory's quality program and accreditation criteria.

Appendices

IV

Appendix A

*Definitions**

Accountability	The quality of subordinate workers being responsible for their own work and answerable to a superior.
Administrative documentation	Records such as case related conversations, evidence receipts, description of evidence packaging and seals, and other pertinent information.
Administrative review	A procedure used to check for consistency with laboratory policy and for editorial correctness.
Approved test provider	A proficiency test provider who has complied with the test manufacturing guidelines established by the Proficiency Review Committees.
Audit	A review conducted to compare the various aspects of the laboratory's performance with a standard for that performance.
Authorized personnel	Individuals with the authority to perform a task or occupy in a location without supervision. These individuals include: Employees of the AGENCY NAME; Individuals designated by the Director of the AGENCY NAME.
Biology (discipline)	The identification and comparison of genetic markers from biological fluids; sub-disciplines include DNA and serology. (Screening and stain identification are considered a fundamental part of the discipline.)
Biological evidence	Bodily fluids in dried or liquid form that possess evidentiary value. These fluids include blood semen, saliva, urine, vaginal fluid and fecal material.

* American Society of Crime Laboratory Directors/Laboratory Accreditation Board, 2003 Manual

Blind sample	A proficiency test sample for which the analyst is unaware of the test nature of the sample at the time of analysis.
Candidate firearms	A firearm submitted to the Firearms Test Fire Section for functionality testing and to obtain projectile and cartridge case exemplars in compliance with the requirements of the National Firearms Registration Act.
Case record (file)	Files containing administrative and examination documentation generated or received by a laboratory pertaining to a particular case.
Competency test	The evaluation of a person's ability to perform work in any functional area prior to the performance of independent casework.
Complaint	A pleading describing some administrative wrong or offense.
Computer forensics	The application of science and engineering to the legal problem of digital evidence.
Computer systems	A complete, working computer to include any software and peripheral devices.
Confidence interval	Range of values that contains the true values at a given level of probability.
Confidence level	Measure of probability, α, associated with a confidence interval, expressing the probability of the truth of a statement that the interval will include the parameter value.
Control sample	A standard of comparison for verifying or checking the finding of an experiment.
Controlled documents	Documents that are: maintained and updated, or are formally approved, and their distribution is traceable to enable changes to be executed.
Controlled substances (discipline)	The identification of controlled drug substances either in pure, legal or illicit dosage forms.

Controlling	Establishing standards of performance, measuring current performance in relation to established standards, and taking corrective action as required.
Controls	Tests performed in parallel with experimental samples and designed to demonstrate that a procedure worked correctly.
Corrective action	The measures taken to reduce risk or correct issues with the quality assurance system.
Corrective action report	A document identifying and issue or risk that is grounds for quality assurance action and the measures taken to address them.
Correspondence, external	Letter, memoranda or other means of written communication, other than examination reports, used to disseminate information outside the AGENCY NAME.
Correspondence, internal	Letter, memoranda or other means of written communication used to disseminate information within the AGENCY NAME.
Crime/forensic laboratory	A laboratory (with at least one full-time scientist) which examines physical evidence in criminal matters and provides opinion testimony with respect to such physical evidence in a court of law.
Crime scene	An area, object or person, external to a laboratory facility, from which evidence is identified, documented, collected, and/or interpreted.
Crime scene (discipline)	The identification, documentation, collection, and or interpretation of material at a location external to a laboratory facility. Scene reconstruction is also part *of* this discipline.
Crime scene documentation (see notes and examination documentation)	May include notes and/or examination documentation, photographs, video, sketches, and other documents (including electronic versions) which are used to record and support the actions and/or conclusions of an examiner.
Crime scene reconstruction	The process *of* determining the nature *of* events that occurred at a scene from an evaluation *of* physical evidence and other relevant information.

Crime scene security and integrity	The actions necessary to: control access to a scene; establish and maintain a record *of* custody and control for a scene and all items collected from a scene; and protect against loss, cross contamination, or deleterious change of evidence or potential evidence within a scene.
Criteria file	An electronic or hard copy file, in numerical sequence, containing responses, which document compliance or non-applicability for each criterion in the accreditation manual. Responses may be in the form of statements; pictures; or excerpts from or references to components of other documents.
Criterion(a)	Objective test(s) to evaluate whether the laboratory activity meets the standard. This is often a restatement of the standard in the form *of* a question which can be answered (yes), (no) or (n/a).
Critical reagent	Reagents such as commercial supplies and kits which have an expiration date. See reagent.
Deficiency	An inadequacy; lacking in some necessary quality or element. Deficiencies include missing data, incomplete data, or incomplete reports.
Desirable (standard)	Standards which have the least affect on the work product or the integrity of the evidence but which nevertheless enhance the professionalism of the laboratory.
Diagonal lines of communication	Communication between subordinate personnel in one unit and supervisory personnel in another unit.
Digital evidence	Information of probative value stored or transmitted in binary form.
Digital video/image/ audio	The capture, processing, analysis, and storage of audio, video, or still images in digital format.
Directing	The process of motivating, leading, guiding, stimulating, and activating people.
Director	The highest ranking manager within an individual laboratory.

Discipline	A major area of casework for which a laboratory may seek accreditation.
Discussion	Information setting forth the rationale used in the adoption of the standards and providing more detailed information of some criteria.
DNA	Deoxyribonucleic acid; a sub-discipline, of biology, which identifies and compares DNA in biological samples.
Duty	A responsibility, task, etc., required by or relating to one's occupation or position.
Error rate	The frequency of the occurrence of an incorrect result.
Essential (standard)	Standards which directly affect and have fundamental impact on the work product of the laboratory or the integrity of the evidence.
Evidence identification (crime scene discipline)	The process of assessing material at a scene for the purpose of determining the value or potential value of that material as evidence of a crime.
Examination documentation (see notes)	Includes reference to procedures followed, test conducted, standards and controls used, diagrams, printouts, audioradiograms, photographs, observations and results of examinations.
Exemplar	See "known" sample.
External proficiency testing program	A test program managed and/or controlled independent of the laboratory system.
Firearms/toolmarks (discipline)	Examination and comparison of evidence resulting from discharge and/or use of firearms; comparison of marks made by various tools.
Freedom of Information Act	The Freedom of Information Act, commonly known as the FOIA, was enacted by Congress in 1966 to give the American public greater access to the Federal Government's records.
General Access Area	An area of the facility in which all authorized personnel have unrestricted access. Unauthorized personnel may have restricted access to General Access Areas under the escort of authorized personnel.

Goal	A statement of purpose defining the mission of an organization.
Grievance	A documented protest about a (real or imaginary) wrong that is grounds for an administrative action.
Important (standard)	Standards which are considered to be key indicators of the overall quality of the laboratory, but may not directly affect the work product nor the integrity of the evidence.
In-Service training	Training intended to maintain a skill in a specified field.
Inconsistency	Any reported results which differ from the consensus results. Inconsistencies may be classified as administrative, systemic, analytical or interpretive.
Interlineations	Words, numbers or other text which is added between the lines of previously written documentation.
Internal proficiency testing program	Proficiency testing program managed and controlled within the laboratory system.
Issue	A factor, thing, element, or course of action that is currently adversely affecting quality.
Key	Any device used to unlock a mechanical or electronic lock
Known sample technique	A quality assurance procedure in which a previously identified substance is submitted to a laboratory for examination to determine the reliability of the laboratory's procedures.
Known sample	A specimen of an identified source acquired for the purpose of comparison with an evidence sample; synonymous with exemplar.
Laboratory branch	An independently managed member of a laboratory system.
Laboratory satellite	A member of a laboratory system which is managed by, but is physically separated from, a parent laboratory.
Laboratory system	An organization containing at least two physically separate laboratory facilities which are independently managed under the control of a single superior in the chain of command.

Latent prints (discipline)	Development and comparison of latent print impressions. (Development alone is not considered a discipline.)
Limited access area	Access limited to personnel authorized by the laboratory director.
Manager	A person with the responsibility for directing and controlling an organizational unit or program.
Media	Objects on which data can be stored.
Method	The course of action or technique followed in conducting a specific analysis or comparison leading to an analytical result.
Must	The word designates a requirement which is not optional.
Natural science	Chemistry, biology, and physics.
Notes (see examination)	The documentation of procedures, standards, controls and instruments used, observations made, results of tests performed, charts, graphs, photos, and other documents generated which are used to support the examiner's conclusions.
Objective	A measurable, definable accomplishment which furthers the goals of the organization.
Open proficiency testing program	A quality assurance program where the examiner is aware that the sample is a test.
Operational manual	A group of policies, procedures or methods used to define the accepted technique of accomplishing non laboratory tasks.
Organizing	The process of identifying, specifying and assigning work, grouping work and resources into a structure and establishing a chain of command between individuals and groups.
Planning	The analysis of relevant information from the present and the past and the assessment of probable future developments so that a course of action (plan) may be determined that enables the organization to meet its stated objectives.
Policy	A guiding principle, operating practice, or plan of action governing decisions made on behalf of an organization.

Pre-distribution testing	Testing done by a laboratory on a proficiency test provided by an approved test provider prior to distribution. A pre-distribution testing laboratory will be considered to have completed a proficiency test, provided the manufacturer's expected conclusions were unknown to the laboratory at the time of the testing.
Principle	A basic rule, assumption or quality; a fixed or predetermined policy or mode of action.
Probation	A laboratory which is on probation remains accredited but is under surveillance for a designated period of time during which it must meet specified requirements as designated by the Board.
Procedure	The manner in which an operation is performed; a set of directions for performing an examination or analysis—the actual parameters of the methods employed.
Proficiency Review Committee (PRC)	A committee appointed by the Board of ASCLD/LAB, whose role is to evaluate the performance of accredited laboratories in proficiency tests.
Proficiency tests	Tests to evaluate the competence of analysts, technical support personnel and the quality performance of a laboratory; in open tests, the analysts and technical support personnel are aware that they are being tested; in blind tests, they are not aware. Internal proficiency tests are conducted by the laboratory itself; external proficiency tests are conducted by an agency independent of the laboratory being tested.
Protocol	A directive listing the procedures to be followed in performing a particular laboratory examination or operation; the overall plan for analysis of a particular type of evidence.
Quality assurance	Those planned and systematic actions necessary to provide sufficient confidence that a laboratory's product or service will satisfy given requirements for quality.
Quality audit	A management tool used to evaluate and confirm activities related to quality. Its primary purpose is to verify compliance with the operational requirements of the quality system.
Quality control	Internal activities, or activities conducted according to externally established standards, used to monitor the quality of analytical data and to ensure that it satisfies specified criteria.

Quality manager (however titled)	An individual designated by top management who, irrespective of other responsibilities, has the defined authority and obligation to ensure that the requirements of the quality system are implemented and maintained.
Quality manual	A document stating the quality policy an describing the various elements of the quality system and quality practices of an organization. It will also reference and note the location of additional material relating to the laboratory's quality arrangement.
Quality system	The 'organizational structure, responsibilities, procedures, processes, and resources for implementing quality management; includes all activities which contribute to quality, directly or indirectly.
Questioned document (discipline)	Examination of printed, typed or written material for the purpose of identifying the source, determining alternations or other means of gaining information about -the item or the circumstances surrounding its production.
Questioned sample	An evidence sample to be examined for the purpose of comparison or identification.
Reagent	A substance used because of its chemical or biological activity.
Re-examination technique	A quality assurance technique whereby a previously examined sample is re-examined by a different person.
Reference materials, primary	Substances obtained from sources which can supply appropriate information regarding the material's identity and specifications whenever possible. They can be used for QUANTITATIVE (if certificate of analysis is available) or QUALITATIVE analysis/quality control and added to instrument libraries for confirmatory tests.
Reference materials, secondary	Substance obtained from cases scheduled for destruction or other sources. Generally there is no documentation/information available for these materials. They are used for indicative purposes only.
Reference standard	A sample acquired or prepared that has known properties (e.g., concentration, chemical composition) for the purpose of calibrating equipment and/or for use as a control in experiments.

Reference standards, primary	Substances obtained or recalibrated/requalified from traceable sources and can be used to qualify secondary reference standards. They should not be used for examinations or equipment monitoring purposes.
Reference standards, secondary	Substances obtained with or without traceability and can be qualified/calibrated in-house using a primary reference standard. These standards can be used for everyday quality control, monitoring, etc.
Reliability	Processing the quality of being dependable; may refer to personnel, materials, and equipment.
Remedial training	Training intended to correct or improve deficient skill in a specified field.
Revocation	The loss of accreditation by action of the Board and/or the Delegate Assembly.
Risk	A factor, thing, element, or course of action that could adversely affect quality.
Rule	An authoritative direction for conduct or procedure.
Safety manager	An individual (however titled) designated by top management who, irrespective of other responsibilities, has the defined authority and obligation to ensure that the requirements of the safety system are implemented and maintained.
Safety manual	A document stating the safety policy and describing the various elements of the safety system of an organization.
Scientist	A person who employs scientific methods in the examination of evidence in a forensic laboratory.
Serology	A sub-discipline of biology, which identifies and compares genetic markers other than DNA, in biological samples.
Should	The word implies a strong recommendation.
Standard	A statement which describes an acceptable level of performance, excellence, or attainment in that particular activity.

Standard sample	See reference standard.
Sub-discipline	A specific type of analysis within an accredited discipline; (subdisciplines include but are not necessarily limited to: arson, hair, fibers, glass, paint, explosives and gunshot residue in trace evidence; serology and DNA in biology; firearms and toolmarks in firearms/toolmarks; alcohol and drugs in toxicology; and footwear/tiretrack evidence in the discipline to which it is assigned).
Supervisor	A person directly responsible for overseeing the work in an organizational unit.
Suspension	A laboratory which is suspended has its accreditation revoked for a designated period of time during which it must comply with requirements designated by the Board in order to have its accreditation restored.
Technical manual	A group of policies, procedures or methods used to define the accepted technique of accomplishing laboratory or examination related tasks.
Technical review	Review of notes, data and other documents which form the basis for a scientific conclusion.
Technical support personnel	A person who performs casework related duties on items of evidence within the laboratory.
Technical training	Training intended to develop or improve one's skill in a specified technical field.
Temporary storage	The gap between the time the employee who seized the evidence leaves it at the station, and the time that it is actually received by a property room employee. During this time, which could vary from a few hours to a few days, the property has left the hands of one person, but has not yet been received by another.
Toxicology (discipline)	Analysis of biological samples for the presence of drugs and other potentially toxic materials. (Analysis for alcohol in blood, breath, or urine may be included in this discipline if it is the only toxicological analysis performed by the laboratory.)

Trace evidence (discipline)	Any analytical procedure utilizing either chemical or instrumental techniques not specifically covered in other disciplines; including, but not limited to fire debris, explosives, paint, glass, hair, fibers and other varieties of trace evidence.
Uncertainty	The estimated amount or percentage by which an observed or calculated value may differ from the true value.
Validation	The process of performing a set of experiments which establish the efficacy and reliability of a technique or procedure or modification thereof.

Appendix B

DOCUMENT INVENTORY

POLICIES AND PROCEDURES

Doc. #	Rev. #	Description	Status	Date Approved	Review Date

FORMS

Doc. #	Rev. #	Description	Status	Date Approved	Review Date

STATIC DOCUMENTS

Doc. #	Rev. #	Description	Status	Date Approved	Review Date

Operational Manual Distribution Log

Manual #	Name	Signature	Date Issued	Date Return
001				
002				
003				
004				
005				
006				
007				
008				
009				
010				
011				
012				
013				
014				
015				
016				
017				
018				
019				
020				
021				
022				
023				
024				
025				

Technical Manual Distribution Log
Discipline_____

Manual #	Name	Signature	Date Issued	Date Return
001				
002				
003				
004				
005				
006				
007				
008				
009				
010				
011				
012				
013				
014				
015				
016				
017				
018				
019				
020				
021				
022				
023				
024				
025				

Name	Title

Administrative Policy and Procedure Orientation

Item	Trainee's Initials	Date Completed	Trainer's Initials	Date Reviewed
Administrative Policy and Procedure Manual Issued				
Lab Management and Organization Overview (Read/Reviewed)				
Physical Plant Requirements (Read/Reviewed)				
Personnel Policies (Read/Reviewed)				
Case Management Policies (Read/Reviewed)				
Document Control Administrative Policies (Read/Reviewed)				
Security Policies (Read/Reviewed)				
Quality Assurance Administrative Policies (Read/Reviewed)				
Administrative Forms (Read/Reviewed)				

Orientation/Training Successfully Completed

Supervisor	Date
Quality Assurance Manager	**Date**

ACTING AUTHORITY ROSTER

Position	Authority	Primary Acting	Secondary Acting

The signatures below recognize the above roster as approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director Date

Mary Doe, Quality Assurance Manager Date

End Of Document

Key Control Log

Section _____

Key #	Name	Date Issued	Initials	Date Return	Initials

Period	Employee Evaluation Form	Date
Name		Title

Work Quality

☐Exceptional	☐Very good	☐Standard	☐Needs improve	☐Substandard
Comments				

Dependability

☐Exceptional	☐Very good	☐Standard	☐Needs improve	☐Substandard
Comments				

Initiative

☐Exceptional	☐Very good	☐Standard	☐Needs improve	☐Substandard
Comments				

Flexibility

☐Exceptional	☐Very good	☐Standard	☐Needs improve	☐Substandard
Comments				

Skill Building

☐Exceptional	☐Very good	☐Standard	☐Needs improve	☐Substandard
Comments				

Job Knowledge

☐Exceptional	☐Very good	☐Standard	☐Needs improve	☐Substandard
Comments				

Punctuality

☐Exceptional	☐Very good	☐Standard	☐Needs improve	☐Substandard
Comments				

Supervisory Ability

☐Exceptional	☐Very good	☐Standard	☐Needs improve	☐Substandard
Comments				

Overall Rating

☐Exceptional	☐Very good	☐Standard	☐Needs improve	☐Substandard
Comments				

Employee Evaluation Review

Examiner	**Date**
Supervisor	**Date**
Deputy Director	**Date**

Period	Management Evaluation Form	Date
Name		Title

ADMINISTRATION

Performance Factor	1	2	3	4	5
Planning	☐	☐	☐	☐	☐
Budgeting and Economic Management	☐	☐	☐	☐	☐
Organization of Work	☐	☐	☐	☐	☐
Compliance	☐	☐	☐	☐	☐
Problem Solving and Decision Making	☐	☐	☐	☐	☐
Evaluation and Control	☐	☐	☐	☐	☐
Risk (Liability) Management	☐	☐	☐	☐	☐

INTERPERSONAL

Performance Factor	1	2	3	4	5
Oral Communication	☐	☐	☐	☐	☐
Written Communication	☐	☐	☐	☐	☐
Coordination/Collaboration	☐	☐	☐	☐	☐
Supervisory Control	☐	☐	☐	☐	☐
Leadership	☐	☐	☐	☐	☐
Staff Appraisal and Development	☐	☐	☐	☐	☐

INDIVIDUAL

Performance Factor	1	2	3	4	5
Effort and Initiative	☐	☐	☐	☐	☐
Professional and Technical Competence	☐	☐	☐	☐	☐
Innovation	☐	☐	☐	☐	☐
Objectivity	☐	☐	☐	☐	☐
Credibility	☐	☐	☐	☐	☐
Flexibility	☐	☐	☐	☐	☐

LEADERSHIP

Performance Factor	1	2	3	4	5
Coaching	☐	☐	☐	☐	☐
Empowering	☐	☐	☐	☐	☐
Modeling	☐	☐	☐	☐	☐
Team Building	☐	☐	☐	☐	☐
Visioning	☐	☐	☐	☐	☐
Self-development	☐	☐	☐	☐	☐

	1	2	3	4	5
OVERALL EVALUATION	☐	☐	☐	☐	☐
COMMENTS					

Employee Evaluation Review

Employee	**Date**
Deputy Director	**Date**
Director	**Date**

Security Equipment Inspection Form

Date			Section
Intrusion Alarm	**Location**	**Functional**	**Comments**
Alarm 1		☐YES ☐NO	
Alarm 2		☐YES ☐NO	
Alarm 3		☐YES ☐NO	
Alarm 4		☐YES ☐NO	
Alarm 5		☐YES ☐NO	
Alarm 6		☐YES ☐NO	
Alarm 7		☐YES ☐NO	
Alarm 8		☐YES ☐NO	
Alarm 9		☐YES ☐NO	
Alarm 10		☐YES ☐NO	
Video Camera	**Location**	**Functional**	**Comments**
Camera 1		☐YES ☐NO	
Camera 2		☐YES ☐NO	
Camera 3		☐YES ☐NO	
Camera 4		☐YES ☐NO	
Camera 5		☐YES ☐NO	
Camera 6		☐YES ☐NO	
Camera 7		☐YES ☐NO	
Camera 8		☐YES ☐NO	
Camera 9		☐YES ☐NO	
Camera 10		☐YES ☐NO	
Fire/Smoke Detectors	**Location**	**Functional**	**Comments**
Detector 1		☐YES ☐NO	
Detector 2		☐YES ☐NO	
Detector 3		☐YES ☐NO	
Detector 4		☐YES ☐NO	
Detector 5		☐YES ☐NO	
Detector 6		☐YES ☐NO	
Detector 7		☐YES ☐NO	
Detector 8		☐YES ☐NO	
Detector 9		☐YES ☐NO	
Detector 10		☐YES ☐NO	

Duress Alarm	Location	Functional	Comments
Alarm 1		☐YES ☐NO	
Alarm 2		☐YES ☐NO	
Alarm 3		☐YES ☐NO	
Alarm 4		☐YES ☐NO	

Security Equipment Inspection Completed

Security Coordinator	**Date**
Deputy Director	**Date**

STATEMENT OF QUALIFICATIONS

http://www.ascld-lab.org/legacy/forms/word/legacyAppendix2StatementofQualifications2005.doc

(Use additional sheets if necessary)

Name _____ **Job Title** _____

Responsibilities(s): Indicate all areas in which you do casework.

☐ Professional/Technical ☐ Administrative/Clerical

Discipline(s): Indicate all areas in which you do casework.

☐ Controlled substances
☐ Toxicology
☐ Trace evidence
☐ Biology
☐ Firearms/toolmarks
☐ Questioned documents
☐ Latent prints
☐ Crime scene
☐ Digital and multimedia evidence

Please list all subdisciplines in which you perform casework:

Education: List all higher academic institutions attended:

Institution	Dates Attended	Major	Degree Completed

Other Training: List continuing education, workshops, in-service and other formal training received.

_____
_____
_____
_____

Courtroom Experience: List all discipline(s) in which you have qualified to testify as an expert witness and indicate over what period of time and approximately how many times you have testified in each.

Professional Affiliations: List any professional organizations of which you are or have been a member. Indicate any offices or other positions held and the date(s) of these activities.

Employment History: List all scientific or technical positions held, particularly those related to forensic science. List current position first. Give a brief summary of principal duties and tenure in each position.

(1) Job Title _____ Employer _____

Principal Duties: _____

_____

_____

_____ Tenure _____

(2) Job Title _____ Employer _____

Principal Duties: _____

_____

_____

_____ Tenure _____

(3) Job Title _____ Employer _____

Principal Duties: _____

_____

_____

_____ Tenure _____

(4) Job Title _____ Employer _____

Principal Duties: _____

_____

_____

_____ Tenure _____

Other Qualifications: List below any scientific publication and/or presentation you have authored or co-authored, research in which you are or have been involved, academic or other teaching positions you have held, and any other information which you consider relevant to your qualification as a forensic scientist. (Use additional sheets if necessary.)

Grievance/Complaint Report Form

Date	GCR-

Grievance/Complaint Source

☐Employee ☐User/Customer ☐Non-User

Grievance or Complaint: Describe grievance or complaint
Resolution: Describe steps taken to address or resolve the grievance or complaint.
Results: Describe effect of the resolution and any follow up action required.
Describe Follow-Up Action Required:

Issue Successfully Resolved

Employee	Date
Supervisor	Date
Deputy Director	Date

Grievance/Compliant Report Record Form

GCR #	Grievance/Complaint Description	Date Initiated	Date Resolved

Name	Title

Training Record Log Form

Training Description	From	To	Hours
New Employee Orientation			
Administrative Policy Orientation			
Health and Safety Orientation			
Property and Evidence Orientation			
Quality Assurance Program Orientation			

Name	Title

Training Record and Critique Form

Course Title				Presenter
☐Vendor	☐Professional Association	☐College/University	☐Law Enforcement Agency	☐Other

Course Description	
	Hours

	Excellent				Poor
Category	**5**	**4**	**3**	**2**	**1**
Overall quality of presentation					
Teaching style					
Interaction with students					
Maintained student interest					
Number of visual aides					
Quality of visual aides					
Amount of handout material					
Quality of handout material					
Number of Practical exercises					
Quality of practical exercises					

Orientation/Training Successfully Completed

Supervisor	Date
Quality Assurance Manager	**Date**

CASE LOG

Section Name _____

Record Number	Examiner	Date Case Assigned	Date Report Approved

EXAMINER CASE LOG

Examiner Name	Month

Record #	Examiner	Exam Code	No. of Exhibits	Exam Time

SECTION CASE LOG

Section Name	Month

Record Number	Examiner	Date Case Assigned	Date Report Approved

Visitor Entry Log

Date	Badge #	Time In	Time Out	Name	Escort	Reason

Vehicle Entry Log

Date	Badge #	Time In	Time Out	Name	Vehicle License #	Reason

HOURLY SECURITY AND SAFETY STATUS Date

Hour	Zone 1	Zone 2	Zone 3	Zone 4	Zone 5	Zone 6	Zone 7	Zone 8	Zone 9	Zone 10	Zone 11	Zone 12	Zone 13	Zone 14	Zone 15	Zone 16	Zone 17	Comments
0000																		
0100																		
0200																		
0300																		
0400																		
0500																		
0600																		
0700																		
0800																		
0900																		
1000																		
1100																		
1200																		
1300																		
1400																		
1500																		

HOURLY SECURITY AND SAFETY STATUS Date

Hour	Zone 1	Zone 2	Zone 3	Zone 4	Zone 5	Zone 6	Zone 7	Zone 8	Zone 9	Zone 10	Zone 11	Zone 12	Zone 13	Zone 14	Zone 15	Zone 16	Zone 17	Comments
1600																		
1700																		
1800																		
1900																		
2000																		
2100																		
2200																		
2300																		

FILE REMOVAL LOG

Record #	File Given To	Date Removed	Date Returned

ASCLD/LAB (2005) Criteria File

http://www.ascld-lab.org/legacy/forms/word/
legacyInteractiveCriteriaFileContentGuide2005revised52506.doc

(Rev. 2006-1)

Underlined Text=hyperlink directly to file or book-marked area of file

OBJECTIVES		
(I) 1.1.1.1	Does the laboratory have a written statement of objectives?	
(I) 1.1.1.2	Do the objectives appear relevant to needs of community serviced by the laboratory?	
(D) 1.1.1.3	Does the laboratory staff understand and support the objectives?	

ADMINISTRATIVE PRACTICES		
(I) 1.1.2.1	Does the laboratory or its parent organization have a formal written budget?	
(I) 1.1.2.2	Is budget adequate to meet written objectives?	

Do clearly written and well understood procedures exist for the following:		
(E) 1.1.2.3	Handling and preserving the integrity of evidence?	
(E) 1.1.2.4	Laboratory security?	
(E) 1.1.2.5	Preparation, storage, security & disposition of case records or reports?	
(E) 1.1.2.6	Control of materials and supplies?	
(E) 1.1.2.7	Maintenance and calibration of equipment and instruments?	
(E) 1.1.2.8	The operation of individual characteristic databases?	
(D) 1.1.2.9	Job requirements and descriptions?	
(D) 1.1.2.10	Personnel evaluations and objectives	
(D) 1.1.2.11	Employee complaints concerning the quality system?	
(I) 1.1.2.12	Does the laboratory have and use an information management system?	

ORGANIZATIONAL STRUCTURE		
(D) 1.2.1.1	Does the organizational structure group the work and personnel in a manner that allows for efficiency of operation, taking into account the interrelation of various forensic disciplines?	
(D) 1.2.1.2	Has the laboratory director considered and taken appropriate action to correct any discrepancies with regard to numbers of personnel when grouping work and resources?	

DELEGATION OF AUTHORITY		
(I) 1.2.2.1	Is the laboratory director's authority well defined?	
(I) 1.2.2.2	Does the laboratory director have authority commensurate with responsibilities?	
(I) 1.2.2.3	Is there sufficient delegation of authority?	
(I) 1.2.2.4	Is the authority of supervisors commensurate with their responsibilities?	
(I) 1.2.2.5	Is each subordinate accountable to one and only one immediate supervisor per function?	
(I) 1.2.2.6	Are performance expectations established and are they understood by laboratory personnel?	

SUPERVISION		
(D) 1.3.1.1	Is there constructive discussion between supervisors & subordinates?	
(I) 1.3.1.2	Do supervisors carefully & objectively review laboratory activities & personnel?	
(D) 1.3.1.3	Do supervisory techniques encourage creative, objective thinking & recognize meritorious performance?	

COMMUNICATION		
(D) 1.3.2.1	Does and effective means of communication exist with the laboratory?	

TRAINING AND DEVELOPMENT		
(E) 1.3.3.1	Does the laboratory have and use a documented training program in each functional area for employees who are new, untrained or in need of remedial training?	
(I) 1.3.3.2	Does the laboratory have an employee development program?	

(I) 1.3.3.3	Does the forensic library contain current books, journals & other literature dealing with each functional area?	
(I) 1.3.3.4	Does a system exist to encourage each examiner to review appropriate new literature?	

EVIDENCE CONTROL		
(E) 1.4.1.1	Does the laboratory have a written or secure electronic chain of custody record with all necessary data which provides for complete tracking of evidence?	
(E) 1.4.1.2	Is all evidence marked for identification?	
(E) 1.4.1.3	Is evidence stored under proper seal?	
(E) 1.4.1.4	Is evidence protected from loss, cross transfer, contamination and/or deleterious change?	
(E) 1.4.1.5	Is there a secure area for overnight and/or long term storage of evidence?	
(E) 1.4.1.6	Has the laboratory established whether individual characteristic database samples are treated as evidence, reference materials, or examination documentation?	
(E) 1.4.1.7	Is each individual characteristic database sample under control of the laboratory uniquely identified?	
(E) 1.4.1.8	Are individual characteristic database samples protected from loss, cross transfer, contamination and/or deleterious change?	
(E) 1.4.1.9	Is access to characteristic database samples restricted to those persons authorized by the laboratory Director?	

QUALITY SYSTEM		
(E) 1.4.2.1	Does the laboratory have a comprehensive Quality Manual?	
(E) 1.4.2.2	Is there an individual designated as Quality Manager?	
(E) 1.4.2.3	Did the laboratory conduct and document an annual audit of its operations and submit an annual accreditation audit report to ASCLD/LAB by the required deadline?	
(E) 1.4.2.4	Does the laboratory conduct and document an annual review of its quality system?	
(E) 1.4.2.5	Are the procedures used generally accepted in the field or supported by data gathered & recorded in a scientific manner?	
(E) 1.4.2.6	Are new technical procedures scientifically validated before being used in casework and is the validation documentation available for review?	

(E) 1.4.2.7	Are the technical procedures used by the laboratory documented and available to laboratory personnel for review?	
(E) 1.4.2.8	Are appropriate controls & standards specified in the procedures & are they used and documented in the case record to ensure the validity of examination results?	
(E) 1.4.2.9	Is the quality of standard samples & reagents adequate for procedures used?	
(E) 1.4.2.10	Does the laboratory routinely check reliability of its reagents?	
(I) 1.4.2.11	Are the instruments/equipment adequate for procedure used?	
(I) 1.4.2.12	Are the instruments/equipment in proper working order?	
(E) 1.4.2.13	Are the instruments/equipment properly calibrated?	
(E) 1.4.2.14	Does the laboratory create and maintain a uniquely identified case record for all examination and administrative documentation generated and/or received by the laboratory for each case involving the analysis of evidence?	
(E) 1.4.2.15	Does the laboratory's unique case identifier appear on each page o the examination documentation and does the handwritten initials (or secure electronic equivalent) of the persons generating the examination documentation appear on each page generated by that person?	
(E) 1.4.2.16	Are conclusions and opinions in reports supported by data available in the case record, and are the examination documents sufficiently detailed such that in the absence of the examiner(s) an other competent examiner or supervisor could evaluate what was done and interpret the data?	
(E) 1.4.2.17	Is examination documentation of a permanent nature and free of obliterations and erasures?	
(E) 1.4.2.18	Has each person(s) in the laboratory who issued findings based on the examination documentation generated by another person, completes a review of all relevant pages of examination documentation and documented the review in the case record?	
(E) 1.4.2.19	Does the laboratory generate written reports for all analytical work performed on evidence, and do the reports contain the conclusions and opinions that address the purpose for which the analytical work was undertaken?	

(E)1.4.2.20	Where associations are made, is the significance of the association communicated clearly and qualified properly in the report?	
(E)1.4.2.21	Does the name of the author(s) appear in the report?	
(E)1.4.2.22	Does the laboratory have, use and document a system of technical review of the reports to ensure that the conclusions of its examiners are reasonable and within the constraints of scientific knowledge?	
(E)1.4.2.23	Does the laboratory conduct and document administrative reviews of all reports issued?	
(E)1.4.2.24	Does the laboratory monitor the testimony of each examiner at least annually and is the examiner given feedback from the evaluation?	
(E)1.4.2.25	If the laboratory has an indication of a significant technical problem, is there a procedure in writing and in use whereby the laboratory initiates a review and takes any corrective action required?	

PROFICIENCY TESTING		
(E) 1.4.3.1	Does the laboratory have a documented program of proficiency testing?	
(E) 1.4.3.2	Does the laboratory participate in proficiency testing programs conducted by approved test providers, or by other external providers(s) when no approved provider is available?	
(I) 1.4.3.3	Was each examiner proficiency tested annually in each subdiscipline in which casework was performed?	
(I) 1.4.3.4	Does the laboratory conduct proficiency testing using re-examination or blind techniques?	

MANAGEMENT		
(I) 2.1.1	Does the laboratory director possess degree in a natural science, criminalistics or in a closely related field, or is the laboratory director supported by scientific personnel of sufficient managerial rank & authority?	
(D) 2.1.2	Does the laboratory director have at least 5 years of forensic science experience?	
(D) 2.1.3	Does the laboratory director have some formal training in management?	
(D) 2.1.4	Does the laboratory director have at least 2 years of managerial experience?	

CONTROLLED SUBSTANCES		
(E) 2.2.1	Does each examiner have a Baccalaureate degree in a natural science, criminalistics, or in a closely related field & does each have experience/training commensurate with the examinations & testimony provided?	
(E) 2.2.2	Does each examiner understand the instruments & the methods & procedures used?	
(E) 2.2.3	Did each examiner successfully complete a competency test prior to assuming casework responsibility?	
(E) 2.2.4	Did each examiner successfully complete an annual proficiency test?	

TOXICOLOGY		
(E) 2.3.1	Does each examiner have a Baccalaureate degree in a natural science, toxicology, criminalistics, or in a closely related field & does each have experience/training commensurate with the examinations & testimony provided?	
(E) 2.3.2	Does each examiner understand the instruments & the methods & procedures used?	
(E) 2.3.3	Did each examiner successfully complete a competency test prior to assuming casework responsibility?	
(E) 2.3.4	Did each examiner successfully complete an annual proficiency test?	

TRACE EVIDENCE		
(E) 2.4.1	Does each examiner have a Baccalaureate degree in a natural science, criminalistics, or in a closely related field & does each have experience/training commensurate with the examinations & testimony provided?	
(E) 2.4.2	Does each examiner understand the instruments & methods & procedures used?	
(E) 2.4.3	Did each examiner successfully complete a competency test in each of the subdisciplines processed prior to assuming casework responsibility?	
(E) 2.4.4	Did each examiner successfully complete an annual proficiency test?	

BIOLOGY		
(E) 2.5.1	Does each examiner have a Baccalaureate degree in a natural science, criminalistics, or in a closely related field & does each have experience/training commensurate with the examinations & testimony provided?	
(E) 2.5.2	Does each examiner performing DNA analysis have education, training and experience consistent with those required by the Quality Assurance Audit Document?	
(E) 2.5.3	Does each examiner understand the instruments & methods & procedures used?	
(E) 2.5.4	Did each examiner successfully complete a competency test prior to assuming casework responsibility?	
(E) 2.5.5	Did each examiner successfully complete an annual proficiency test?	
(E) 2.5.6	Did each examiner performing DNA analysis successfully complete two annual proficiency tests from an approved test provider?	

FIREARMS/TOOLMARKS		
(I) 2.6.1	Does each examiner have a Baccalaureate degree with science courses?	
(E) 2.6.2	Does each examiner understand the instruments and the methods & procedures used?	
(E) 2.6.3	Did each examiner have extensive training from a qualified examiner & does each have experience commensurate with the examinations & testimony provided?	
(E) 2.6.4	Did each examiner successfully complete a competency test prior to assuming casework responsibility?	
(E) 2.6.5	Did each examiner successfully complete an annual proficiency test?	

QUESTIONED DOCUMENTS		
(I) 2.7.1	Does each examiner have a Baccalaureate degree with science courses?	
(E) 2.7.2	Does each examiner understand the instruments & the methods & procedures used?	
(E) 2.7.3	Did each examiner have extensive training from a qualified examiner & does each have experience commensurate the examinations & testimony provided?	
(E) 2.7.4	Did each examiner successfully complete a competency test prior to assuming casework responsibility?	
(E) 2.7.5	Did each examiner successfully complete an annual proficiency test?	

LATENT PRINTS		
(I) 2.8.1	Does each examiner have a Baccalaureate degree with science courses?	
(E) 2.8.2	Does each examiner understand the instruments & the methods & procedures used?	
(E) 2.8.3	Did each examiner have extensive training from a qualified examiner & does each have experience commensurate the examinations & testimony provided?	
(E) 2.8.4	Did each examiner successfully complete a competency test prior to assuming casework?	
(E) 2.8.5	Did each examiner successfully complete an annual proficiency test?	

TECHNICAL SUPPORT		
(E) 2.9.1	Do technical support personnel meet the requirements of their job descriptions?	
(E) 2.9.2	Are the job descriptions & the duties performed in agreement?	
(E) 2.9.3	Did each member of the technical support staff successfully complete an appropriate competency test prior to assuming casework responsibility?	
(E) 2.9.4	Did all technical support personnel complete an appropriate proficiency test, annually?	
(E) 2.9.5	Did DNA analytical support personnel successfully complete two annual proficiency tests from an approved test provider?	

CRIME SCENE		
(E) 2.10.1	Do examiners meet the requirements of their job descriptions?	
(E) 2.10.2	Does each examiner understand the equipment, methods and procedures used?	
(E) 2.10.3	Did each examiner have extensive training and experience commensurate with their examinations?	
(E) 2.10.4	Did each examiner successfully complete a competency test prior to primary responsibility for the examination, documentation and processing of a crime scene?	
(E) 2.10.5	Did each examiner successfully complete an annual proficiency test?	

DIGITAL EVIDENCE		
(I) 2.11.1	Does each examiner have a Baccalaureate degree with science courses?	
(E) 2.11.2	Does each examiner understand the equipment, programs, methods and procedures used?	
(E) 2.11.3	Did each examiner have experience commensurate the examinations/documentation & testimony provided?	
(E) 2.11.4	Did each examiner successfully complete a competency test in each sub-discipline prior to assuming casework?	
(E) 2.11.5	Did each examiner successfully complete an annual proficiency test?	

SPACE		
(I) 3.1.1	Does each employee have adequate work space to accomplish assigned tasks?	
(D) 3.1.2	Is there sufficient space provided for storage of supplies, equipment & tools?	
(I) 3.1.3	Is there adequate space available for examiners for writing reports & other official communications?	
(I) 3.1.4	Is there adequate & appropriate space available for records, reference works & other necessary documents?	
(I) 3.1.5	Is there adequate space available for each instrument/ equipment to facilitate its operation?	
(D) 3.1.6	Are accessories stored near instrumentation/equipment to facilitate its use & operation?	

DESIGN		
(I) 3.2.1	Does the physical design permit the efficient flow of evidence from the time of its acceptance until its proper disposal?	
(D) 3.2.2	Do the relative locations of functional areas facilitate the use of equipment & instruments?	
(I) 3.2.3	Is there adequate & proper lighting available for personnel to carry out assigned tasks?	
(I) 3.2.4	Is there adequate & proper plumbing & wiring available & accessible to carry out assigned tasks?	
(I) 3.2.5	Does the laboratory have proper general ventilation?	
(I) 3.2.6	Is the heating, cooling & humidity control in the laboratory adequate?	

SECURITY		
(E) 3.3.1	Is access to the operational area of the laboratory controllable & limited?	
(E) 3.3.2	Do all exterior entrance/exit points have adequate security control?	
(E) 3.3.3	Do all internal areas requiring limited/controlled access have a lock system?	
(E) 3.3.4	Is distribution of all keys, magnetic cards, etc., documented and is distribution limited to those individuals designated by the laboratory director to have access?	
(E) 3.3.5	Is the laboratory secured during vacant hours by means of an intrusion alarm or by security personnel?	
(I) 3.3.6	Does the laboratory have a fire detection system?	

HEALTH AND SAFETY		
(I) 3.4.1	Does the laboratory have an effective health & safety program documented in a manual?	
(I) 3.4.2	Is an individual designated as the Health & Safety Manager?	
(I) 3.4.3	Is the health & safety program monitored regularly & reviewed annually to ensure that its requirements are being?	
(I) 3.4.4	Does the laboratory have available & encourage the use of safety devices, particularly those required by its health & safety manual?	
(I) 3.4.5	Does the laboratory have proper equipment & material available for the handling of carcinogenic, toxic and/or other dangerous material spills?	
(I) 3.4.6	Does the laboratory have safety shower & eye wash equipment in appropriate locations & in good working condition?	
(I) 3.4.7	Are sufficient exhaust hoods available to maintain a safe work environment?	
(I) 3.4.8	Are sufficient first aid kits available & strategically located?	
(I) 3.4.9	Does the laboratory have an adequate number of personnel holding current certification in first aid?	
(I) 3.4.10	Is appropriate space provided for safe storage of volatile, flammable, explosive & other hazardous materials?	
(I) 3.4.11	Are the emergency exits from the laboratory adequate for safe exit in an emergency?	
(D) 3.4.12	Is there general cleanliness & apparent good housekeeping in the laboratory?	

The signatures below recognize the above Administrative Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

ISO 17025:2005 Criteria File
(Rev. 01/01/2005)

Underlined Text=hyperlink directly to file or book-marked area of file

No.	Requirement	Policy # Hyperlinks
4.0	**MANAGEMENT REQUIREMENTS**	
4.1	**Organization**	
4.1.1	The laboratory or the organization of which it is part shall be an entity that can be held legally responsible.	
4.1.2	It is the responsibility of the laboratory to carry out its testing and calibration activities in such a way as to meet the requirements of this International Standard and to satisfy the needs of the customer, the regulatory authorities or organizations providing recognition.	
4.1.3	The laboratory management system shall cover work carried out in the laboratory's permanent facilities, at sites away from its permanent facilities, or in associated temporary or mobile facilities.	
4.1.4	If the laboratory is part of an organization performing activities other than testing and/or calibration, the responsibilities of key personnel in the organization that have an involvement or influence on the testing and/or calibration activities of the laboratory shall be defined in order to identify potential conflicts of interest.	
	Note 1: Where a laboratory is part of a larger organization, the organizational arrangements should be such that departments having conflicting interests, such as production, commercial marketing or financing do not adversely influence the laboratory's compliance with the requirements of this International Standard. ***Note 2:*** If the laboratory wishes to be recognized as a third-party laboratory, it should be able to demonstrate that it is impartial and that it and its personnel are free from any undue commercial, financial and other pressures which might influence their technical judgment. The third-party testing or calibration laboratory should not engage in any activities that may endanger the trust in its independence of judgment and integrity in relation to its testing or calibration activities.	
4.1.5	The laboratory shall:	
a)	Have managerial and technical personnel with the authority and resources needed to carry out their duties and to identify the occurrence of departures from the quality system or from the procedures for performing tests and/or calibrations, and to initiate actions to prevent or minimize such departures (see also 5.2).	

No.	Requirement	Policy # Hyperlinks
b)	Have arrangements to ensure that its management and personnel are free from any undue internal and external commercial, financial and other pressures and influences that may adversely affect the quality of their work.	
c)	Have policies and procedures to ensure the protection of its customers' confidential information and proprietary rights, including procedures for protecting the electronic storage and transmission of results.	
d)	Have policies and procedures to avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgement or operational integrity.	
e)	Define the organization and management structure of the laboratory, its place in any parent organization, and the relationships between quality management, technical operations and support services.	
f)	Specify the responsibility, authority and interrelationships of all personnel who manage, perform and verify work affecting the quality of the tests and/or calibrations.	
g)	Provide adequate supervision of testing and calibration staff, including trainees, by persons familiar with methods and procedures, purpose of each test and/or calibration, and with the assessment of the test or calibration results.	
h)	Have technical management which has overall responsibility for the technical operations and the provision of the resources needed to ensure the required quality of laboratory operations.	
i)	Appoint a member of staff as quality manager (however named) who, irrespective of other duties and responsibilities, shall have defined responsibility and authority for ensuring that the quality system is implemented and followed at all times; the quality manager shall have direct access to the highest level of management at which decisions are made on laboratory policy or resources.	
j)	Appoint deputies for key managerial personnel.	
	Note: Individuals may have more than one function and it may be impractical to appoint deputies for every function.	
k)	Ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the objectives of the management system.	
4.1.6	Top management shall ensure that appropriate communication processes are established within the laboratory and that communication takes place regarding the effectiveness of the management system.	

No.	Requirement	Policy # Hyperlinks
4.2	**Quality System**	
4.2.1	The laboratory shall establish, implement and maintain a quality system appropriate to the scope of its activities. The laboratory shall document its policies, systems, programs, procedures and instructions to the extent necessary to assure the quality of the test and/or calibration results. The system's documentation shall be communicated to, understood by, available to, and implemented by the appropriate personnel.	
4.2.2	The laboratory's quality system policies and objectives shall be defined in a quality manual (however named). The overall objectives shall be documented in a quality policy statement. The quality policy statement shall be issued under the authority of the chief executive. It shall include at least the following:	
a)	The laboratory management's commitment to good professional practice and to the quality of its testing and calibration in servicing its customers.	
b)	The management's statement of the laboratory's standard of service.	
c)	The purpose of the management system related to quality.	
d)	A requirement that all personnel concerned with testing and calibration activities within the laboratory familiarize themselves with the quality documentation and implement the policies and procedures in their work.	
e)	The laboratory management's commitment to comply with this International Standard and to continually improve the effectiveness of the management system.	
	Note: The quality policy statement should be concise and may include the requirement that tests and/or calibrations shall always be carried out in accordance with stated methods and customers' requirements. When the test and/or calibration laboratory is pat of a larger organization, some quality policy elements may be in other documents.	
4.2.3	Top management shall provide evidence of commitment to the development and implementation of the management system and to continually improving its effectiveness.	
4.2.4	Top management shall communicate to the organization the importance of meeting customer requirements as well as statutory and regulatory requirements.	
4.2.5	The quality manual shall include or make reference to the supporting procedures including technical procedures. It shall outline the structure of the documentation used in the quality system.	

No.	Requirement	Policy # Hyperlinks
4.2.6	The roles and responsibilities of technical management and the quality manager, including their responsibility for ensuring compliance with this International Standard, shall be defined in the quality manual.	
4.2.7	Top management shall ensure that the integrity of the management system is maintained when changes to the management system are planned and implemented.	
4.3	**Document Control**	
4.3.1	General	
	The laboratory shall establish and maintain procedures to control all documents that form part of its quality system (internally generated or from external sources), such as regulations, standards, other normative documents, test and/or calibration methods, as well as drawings, software, specifications, instructions and manuals.	
	Note 1: In this context "document" could be policy statements, procedures, specifications, calibration tables, charts, text books, posters, notices, memoranda, software, drawings, plans, etc. These may be on various media, whether hard copy or electronic, and they may be digital, analog, photographic or written. ***Note 2:*** The control of data related to testing and calibration is covered in 5.4.7. The control of records is covered in 4.13.	
4.3.2	Document Approval and Issue	
4.3.2.1	All documents issued to personnel in the laboratory as part of the quality system shall be reviewed and approved for use by authorized personnel prior to issue. A master list or an equivalent document control procedure identifying the current revision status and distribution of documents in the quality system shall be established and be readily available to preclude the use of invalid and/or obsolete documents.	
4.3.2.2	The procedure(s) adopted shall ensure that:	
a)	Authorized editions of the appropriate documents are available at all locations where operations essential to the effective functioning of the laboratory are performed.	
b)	Documents are periodically reviewed and, where necessary, revised to ensure continuing suitability and compliance with applicable requirements.	
c)	Invalid or obsolete documents are promptly removed from all points of issue or use, or otherwise assured against unintended use.	
d)	Obsolete documents retained for either legal or knowledge preservation purposes are suitably marked.	

No.	Requirement	Policy # Hyperlinks
4.3.2.3	Management system documents generated by the laboratory shall be uniquely identified. Such identification shall include the date of issue and/or revision identification, page numbering, the total number of pages or a mark to signify the end of the document, and the issuing authority(ies).	
4.3.3	Document Change	
4.3.3.1	Changes to documents shall be reviewed and approved by the same function that performed the original review unless specifically designated otherwise. The designated personnel shall have access to pertinent background information upon which to base their review and approval.	
4.3.3.2	Where practicable, the altered or new test shall be identified in the document or the appropriate attachments.	
4.3.3.3	If the laboratory's documentation control system allows for the amendment of documents by hand pending the re-issue of the documents, the procedures and authorities for such amendments shall be defined. Amendments shall be clearly marked, initialed and dated. A revised document shall be formally re-issued as soon as practicable.	
4.3.3.4	Procedures shall be established to describe how changes in documents maintained in computerized systems are made and controlled.	
4.4	**Removal of Requests, Tenders and Contracts**	
4.4.1	The laboratory shall establish and maintain procedures for the review of requests, lenders and contracts. The policies and procedures for these reviews leading to a contract for testing and/or calibration shall ensure that:	
a)	The requirements, including the methods to be used, are adequately defined, documented and understood (see 5.4.2);	
b)	The laboratory has the capability and resources to meet the requirements;	
c)	The appropriate test and/or calibration method is selected and capable of meeting the customer's requirements; (see 5.4.2).	
	Any differences between the request or tender and the contract shall be resolved before any work commences. Each contract shall be acceptable both to the laboratory and the customer.	
	Note 1: The request, tender and contract review shall be conducted in a practical and efficient manner, and the effect of financial, legal and time schedule aspects should be taken into account For internal customers, reviews of requests, tenders and contracts can be performed in a simplified way.	

No.	Requirement	Policy # Hyperlinks
	Note 2: The review of capability should establish that the laboratory possesses the necessary physical, personnel and information resources, and that the laboratory's personnel have the skills and expertise necessary for the performance of the tests and/or calibrations in question. The review may also encompass results of earlier participation in inter laboratory comparisons or proficiency testing and/or the running of trial test or calibration programs using certified reference materials in order to determine uncertainties of measurement, limits of detection, confidence limits, etc. ***Note 3:*** A contract may be any written or oral agreement to provide a customer with testing and/or calibration services.	
4.4.2	Records of reviews, including any significant changes, shall be maintained. Records shall also be maintained of pertinent discussions with a customer relating to the customer's requirements or the results of the work during the period of execution of the contract.	
	Note: For review of routine and other simple tasks, the date and the identification (e.g., the initials) of the person in the laboratory responsible for carrying out the contracted work are considered adequate. For repetitive routine tasks, the review need be made only at the initial enquiry stage or on granting of the contract for on-going routine work performed under a general agreement with the customer, provided that the customer's requirements remain unchanged. For new, complex or advanced testing and/or calibration tasks, a more comprehensive record should be maintained	
4.4.3	The review shall also cover any work that is subcontracted by the laboratory.	
4.4.4	The customer shall be informed of any deviation from the contract.	
4.4.5	If a contract needs to be amended after work has commenced, the same contract review process shall be repeated and any amendments shall be communicated to all affected personnel.	
4.5	**Subcontracting of Tests and Calibrations**	
4.5.1	When a laboratory subcontracts work whether because of unforeseen reasons (e.g., workload, need for further expertise or temporary incapacity) or on a continuing basis (e.g., through permanent subcontracting, agency or franchising arrangements), this work shall be placed with a competent subcontractor. A competent subcontractor is one that, for example, complies with this International Standard for the work in question.	
4.5.2	The laboratory shall advise the customer of the arrangement in writing and, when appropriate, gain the approval of the customer, preferably in writing.	

No.	Requirement	Policy # Hyperlinks
4.5.3	The laboratory is responsible to the customer for the subcontractor's work, except in the case where the customer or a regulatory authority specifies which subcontractor is to be used.	
4.5.4	The laboratory shall maintain a register of all subcontractors that it uses for tests and/or calibrations and a record of the evidence of compliance with this International Standard for the work in question.	
4.6	**Purchasing Services and Supplies**	
4.6.1	The laboratory shall have a policy and procedure(s) for the selection and purchasing of services and supplies it uses that affect the quality of the tests and/or calibrations. Procedures shall exist for the purchase, reception and storage of reagents and laboratory consumable materials relevant for the tests and calibrations.	
4.6.2	The laboratory shall ensure that purchased supplies and reagents and consumable materials that affect the quality of tests and/or calibrations are not used until they have been inspected or otherwise verified as complying with standard specifications or requirements defined in the methods for the tests and/or calibrations concerned. These services and supplies used shall comply with specified requirements. Records of actions taken to check compliance shall be maintained.	
4.6.3	Purchasing documents for items affecting the quality of laboratory output shall contain data describing the services and supplies ordered. These purchasing documents shall be reviewed and approved for technical content prior to release.	
	Note: The description may include type, class, grade, precise identification, specifications, drawings, inspection instructions, other technical data including approval of test results, the quality required and the quality system standard under which they were made.	
4.6.4	The laboratory shall evaluate suppliers of critical consumables, supplies and services which affect the quality of testing and calibration, and shall maintain records of these evaluations and list those approved.	
4.7	**Service to the Customer**	
4.7.1	The laboratory shall afford customers or their representatives cooperation to clarify the customer's request and to monitor the laboratory's performance in relation to the work performed, provided that the laboratory ensures confidentiality to their customers.	

No.	Requirement	Policy # Hyperlinks
	Note 1: Such cooperation may include: • Providing the customer of the customer's representative reasonable access to relevant areas of the laboratory for the witnessing of tests and/or calibrations performed for the customer. • Preparation, packaging, and dispatch of test and/or calibration items needed by the customer for verification purposes. ***Note 2:*** Customer's value the maintenance of good communication, advice and guidance in technical matters, and opinions and interpretations based on results. Communication with the customer, especially in large assignments, should be maintained throughout the work. The laboratory should inform the customer of any delays or major deviations in the performance of the tests and/or calibrations.	
4.7.2	The laboratory shall seek feedback, both positive and negative, from its customers. The feedback shall be used and analyzed to improve the management system, testing and calibration activities and customer service.	
	Note: Examples of the types of feedback include customer satisfaction surveys and review of test or calibration reports with customers.	
4.8	**Complaints**	
	The laboratory shall have a policy and procedure for the resolution of complaints received from customers or other parties. Records shall be maintained of all complaints and of the investigations and corrective actions taken by the laboratory (see also 4.11).	
4.9	**Control of Nonconforming Testing and/or Calibration Work**	
4.9.1	The laboratory shall have a policy and procedures that shall be implemented when any aspect of its testing and/or calibration work, or the results of this work, do not conform to its own procedures or the agreed requirements of the customer. The policy and procedures shall ensure that:	
a)	The responsibilities and authorities for the management of nonconforming work are designated and actions (including halting of work and withholding of test reports and calibration certificates, as necessary) are defined and taken when nonconforming work is identified.	
b)	An evaluation of the significance of the nonconforming work is made.	
c)	Remedial actions are taken immediately, together with any decision about the acceptability of the nonconforming work.	

No.	Requirement	Policy # Hyperlinks
d)	Where necessary, the customer is notified and work is recalled.	
e)	The responsibility for authorizing the resumption of work is defined.	
	Note: Identification of nonconforming work or problems with the quality system or with testing and/or calibration activities can occur at various places within the quality system and technical operations. Examples are customer complaints, quality control, instrument calibration, checking of consumable materials, staff observations or supervision, test report and calibration certificate checking, management reviews and internal or external audits.	
4.9.2	Where the evaluation indicates that the nonconforming work could recur or that there is doubt about the compliance of the laboratory's operations with its own policies and procedures, the corrective action procedures given in 4.11 shall be promptly followed.	
4.10	**Improvement**	
	The laboratory shall continually improve the effectiveness of its management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.	
4.11	**Corrective Action**	
4.11.1	General	
	The laboratory shall establish a policy and procedure and shall designate appropriate authorities for implementing corrective action when nonconforming work or departures from the policies and procedures in the quality system or technical operations have been identified.	
	Note: A problem with the quality system or with the technical operations of the laboratory may be identified through a variety of activities, such as control of nonconforming work, internal or external audits, management reviews, feedback from customers or staff observations.	
4.11.2	Cause Analysis	
	The procedure for corrective action shall start with an investigation to determine the root cause(s) of the problem.	
	Note: Cause analysis is the key and sometimes the most difficult part in the corrective action procedure. Often the root cause is not obvious and thus a careful analysis of all potential causes of the problem is required. Potential causes could include customer requirements, the samples, sample specifications, methods and procedures, staff skills and training, consumables, or equipment and its calibration.	

No.	Requirement	Policy # Hyperlinks
4.11.3	Selection and Implementation of Corrective Action	
	Where corrective action is needed, the laboratory shall identify potential corrective actions. It shall select and implement the action(s) most likely to eliminate the problem and to prevent recurrence.	
	Corrective actions shall be to a degree appropriate to the magnitude and the risk of the problem.	
	The laboratory shall document and implement any required changes resulting from corrective action investigations.	
4.11.4	Monitoring of Corrective Actions	
	The laboratory shall monitor the results to ensure that the corrective actions taken have been effective.	
4.11.5	Additional Audits	
	Where the identification of nonconformance's or departures casts doubts on the laboratory's compliance with its own policies and the procedures, or on its compliance with this International Standard, the laboratory shall ensure that the appropriate areas of activity are audited in accordance with 4.14 as soon as possible.	
	Note: Such additional audits often follow the implementation of the corrective actions to confirm their effectiveness. An additional audit should be necessary only when a serious issue or risk to the business is identified.	
4.12	**Preventive Actions**	
4.12.1	Needed improvements and potential sources of nonconformities, either technical or concerning the management system, shall be identified. When improvement opportunities are identified or if preventive action is required, action plans shall be developed, implemented and monitored to reduce the likelihood of the occurrence of such nonconformities and to take advantage of the opportunities for improvement.	
4.12.2	Procedures for preventive actions shall include the initiation of such actions and application of controls to ensure that they are effective.	
	Note 1: Preventive action is a pro-active process to identify opportunities for improvement rather than a reaction to the identification of problems or complaints. ***Note 2:*** Apart from the review of the operational procedures, the preventive action might involve analysis of data, including trend and risk analyses and proficiency-testing results.	

No.	Requirement	Policy # Hyperlinks
4.13	**Control of Records**	
4.13.1	General	
4.13.1.1	The Laboratory shall establish and maintain procedures for identification, collection, indexing, access, filing, storage, maintenance and disposal of quality and technical records. Quality records shall include reports from internal audits and management reviews as well as records of corrective and preventive actions.	
4.13.1.2	All records shall be legible and shall be stored and retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss. Retention times of records shall be established.	
	Note: Records may be in any media, such as hard copy or electronic media.	
4.13.1.3	All records shall be held secure and in confidence.	
4.13.1.4	The laboratory shall have procedures to protect and back-up records stored electronically and to prevent unauthorized access to or amendment of these records.	
4.13.2	Technical Records	
4.13.2.1	The laboratory shall retain records of original observations, derived data and sufficient information to establish an audit trail, calibration records, staff records and a copy of each test report or calibration certificate issued, for a defined period. The records for each test or calibration shall contain sufficient information to facilitate, if possible, identification of factors affecting the uncertainty and to enable the test or calibration to be repeated under conditions as close as possible to the original. The records shall include the identity of personnel responsible for the sampling, performance of each test and/or calibration and checking of results.	
	Note 1: In certain fields it may be impossible or impracticable to retain records of all original observations. ***Note 2:*** Technical records are accumulations of data (see 5.4.7) and information, which result from carrying out tests and/or calibrations and which indicate whether specified quality or process parameters are achieved. They may include forms, contracts, work sheets, work books, check sheets, work notes, control graphs, external and internal test reports and calibration certificates, customers' notes, papers and feedback.	
4.13.2.2	Observations, data and calculations shall be recorded at the time they are made and shall be identifiable to the specific task.	

No.	Requirement	Policy # Hyperlinks
4.13.2.3	When mistakes occur in records, each mistake shall be crossed out, not erased, made illegible or deleted, and the correct value entered alongside. All such alterations to records shall be signed or initialed by the person making the correction. In the case of records stored electronically, equivalent measures shall be taken to avoid loss or change or original data.	
4.14	**Internal Audits**	
4.14.1	The laboratory shall periodically, and in accordance with a predetermined schedule and procedure, conduct internal audits of its activities to verify that its operations continue to comply with the requirements of the quality system and this International Standard. The internal audit program shall address all elements of the quality system, including the testing and/or calibration activities. It is the responsibility of the quality manager to plan and organize audits as required by the schedule and requested by management. Such audits shall be carried out by trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited.	
	Note: The cycle for internal auditing shall normally be completed in one year.	
4.14.2	When audit findings cast doubt on the effectiveness of the operations or on the correctness or validity of the laboratory's test or calibration results, the laboratory shall take timely corrective action, and shall notify customers in writing if investigations show that the laboratory results may have been affected.	
4.14.3	The area of activity audited, the audit findings and corrective actions that arise from them shall be recorded.	
4.14.4	Follow-up audit activities shall verify and record the implementation and effectiveness of the corrective action taken.	
4.15	**Management Reviews**	
4.15.1	In accordance with a predetermined schedule and procedure, the laboratory's executive management shall periodically conduct a review of the laboratory's quality system and testing and/or calibration activities to ensure their continuing suitability and effectiveness, and to introduce necessary changes or improvements. The review shall take account of:	
a)	The suitability of policies and procedures	
b)	Reports from managerial and supervisory personnel	
c)	The outcome of recent internal audits	
d)	Corrective and preventive actions	

No.	Requirement	Policy # Hyperlinks
e)	Assessments by external bodies	
f)	The results of inter laboratory comparisons or proficiency tests	
g)	Changes in the volume and type of the work	
h)	Customer feedback	
i)	Complaints	
j)	Recommendations for improvement	
k)	Other relevant factors, such as quality control activities, resources and staff training	
	Note 1: A typical period for conducting a management review is once every 12 months. ***Note 2:*** Results should feed into the laboratory planning system and should include the goals, objectives and action plans for the coming year. ***Note 3:*** A management review includes consideration of related subjects at regular management meetings.	
4.15.2	Findings from management reviews and the actions that arise from them shall be recorded. The management shall ensure that those actions are carried out within an appropriate and agreed timescale.	
5.0	**TECHNICAL REQUIREMENTS**	
5.1	**General**	
5.1.1	Many factors determine the correctness and reliability of the tests and/or alibrations performed by a laboratory. These factors include contributions from: • Human factors (5.2) • Accommodation and environmental conditions (5.3) • Test and calibration methods and method validation (5.4) • Equipment (5.5) • Measurement traceability (5.6) • Sampling (5.7) • The handling of test and calibration items (5.8)	
5.1.2	The extent to which the factors contribute to the total uncertainty of measurement differs considerably between (types of) tests and between (types of) calibrations. The laboratory shall take account of these factors in developing test and calibration methods and procedures, in the training and qualification of personnel, and in the selection and calibration of the equipment it uses.	

No.	Requirement	Policy # Hyperlinks
5.2	**Personnel**	
5.2.1	The laboratory management shall ensure the competence of all who operate specific equipment, perform tests and/or calibrations, evaluate results, and sign test reports and calibration certificates. When using staff who are undergoing training, appropriate supervision shall be provided. Personnel performing specific tasks shall be qualified on the basis of appropriate education, training, experience and/or demonstrated skills, as required.	
	Note 1: In some technical areas (e.g., non-destructive testing) it may be required that the personnel performing certain tasks hold personnel certification. The laboratory is responsible for fulfilling specified personnel certification requirements. The requirements for personnel certification might by regulatory, included in the standards for specific technical field, or required by the customer. ***Note 2:*** The personnel responsible for the opinions and interpretation included in test reports should, in addition to the appropriate qualifications, training, experience and satisfactory knowledge of the testing carried out, also have: • relevant knowledge of the technology used for the manufacturing of the items, materials, products, etc. tested, or the way they are used or intended to be used, and of the defects or degradations which may occur during or in service; • knowledge of the general requirements expressed in the legislation and standards; and • an understanding of the significance of deviations found with regard to the normal use of the items, materials, products, etc. concerned.	
5.2.2	The management of the laboratory shall formulate the goals with respect to the education, training and skills of the laboratory personnel. The laboratory shall have a policy and procedures for identifying training needs and providing training of personnel. The training program shall be relevant to the present and anticipated tasks of the laboratory.	
5.2.3	The laboratory shall use personnel who are employed by, or under contract to, the laboratory. Where contracted and additional technical and key support personnel are used, the laboratory shall ensure that such personnel are supervised and competent and that they work in accordance with the laboratory's quality system.	

No.	Requirement	Policy # Hyperlinks
5.2.4	The laboratory shall maintain current job descriptions for managerial, technical and key support personnel involved in tests and/or calibrations.	
	Note: Job descriptions can be defined in may ways. As a minimum, the following should be defined: • The responsibilities with respect to performing tests and/or calibrations • The responsibilities with respect to the planning of tests and/or calibrations and evaluation of results • The responsibilities for reporting opinions and interpretations • The responsibilities with respect to method modification and development and validation of new methods • Expertise and experience required • Qualifications and training programs • Managerial duties	
5.2.5	The management shall authorize specific personnel to perform particular types of sampling, test and/or calibration, to issue test reports and calibration certificates, to give opinions and interpretations and to operate particular types of equipment. The laboratory shall maintain records of the relevant authorization(s), competence, educational and professional qualifications training, skills and experience of all technical personnel, including contracted personnel. This information shall be readily available and shall include the date on which authorization and/or competence is confirmed.	
5.3	**Accommodation and Environmental Conditions**	
5.3.1	Laboratory facilities for testing and/or calibration, including but not limited to energy sources, lighting and environmental conditions, shall be such as to facilitate correct performance of the tests and/or calibrations.	
	The laboratory shall ensure that the environmental conditions do not invalidate the results or adversely affect the required quality of any measurement. Particular care shall be taken when sampling and test and/or calibrations are undertaken at sites other than a permanent laboratory facility. The technical requirements for accommodation and environmental conditions that can affect the results of tests and calibrations shall be documented.	

No.	Requirement	Policy # Hyperlinks
5.3.2	The laboratory shall monitor, control and record environmental conditions as required by the relevant specifications, methods and procedures or where thy influence the quality of the results. Due attention shall be paid, for example, to biological sterility, dust, electromagnetic disturbances, radiation, humidity, electrical supply, temperature, and sound and vibration levels, as appropriate to the technical activities concerned. Tests and calibrations shall be stopped when the environmental conditions jeopardize the results of the tests and/or calibrations.	
5.3.3	There shall be effective separation between neighboring areas in which there are incompatible activities. Measures shall be taken to prevent cross-contamination.	
5.3.4	Access to and use of areas affecting the quality of the tests and/or calibrations shall be controlled. The laboratory shall determine the extent of control based on its particular circumstances.	
5.3.5	Measures shall be taken to ensure good housekeeping in the laboratory. Special procedures shall be prepared where necessary.	
5.4	**Test and Calibration Methods and Methods Validation**	
5.4.1	General	
	The laboratory shall use appropriate methods and procedures for all tests and/or calibrations within its scope. These include sampling, handling, transport, storage and preparation of items to be tested and/or calibrated, and, where appropriate, an estimation of the measurement uncertainty as well as statistical techniques for analysis of test and/or calibration data.	
	The laboratory shall have instructions on the use and operation of all relevant equipment, and on the handling and preparation of items for testing and/or calibration, or both, where the absence of such instructions could jeopardize the results of tests and/or calibrations. All instructions, standards, manuals and reference data relevant to the work of the laboratory shall be kept up to date and shall be made readily available to personnel (see 4.3). Deviation from test and calibration methods shall occur only if the deviation has been documented, technically justified, authorized, and accepted by the customer.	

No.	Requirement	Policy # Hyperlinks
	Note: International, regional or national standards or other recognized specifications that contain sufficient and concise information on how to perform the tests and/or calibrations do not need to be supplemented or rewritten as internal procedures if these standards are written in a way that they can be used as published by the operating staff in a laboratory. It may be necessary to provide additional documentation for optional steps in the method or additional details.	
5.4.2	Selection of Methods	
	The laboratory shall use test and/or calibration methods, including methods for sampling, which meet the needs of the customer and which are appropriate for the tests and/or calibrations it undertakes. Methods published in international, regional, or national standards shall preferably be used. The laboratory shall ensure that it uses the latest valid edition of a standard unless it is not appropriate or possible to do so. When necessary, the standard shall be supplemented with additional details to ensure consistent application.	
	When the customer does not specify the method to be used, the laboratory shall select appropriate methods that have been published either in international, regional or national standards, or by reputable technical organizations, or in relevant scientific texts or journals, or as specified by the manufacturer of the equipment. Laboratory-developed methods or methods adopted by the laboratory may also be used if they are appropriate for the intended use and if they are validated. The customer shall be informed as to the method chosen. The laboratory shall confirm that it can properly operate standard methods before introducing the tests or calibrations. If the standard method changes, the confirmation shall be repeated.	
	The laboratory shall inform the customer when the method proposed by the customer is considered to be inappropriate or out of date.	
5.4.3	Laboratory Developed Methods	
	The introduction of test and calibration methods developed by the laboratory for its own use shall be a planned activity and shall be assigned to qualified personnel equipped with adequate resources.	
	Plans shall be updated as development proceeds and effective communication amongst all personnel involved shall be ensured.	

No.	Requirement	Policy # Hyperlinks
5.4.4	Non-standard Methods	
	When it is necessary to use methods not covered by standard methods, these shall be subject to agreement with the customer and shall include a clear specification of the customer's requirements and the purpose of the test and/or calibration. The method developed shall have been validated appropriately before use.	

	Note: For new test and/or calibration methods, procedures should be developed prior to the tests and/or calibrations being performed and should contain at least the following information:
	• Parameters or quantities and ranges to be determined
	• Apparatus and equipment, including technical performance requirements
	• Reference standards and reference materials required
	• Environmental conditions required and any stabilization period needed
	• Description of the procedure, including
	  • Affixing of identification marks, handling, transporting, storing and preparation of items
	  • Checks to be made before the work is started
	  • Checks that the equipment is working properly and, where required, calibration and adjustment of the equipment before each use
	  • The method of recording the observations and results,
	  • Any safety measures to be observed
	• Criteria and/or requirements for approval/rejection
	• Data to be recorded and method of analysis and presentation
	• The uncertainty or the procedure for estimating uncertainty	

5.4.5	Validation of Methods	
5.4.5.1	Validation is the confirmation by examination and the provision of objective evidence that the particular requirements for a specific intended use are fulfilled.	
5.4.5.2	The laboratory shall validate non-standard methods, laboratory-designed/developed methods, standard methods used outside their intended scope, and amplifications and modifications of standard methods to confirm that the methods are fit for the intended use. The validation shall be as extensive as is necessary to meet the needs of the given application or field of application. The laboratory shall record the results obtained, the procedure used for the validation, and a statement as to whether the method is fit for the intended use.	

No.	Requirement	Policy # Hyperlinks
	Note 1: Validation may include procedures for sampling, handling and transportation. ***Note 2:*** The techniques used for the determination of the performance of a method should be one of, or a combination of the following: • Calibration using reference standards or reference materials • Comparison of results achieved with other methods • Interlaboratory comparisons • Systematic assessment of the factors influencing the results • Assessment of the uncertainty of the results based on scientific understanding of the theoretical principles of the method and practical experience ***Note 3:*** When some changes are made in the validated non-standard methods, the influence of such changes should be documented and, if appropriate, a new validation should be carried out.	
5.4.5.3	The range and accuracy of the values obtainable from validated methods (e.g., the uncertainty of the results, detection limit, selectivity of the method, linearity, limit of repeatability and/or reproducibility, robustness against external influences and/or cross-sensitivity against interference from the matrix of the sample/test object), as assessed for the intended use, shall be relevant to the customers' needs.	
	Note 1: Validation includes specification of the requirements, determination of the characteristics of the methods, a check that the requirements can be fulfilled by using the method, and a statement on the validity. ***Note 2:*** As method-development proceeds, regular review should be carried out to verify that the needs of the customer are still being fulfilled. Any change in requirements requiring modifications to the development plan should be approved and authorized. ***Note 3:*** Validation is always a balance between costs, risks and technical possibilities. There are many cases in which the range and uncertainty of the values (e.g., accuracy, detection limit, selectivity, linearity, repeatability, reproducibility, robustness and cross-sensitivity) can only be given in a simplified way due to lack of information.	
5.4.6	Estimation of Uncertainty of Measurements	

No.	Requirement	Policy # Hyperlinks
5.4.6.1	A calibration laboratory, or a testing laboratory performing its own calibrations, shall have and shall apply a procedure to estimate the uncertainty of measurement for all calibrations and types of calibrations.	
5.4.6.2	Testing laboratories shall have and shall apply procedures for estimating uncertainty of measurement. In certain cases the nature of the test method may preclude rigorous, metrologically and statistically valid calculation of uncertainty of measurement. In these cases the laboratory shall at least attempt to identify all the components of uncertainty and make a reasonable estimation, and shall ensure that the form of reporting of the result does not give a wrong impression of the uncertainty. Reasonable estimation shall be based on knowledge of the performance of the method and on the measurement scope and shall make use of, for example, previous experience and validation data.	
	Note 1: The degree of rigor needed in an estimation of uncertainty of measurement depends on factors such as: • The requirements of the test method • The requirements of the customer • The existence of narrow limits on which decisions on conformance to a specification are based ***Note 2:*** In those cases where a well-recognized test method specifies limits to the values of the major sources of uncertainty of measurement and specifies the form of presentation of calculated results, the laboratory is considered to have satisfied this clause by following the test method and reporting instructions (see 5.10).	
5.4.6.3	When estimating the uncertainty of measurement, all uncertainty components which are of importance in the given situation shall be taken into account using appropriate methods of analysis.	
	Note 1: Sources contributing to the uncertainty include, but are not necessarily limited to, the reference standards and reference materials used, methods and equipment used, environmental conditions, properties and condition of the item being tested or calibrated, and the operator. ***Note 2:*** The predicted long-term behavior of the tested and/or calibrated item is not normally taken into account when estimating the measurement uncertainty. ***Note 3:*** For further information, see ISO 5725 and the Guide to the Expression of Uncertainty in Measurement.	

No.	Requirement	Policy # Hyperlinks
5.4.7	Control of Data	
5.4.7.1	Calculations and data transfers shall be subject to appropriate checks in a systematic manner.	
5.4.7.2	When computers or automated equipment are used for the acquisition, processing, recording, reporting, storage or retrieval of test or calibration data, the laboratory shall ensure that:	
a)	Computer software developed by the user is documented in sufficient detail and is suitably validated as being adequate for use;	
b)	procedures are established and implemented for protecting data; such procedures shall include, but not be limited to, integrity and confidentiality of data entry or collection, data storage, data transmission and data processing;	
c)	computers and automated equipment are maintained to ensure proper functioning and are provided with the environmental and operating conditions necessary to maintain the integrity of test and calibration data.	
	Note: Commercial off-the-shelf software (e.g., word processing, database and statistical programs) in general use within their designed application range may be considered to be sufficiently validated. However, laboratory software configuration/ modifications should be validated as in 5.4.7.2.a.	
5.5	**Equipment**	
5.5.1	The laboratory shall be furnished with all items of sampling, measurement and test equipment required for the correct performance of the tests and/or calibrations (including sampling, preparation of test and/or calibration items, processing and analysis of test and/or calibration data). In those cases where the laboratory needs to use equipment outside its permanent control, it shall ensure that the requirements of this International Standard are met.	
5.5.2	Equipment and its software used for testing, calibration and sampling shall be capable of achieving the accuracy required and shall comply with specifications relevant to the tests and/or calibrations concerned. Calibration programs shall be established for key quantities or values of the instruments where these properties have a significant effect on the results. Before being placed into service, equipment (including that used for sampling) shall be calibrated or checked to establish that it meets the laboratory's specification requirements and complies with the relevant standard specifications. It shall be checked and/or calibrated before use (see 5.6).	

No.	Requirement	Policy # Hyperlinks
5.5.3	Equipment shall be operated by authorized personnel. Up-to-date instructions on the use and maintenance of equipment (including any relevant manuals provided by the manufacturer of the equipment) shall be readily available for use by the appropriate laboratory personnel.	
5.5.4	Each item of equipment and its software used for testing and calibration and significant to the result shall, when practicable, be uniquely identified.	
5.5.5	Records shall be maintained for each item of equipment and its software significant to the tests and/or calibrations performed. The records shall include at least the following: • The identity of the item of equipment and its software; • the manufacturer's name, type identification, and serial number or other unique identification; • check that equipment complies with the specification (see 5.5.2); • the current location, where appropriate; • the manufacturer's instructions, if available, or reference to their location; • dates, results and copies of reports and certificates of all calibrations, adjustments, acceptance criteria, and the due date of next calibration; • the maintenance plan, where appropriate, and maintenance carried out to date; • any damage, malfunction, modification or repair to the equipment.	
5.5.6	The laboratory shall have procedures for safe handling, transport, storage, use and planned maintenance of measuring equipment to ensure proper functioning and in order to prevent contamination or deterioration.	
	Note: Additional procedures may be necessary when measuring equipment is used outside the permanent laboratory for tests, calibrations or sampling.	
5.5.7	Equipment that has been subjected to overloading or mishandling, gives suspect results, or has been shown to be defective or outside specified limits, shall be taken out of service. It shall be isolated to prevent its use or clearly labeled or marked as being out of service until it has been repaired and shown by calibration or test to perform correctly. The laboratory shall examine the effect of the defect or departure from specified limits on previous tests and/or calibrations and shall institute the "Control of nonconforming work" procedure (see 4.9).	

No.	Requirement	Policy # Hyperlinks
5.5.8	Whenever practicable, all equipment under the control of the laboratory and requiring calibration shall be labeled, coded or otherwise identified to indicate the status of calibration, including the date when last calibrated and the date or expiration criteria when recalibration is due.	
5.5.9	When, for whatever reason, equipment goes outside the direct control of the laboratory, the laboratory shall ensure that the function and calibration status of the equipment are checked and shown to be satisfactory before the equipment is returned to service.	
5.5.10	When intermediate checks are needed to maintain confidence in the calibration status of the equipment, these checks shall be carried out according to a defined procedure.	
5.5.11	Where calibrations give rise to a set of correction factors, the laboratory shall have procedures to ensure that copies (e.g., in computer software) are correctly updated.	
5.5.12	Test and calibration equipment, including both hardware and software, shall be safeguarded from adjustments which would invalidate the test and/or calibration results.	
5.6	**Measurement Traceability**	
5.6.1	General	
	All equipment used for tests and/or calibrations, including equipment for subsidiary measurements (e.g. for environmental conditions) having a significant effect on the accuracy or validity of the result of the test, calibration or sampling shall be calibrated before being put into service. The laboratory shall have an established program and procedure for the calibration of its equipment.	
	Note: Such a program should include a system for selecting, using, calibrating, checking, controlling and maintaining measurement standards, reference materials used as measurement standards, and measuring and test equipment used to perform tests and calibrations.	
5.6.2	Specific Measurements	
5.6.2.1	Calibration	
5.6.2.1.1.1	For calibration laboratories, the program for calibration of equipment shall be designated and operated so as to ensure that calibrations and measurements made by the laboratory are traceable to the International System of Units (SI).	

No.	Requirement	Policy # Hyperlinks
	A calibration laboratory establishes traceability of its own measurement standards and measuring instruments to the SI by means of an unbroken chain of calibrations or comparisons linking them to relevant primary standards of the SI units of measurement. The link to SI units may be achieved by reference to national measurement standards. National measurement standards may be primary standards, which are primary realizations of the SI units or agreed representations of SI units based on fundamental physical constants, or they may be secondary standards which are standards calibrated by another national metrology institute. When using external calibration services, traceability of measurement shall be assured by the use of calibration services from laboratories that can demonstrate competence, measurement capability and traceability. The calibration certificates issued by these laboratories shall contain the measurement results, including the measurement uncertainty and/or a statement of compliance with an identified metrological specification (see also 5.10.4.2).	
	Note 1: Calibration laboratories fulfilling the requirements of this International Standard are considered to be competent. A calibration certificate bearing an accreditation body logo from a calibration laboratory accredited to this International Standard, for the calibration concerned, is sufficient evidence of traceability to the calibration data reported. ***Note 2:*** Traceability of SI units of measurement may be achieved by reference to an appropriate primary standard (see VIM:1993, 6.4) or by reference to a natural constant, the value of which in terms of the relevant SI unit is known and recommended by the General Conference of Weight and Measures (CGPM) and the International Committee for Weights and Measures (CIPM). ***Note 3:*** Calibration laboratories that maintain their own primary standard or representation of SI units based on fundamental physical constants can claim traceability to the SI system only after these standards have been compared, directly or indirectly, with other similar standards of a national metrology institute. ***Note 4:*** The term "identified metrological specification" means that it must be clear from the calibration certificate which specification the measurements have been compared with, by including the specification or by giving an unambiguous reference to the specification.	

No.	Requirement	Policy # Hyperlinks
	Note 5: When the terms "international standard" or "national standard" are used in connection with traceability, it is assumed that these standards fulfil the properties of primary standards for the realization of SI units. ***Note 6:*** Traceability to national measurement standards does not necessarily require the use of the national metrology institute of the country in which the laboratory is located. ***Note 7:*** If a calibration laboratory wishes or needs to obtain traceability from a national metrology institute other than in its own country, this laboratory should select a national metrology institute that actively participated in the activities of BIPM either directly or through regional groups. ***Note 8:*** The unbroken chain of calibrations or comparisons may be achieved in several steps carried out by different laboratories that can demonstrate traceability.	
5.6.2.1.2	There are certain calibrations that currently cannot be strictly made in SI units. In these cases calibration shall provide confidence in measurements by establishing traceability to appropriate measurement standards such as:	
a)	The use of certified reference materials provided by a competent supplier to give a reliable physical or chemical characterization of a material.	
b)	the use of specified methods and/or consensus standards that are clearly described and agreed by all parties concerned.	
	Participation in a suitable program of interlaboratory comparisons is required where possible.	
5.6.2.2	Testing	
5.6.2.2.1	For testing laboratories, the requirements given in 6.6.2.1 apply for measuring and test equipment with measuring functions used, unless it has been established that the associated contribution from the calibration contributes little to the total uncertainty of the test result. When this situation arises, the laboratory shall ensure that the equipment used can provide the uncertainty of measurement needed.	
	Note: The extent to which the requirements in 5.6.2.1 should be followed depends on the relative contribution of the calibration uncertainty to the total uncertainty. If calibration is the dominant factor, the requirements should be strictly followed.	

No.	Requirement	Policy # Hyperlinks
5.6.2.2.2	Where traceability of measurements to SI units is not possible and/or not relevant, the same requirements for traceability to, for example, certified reference materials, agreed methods and/or consensus standards are required as for calibration laboratories (see 5.6.2.1.2).	
5.6.3	Reference Standards and Reference Materials	
5.6.3.1	Reference Standards	
	The laboratory shall have a program and procedure for the calibration of its reference standards. Reference standards shall be calibrated by a body that can provide traceability as described in 5.6.2.1. Such reference standards of measurement held by the laboratory shall be used for calibration only and for no other purpose, unless it can be shown that their performance as reference standards would not be invalidated. Reference standards shall be calibrated before and after any adjustment.	
5.6.3.2	Reference Materials	
	Reference materials shall, where possible, be traceable to SI units of measurement, or to certified reference materials. Internal reference materials shall be checked as far as is technically and economically practicable.	
5.6.3.3	Intermediate Checks	
	Checks needed to maintain confidence in the calibration status of reference, primary, transfer or working standards and reference materials shall be carried out according to defined procedures and schedules.	
5.6.3.4	Transport and Storage	
	The laboratory shall have procedures for safe handling, transport, storage and use of reference standards and reference materials in order to prevent contamination or deterioration and in order to protect their integrity. ***Note:*** Additional procedures may be necessary when reference standards and reference materials are used outside the permanent laboratory for tests, calibrations or sampling.	
5.7	**Sampling**	
5.7.1	The laboratory shall have a sampling plan and procedures for sampling when it carries out sampling of substances, materials or products for subsequent testing or calibration. The sampling plan as well as the sampling procedure shall be available at the location where sampling is undertaken. Sampling plans shall, whenever reasonable, be based on appropriate statistical methods. The sampling process shall address the factors to be controlled to ensure the validity of the test and calibration results.	

No.	Requirement	Policy # Hyperlinks
	Note 1: Sampling is a defined procedure whereby a part of a substance, material or product is taken to provide for testing or calibration of a representative sample of the whole. Sampling may also be required by the appropriate specification for which the substance, material or product is to be tested or calibrated. In certain cases (e.g., forensic analysis), the sample may not be representative but is determined by availability. ***Note 2:*** Sampling procedures should describe the selection, sampling plan, withdrawal and preparation of a sample or samples from a substance, material or product to yield the required information.	
5.7.2	Where the customer requires deviations, additions or exclusions from the documented sampling procedure, these shall be recorded in detail with the appropriate sampling data and shall be included in all documents containing test and/or calibration results, and shall be communicated to the appropriate personnel.	
5.7.3	The laboratory shall have procedures for recording relevant data and operations relating to sampling that forms part of the testing or calibration that is undertaken. These records shall include the sampling procedure used, the identification of the sampler, environmental conditions (if relevant) and diagrams or other equivalent means to identify the sampling location as necessary and, if appropriate, the statistics the sampling procedures are based upon.	
5.8	**Handling of Test and Calibration Items**	
5.8.1	The laboratory shall have procedures for the transportation, receipt, handling, protection, storage, retention and/or disposal of test and/or calibration items, including all provisions necessary to protect the integrity of the test or calibration item, and to protect the interests of the laboratory and the customer.	
5.8.2	The laboratory shall have a system for identifying test and/or calibration items. The identification shall be retained throughout the life of the item in the laboratory. The system shall be designed and operated so as to ensure that items cannot be confused physically or when referred to in records or other documents. The system shall, if appropriate, accommodate a sub-division of groups of items and the transfer of items within and from the laboratory.	

No.	Requirement	Policy # Hyperlinks
5.8.3	Upon receipt of the test or calibration item, abnormalities or departures from normal or specified conditions, as described in the test or calibration method, shall be recorded. When there is doubt as to the suitability of an item for test or calibration, or when an item does not conform to the description provided, or the test or calibration required is not specified in sufficient detail, the laboratory shall consult the customer for further instructions before proceeding and shall record the discussion.	
5.8.4	The laboratory shall have procedures and appropriate facilities for avoiding deterioration, loss or damage to the test or calibration item during storage, handling and preparation. Handling instructions provided with the item shall be followed. When items have to be stored or conditioned under specified environmental conditions, these conditions shall be maintained, monitored and recorded. Where a test or calibration item or a portion of an item is to be held secure, the laboratory shall have arrangements for storage and security that protect the condition and integrity of the secured items or a portion of an item is to be held secure, the laboratory shall have arrangements for storage and security that protect the condition and integrity of the secured items or portions concerned.	
	Note 1: Where test items are to be returned into service after testing, special care is required to ensure that they are not damaged or injured during the handling, testing or storing/ waiting process. ***Note 2:*** A sampling procedure and information on storage and transport of samples, including information on sampling factors influencing the test or calibration result, should be provided to those responsible for taking and transporting the samples. ***Note 3:*** Reasons for keeping a test or calibration item secure can be the reasons of record, safety or value, or to enable complementary tests and/or calibrations to be performed later.	
5.9	**Assuring the Quality of Test and Calibration Results**	
5.9.1.	The laboratory shall have quality control procedures for monitoring the validity of tests and calibrations undertaken. The resulting data shall be recorded in such a way that trends are detectable and where practicable, statistical techniques shall be applied to the reviewing of the results. This monitoring shall be planned and reviewed and may include, but not be limited to the following:	

No.	Requirement	Policy # Hyperlinks
a)	Regular use of certified reference materials and/or internal quality control using secondary reference materials;	
b)	participation in interlaboratory comparison or proficiency-testing programs;	
c)	replicate tests or calibrations using the same or different methods;	
d)	retesting or recalibration of retained items;	
e)	correlation of results for different characteristics of an item.	
	Note: The selected methods should be appropriate for the type and volume of work undertaken.	
5.9.2.	Quality control data shall be analyzed and, where they are found to be outside pre-defined, planned action shall be taken to correct the problem and to prevent incorrect results from being reported.	
5.10	**Reporting the Results**	
5.10.1	General	
	The results of each test, calibration, or series of tests or calibrations carried out by the laboratory shall be reported accurately, clearly, unambiguously and objectively, and in accordance with any specific instructions in the test or calibration methods.	
	The results shall be reported, usually in a test report or a calibration certificate (see Note 1), and shall include all the information requested by the customer and necessary for the interpretation of the test or calibration results and all information required by the method used. This information is normally that required by 5.10.2, and 5.10.3 or 5.10.4.	
	In the case of tests or calibrations performed for internal customers, or in the case of a written agreement with the customer, the results may be reported in a simplified way. Any information listed in 5.10.2 to 5.10.4 which is not reported to the customer shall be readily available in the laboratory which carried out the tests and/or calibrations.	
	Note 1: Test reports and calibration certificates are sometimes called test certificates and calibration reports, respectively. ***Note 2:*** The test reports or calibration certificates may be issued as hard copy or by electronic data transfer provided that the requirements of this International Standard are met.	
5.10.2	Test Reports and Calibration Certificates	

No.	Requirement	Policy # Hyperlinks
	Each test report or calibration certificate shall include at least the following information, unless the laboratory has valid reasons for not doing do: 1. A title (e.g., "Test Report" or Calibration Certificate"); 2. the name and address of the laboratory, and the location where the tests and/or calibrations were carried out, if different from the address of the laboratory; 3. unique identification of the test report or calibration certificate (such as the serial number), and on each page the identification in order to ensure that the page is recognized as part of the test report or calibration certificate, and a clear identification of the end of the test report or calibration certificate; 4. the name and address of the customer; 5. identification of the method used; 6. a description of, the condition of, and unambiguous identification of the item(s) tested or calibrated; 7. the date of receipt of the test or calibration item(s) where this is critical to the validity and application of the results, and the date(s) of performance of the test or calibration; 8. reference to the sampling plan and procedures used by the laboratory or other bodies where these are relevant to the validity or application of the results; 9. the test or calibration results with, where appropriate, the units of measurement; 10. the name(s), function(s) and signature(s) or equivalent identification of person(s) authorizing the test report or calibration certificate; 11. where relevant, a statement to the effect that the results relate only to the items tested or calibrated.	
	Note 1: Hard copies of test reports and calibration certificates should also include the page number and total number of pages. ***Note 2:*** It is recommended that laboratories include a statement specifying that the test report or calibration certificate shall not be reproduced except in full, without written approval of the laboratory.	
5.10.3	Test Reports	
5.10.3.1	In addition to the requirements listed in 5.10.2, test reports shall, where necessary for the interpretation of the test results, include the following:	

No.	Requirement	Policy # Hyperlinks
a)	deviations from, additions to, or exclusions from the test method, and information on specific test conditions, such as environmental conditions;	
b)	where relevant, a statement of compliance/non-compliance with requirements and/or specifications;	
c)	where applicable, a statement on the estimated uncertainty of measurement; information on uncertainty is needed in test reports when it is relevant to the validity or application of the test results, when a customer's instructions so requires, or when the uncertainty affects compliance to a specification limit;	
d)	where appropriate and needed, opinions and interpretations (see 5.10.5);	
e)	additional information which may be required by specific methods, customers or groups of customers.	
5.10.3.2	In addition to the requirements listed in 5.10.2 and 5.10.3.1, test reports containing the results of sampling shall include the following, where necessary for the interpretation of test results: • The date of sampling; • unambiguous identification of the substance, material or product sampled (including the name of the manufacturer, the model or type of designation and serial numbers as appropriate); • the location of sampling, including any diagrams, sketches or photographs; • a reference to the sampling plan and procedures used; • details of any environmental conditions during sampling that may affect the interpretation of the test results; • any standard or other specification for the sampling method or procedure, and deviations, additions to or exclusions from the specification concerned.	
5.10.4	Calibration Certificates	
	In addition to the requirements listed in 5.10.2, calibration certificates shall include the following, where necessary for the interpretation of calibration results: • The conditions (e.g., environmental) under which the calibrations were made that have an influence on the measurement results; • the uncertainty of measurement and/or a statement of compliance with an identified metrological specification or clauses thereof; • evidence that the measurements are traceable (see Note 2 in 5.6.2.1.1).	

No.	Requirement	Policy # Hyperlinks
5.10.4.2	The calibration certificate shall relate only to quantities and the results of functional tests. If a statement of compliance with a specification is made, this shall identify which clauses of the specification are met or net met.	
	When a statement of compliance with a specification is made omitting the measurement results and associated uncertainties, the laboratory shall record those results and maintain them for possible future reference.	
	When statements of compliance are made, the uncertainty of measurement shall be taken into account	
5.10.4.3	When an instrument for calibration has been adjusted or repaired, the calibration results before and after adjustment or repair, if available, shall be reported.	
5.10.4.4	A calibration certificate (or calibration label) shall not contain any recommendation on the calibration interval except where this has been agreed with the customer. This requirement may be superseded by legal regulations.	
5.10.5	Opinions and Interpretations	
	When opinions and interpretations are included, the laboratory shall document the basis upon which the opinions and interpretations have been made. Opinions and interpretations shall be clearly marked as such in a test report.	
	Note 1: Opinions and interpretations should not be confused with inspections and product certifications as intended in ISO/IEC 17020 and ISO/IEC Guide 65. ***Note 2:*** Opinions and interpretations included in a test report may comprise, but not be limited to the following: • An opinion on the statement of compliance/noncompliance of the results with requirements; • fulfillment of contractual requirements; • recommendations on how to use the results; • guidance to be used for improvements. ***Note 3:*** In many cases it might be appropriate to communicate the opinions and interpretations by direct dialogue with the customer. Such dialogue should be written down.	
5.10.6	Testing Calibration Results Obtained from Subcontractors	
	When the test report contains results of tests performed by subcontractors, these results shall be clearly identified. The subcontractor shall report the results in writing or electronically.	

No.	Requirement	Policy # Hyperlinks
	When a calibration has been subcontracted, the laboratory performing the work shall issue the calibration certificate to the contracting laboratory.	
5.10.7	Electronic Transmission of Results	
	In the case of transmission of test or calibration results by telephone, telex, facsimile or other electronic or electromagnetic means, the requirements of this International Standard shall be met (see also 5.4.7).	
5.10.8	Format of Reports and Certificates	
	The format shall be designed to accommodate each type of test or calibration carried out and to minimize the possibility of misunderstanding or misuse.	
	Note 1: Attention should be given to the lay-out of the test report or calibration certificate, especially with regard to the presentation of the test or calibration data and ease of assimilation by the reader. ***Note 2:*** The headings should be standardized as far as possible.	
5.10.9	Amendments to Test Reports and Calibration Certificates	
	Material amendments to a test report or calibration certificate after issue shall be made only in the form of a further document, or data transfer, which includes the statement: "Supplement to Test Report (or Calibration Certificate), serial number…(or otherwise identified)", or an equivalent form of wording.	
	Such amendments shall meet all the requirements of this International Standard.	
	When it is necessary to issue a complete new report or calibration certificate, this shall be uniquely identified and shall contain a reference to the original that it replaces.	

DNA Quality Audit Criteria File

http://www.fbi.gov/hq/lab/fsc/backissu/july2004/pdfs/seubert.pdf#search=%22DNA%20Quality%20Assurance%20Audit%20Criteria%20File%22

(Rev. 2006-1)

KEY: Underlined Text = hyperlink directly to file or book-marked area of file

QUALITY ASSURANCE PROGRAM		
3.1	Does the DNA laboratory have an established and maintained documented quality system that is appropriate to the testing activities?	
3.1.1 Do clearly written and well understood procedures exist for the following:		
A	Goals and objectives	
B	Organization and management structure	
C	Personnel qualifications and training	
D	Facilities	
E	Evidence Control	
F	Validation	
G	Analytical procedures	
H	Calibration and maintenance	
I	Proficiency testing	
J	Corrective action	
K	Reports	
L	Review	
M	Safety	
N	Audits	

ORGANIZATION AND MANAGEMENT		
4.1.a	Has the managerial staff of the laboratory been provided the authority and resources needed to discharge their duties and meet the requirements of the standards in this document?	
4.1.b	Does the laboratory have a designated technical manager or leader who is accountable for the technical operations?	
4.1.c	Does the laboratory specify and document the responsibility, authority, and interrelation of all personnel who manage, perform or verify work affecting the validity of the DNA analysis? (CO 4.1.c)	
4.1.c (CO)	Does the laboratory have a CODIS manager or custodian who is accountable for CODIS operations?	

PERSONNEL		
5.1	Do the laboratory personnel have the education, training and experience commensurate with the examination and testimony provided?	
5.1.1	Does the laboratory have written job descriptions for all personnel to include responsibilities, duties and skills?	
5.1.2	Does the laboratory have a documented training program for qualifying all technical laboratory personnel?	
5.1.3	Does the laboratory have a documented program to ensure that technical qualifications are maintained through continuing education?	
5.1.3.1.a	Over the last year, has the technical manager or leader read current scientific literature?	
5.1.3.1.b	Over the last year, has the technical manager or leader attended at least one seminar, course, professional meeting or training session/class which addresses subject matter related to DNA analysis?	
5.1.3.1.c (CO)	Over the last year, has the CODIS manager read current scientific literature?	
5.1.3.1.d (CO)	Over the last year, has the CODIS manager attended at least one seminar, course, professional meeting or training session/class which addresses subject matter related to DNA analysis?	
5.1.3.1.e	Over the last year, has each examiner/analyst read current scientific literature?	
5.1.3.1.f	Over the last year, has each examiner/analyst attended at least one seminar, course, professional meeting or training session/class which addressed subject matter related to DNA analysis?	
5.1.4	Does the laboratory maintain records on the relevant qualifications, training, skills and experience of all technical personnel?	
5.2	Does the technical manager or leader satisfy the degree/educational, experience and duty requirements as listed in standards 5.2.1 through 5.2.3?	
5.2.1	Does the technical manager or leader of the laboratory meet the following degree/educational requirements or have a waiver as stated in standard 5.2.1.1?	
5.2.1.A	A graduate degree in a biology, chemistry or forensic science related area.	

5.2.1.B A minimum of 12 credit hours or its equivalent including a combination of graduate and undergraduate course work or classes covering the subject areas of:		
a	Biochemistry	
b	Genetics	
c	Molecular biology	
d	Statistics and/or population genetics	
5.2.1.1	Does the technical manager or leader possess a waiver from the ASCLD or other organization designated by the Director of the FBI?	
5.2.2	Does the technical manager or leader of the laboratory have a minimum of three years forensic DNA laboratory experience?	
5.2.3	Does the technical manager or leader of the laboratory meet the duty requirements of this standard?	
5.2.3.1	Does the technical manager or leader manage the technical operations of the laboratory?	
5.2.3.2.a-1	Is the technical manager or leader responsible for evaluation all methods used by the laboratory?	
5.2.3.2.a-2	Is the technical manager or leader responsible for proposing new or modified analytical procedures to be used by the examiners?	
5.2.3.2.b-1	Is the technical manager or leader responsible for technical problem solving of analytical methods?	
5.2.3.2.b-2	Is the technical manager or leader responsible for the oversight of training, quality assurance, safety and proficiency testing in the laboratory?	
5.2.3.3	Is the technical manager or leader accessible to the laboratory to provide onsite, telephonic or electronic consultation as needed?	
5.3 (FO)	Does each examiner/analyst satisfy the degree/ educational, experience and duty requirements as listed in standards 5.3.1 through 5.3.3?	
5.3.1	Does each examiner/analyst meet the following degree/ educational requirements?	
5.3.1.A	A BA/BS degree or its equivalent in a biology, chemistry, or forensic science related area?	
5.3.1.B College course work or classes covering the subject areas of:		
a	Biochemistry	
b	Genetics	
c	Molecular Biology	
5.3.1.C	College coursework or training which covers the subject area of statistics and/or population genetics?	

5.3 (CO)	Does the CODIS manager or custodian satisfy the degree/educational, experience and duty requirements as listed in the Convicted Offender standards 5.3.1 through 5.3.3?	
5.3.1	Does the CODIS manager or custodian possess a bachelor's degree in a natural science or computer science?	
5.3.2.a Does the CODIS manager or custodian have a working knowledge of the following:		
a	Computers	
b	Computer networks	
c	Computer database management	
5.3.2.b	Does the CODIS manager or custodian have an understanding of DNA profile interpretation?	
5.3.3	Does the CODIS manager or custodian meet the duty requirements of this position?	
5.3.3.a-1	Does the CODIS manager or custodian function as the system administrator of the laboratory's CODIS network?	
5.3.3.a-2	Is the CODIS manager or custodian responsible for the security of the DNA profile data stored in CODIS?	
5.3.3.b	Is the CODIS manager or custodian responsible for oversight of the CODIS computer training and quality assurance of data?	
5.5.3.c-1	Does the CODIS manager or custodian have the authority to terminate the laboratory's participation in CODIS in the event of a problem until the reliability of the computer data can be assured?	
5.3.3.c-2	Does the state CODIS manager or custodian have this authority over all CODIS sites under is/her jurisdiction?	
5.4	Does each technician meet the training and qualification requirements as stated in standards 5.4.1 and 5.4.2?	
5.4.1	Did each technician receive on the job training specific to their job function?	
5.4.2	Did each technician successfully complete a qualifying test before participating in forensic DNA typing responsibilities?	
5.5	Do all laboratory support personnel meet the requirements as stated in standard 5.5.1?	
5.5.1	Do all laboratory support personnel possess the training, education and experience commensurate with their responsibilities as outlined in their job descriptions?	

FACILITIES		
6.1	Is the laboratory designed to provide adequate security and minimize contamination?	
6.1.1	Is access to the laboratory controlled and limited?	
6.1.2	Are evidence examinations, DNA extractions and PCR setup conducted at separate times or in separate spaces?	
6.1.2 (CO)	Are evidence examinations, liquid sample examinations, DNA extractions and PCR setup conducted at separate times or in separate spaces?	
6.1.3	Is amplified DNA product generated, processed and maintained in a room(s) separate from the evidence examination, DNA extractions and PCR setup areas?	
6.1.3 (CO)	Is amplified DNA product generated, processed and maintained in a room(s) separate from the evidence examination, liquid sample examinations, DNA extractions and PCR setup areas?	
6.1.4 (CO)	If a robotic work station is used to carry out DNA extraction and amplification in a single room, can it be demonstrated that contamination is minimized and equivalent to that when performed manually in separate rooms?	
6.1.4	Does the laboratory follow written procedures for monitoring, cleaning and decontaminating facilities and equipment?	

EVIDENCE OR SAMPLE CONTROL		
7.1	Does the laboratory have and follow a documented evidence control system or sample inventory control system (Convicted Offender) for handling and preserving the integrity of physical evidence?	
7.1.1	Is each evidence sample (including Convicted Offender samples) labeled with a unique identifier in accordance with established agency policy?	
7.1.2	Does the laboratory maintain a chain of custody for all evidence?	
7.1.2 (CO)	Does the laboratory document and maintain the identity, collection, receipt, storage and disposition of samples?	
7.1.3	Does the laboratory follow documented procedures that minimize loss, contamination, and/or deleterious change of evidence?	

7.1.4	Does the laboratory have secure areas for evidence storage?	
7.1.4 (CO)	Does the laboratory have secure areas for sample storage including environmental controls consistent with the form or nature of the sample?	
7.2	Does the laboratory retain or return a portion of the evidence sample or extract where possible?	
7.2.1 (FO)	Does the laboratory have a procedure requiring that evidence samples/extract(s) be stored in a manner that minimizes degradation?	

VALIDATION		
8.1	Does the laboratory use methods and procedures for forensic DNA analysis which have been validated prior to casework implementation?	
8.1.1	Have developmental validation studies been conducted and appropriately documented?	
8.1.2	Have novel forensic or database DNA methodologies utilized by the laboratory undergone developmental validation to ensure the accuracy, precision and reproducibility of the procedure?	
8.1.2.1	Is there documentation and is it available which defines and characterizes each locus?	
8.1.2.2 (FO)	Have species' specificity, sensitivity, stability and mixture studies been conducted?	
8.1.2.3 (FO)	Does the laboratory have access to a population data base which is documented and available for use in population statistics?	
8.1.2.3.1 (FO-a)	Where appropriate, has the database been tested for independence expectations?	
8.1.2.3.1 (FO-b)	Does the data base information include allele and frequency distribution for the locus or loci obtained from relevant populations?	
8.1.3	Has the laboratory completed and documented internal validation studies?	
8.1.3.1.a	Has the procedure been tested using known and non-probative evidence samples?	
8.1.3.1.a-CO	Has the procedure been tested using known samples?	
8.1.3.1.b	Has the reproducibility and precision of the procedure been monitored and documented using human DNA control(s)?	
8.1.3.2 (FO)	Based on empirical data, have match criteria been established and documented?	

8.1.3.3	Has the analyst or examination team successfully completed a qualifying test utilizing the DNA analysis procedure prior to its incorporation into case work or database applications? (CO8.1.3.2)	
8.1.3.4	Have material modifications to analytical procedures been documented and subjected to validation testing?	
8.1.4 (FO)	If methods are not specified, does the laboratory, wherever possible, select methods that have been published by reputable technical organizations or in relevant scientific texts or journals, or which have been appropriately evaluated for a specific or unique application?	

ANALYTICAL PROCEDURES		
9.1	Does the laboratory have and follow written analytical procedures approved by laboratory management/ technical manager or leader?	
9.1.1	Does the laboratory have a documented standard operating protocol for each analytical technique used?	
9.1.2	Do the analytical procedures describe reagents, sample preparation, extraction, equipment and controls which ware standard for DNA analysis and interpretation?	
9.1.3 (FO)	Does the laboratory have a procedure for the differential extraction of stains which contain semen?	
9.2	Does the laboratory use reagents that are suitable for the methods employed?	
9.2.1	Does the laboratory have written procedures for documenting commercial supplies and for the formulation of reagents?	
9.2.2	Are reagents labeled with the identity of the reagent, the date of preparation or expiration, and the identity of the individual preparing the reagent?	
9.2.3 (a)	Has the laboratory identified and evaluated the reagents critical to the analysis process prior to use in casework?	
9.2.3 (b)	Has the laboratory identified and evaluated the following critical reagents?	
a	Restriction enzyme	
b	Commercial kits for performing genetic typing	
c	Agarose for analytical RFLP gels	
d	Membranes for Southern blotting	
e	K562 DNA or other human DNA controls	
f	Molecular weight markers used as RFLP sizing standards	
g	Primer sets	
h	Thermostable DNA polymerase	

9.3 (FO)	Does the laboratory have and follow a procedure for evaluating the quantity of DNA in samples?	
9.3.1	Does the laboratory use procedures for establishing the presence of high molecular weight DNA from RFLP casework samples?	
9.4	Does the laboratory monitor the analytical procedures using appropriate controls and standards? (CO 9.3)	
9.4.1	Does the laboratory use the following controls for RFLP casework analysis? (CO 9.3.1)	
9.4.1.1	Quantitation standards which estimate the amount of DNA recovered by extraction? (CO 9.3.1.1)	
9.4.1.2	K562 as a human DNA control? (CO 9.3.1.2)	
9.4.1.3	Molecular weight size markers, at defined intervals, for bracketing known and evidence samples? (CO 9.3.1.3)	
9.4.1.4	Procedure to monitor the completeness of restriction enzyme digestion? (CO 9.3.1.4)	
9.4.2	Does the laboratory use the following controls for PCR casework or database analysis? (CO 9.3.2)	
9.4.2.1	Quantitation standards which estimate the amount of human nuclear DNA recovered by extraction? (CO 9.3.2.1)	
9.4.2.2	Positive and negative amplification controls? (CO 9.3.2.2)	
9.4.2.3 (FO)	Reagent blanks?	
9.4.2.4	Allelic ladders and/or internal size markers for variable number tandem repeat sequence PCR based systems. (CO 9.3.2.4)	
9.5	Does the laboratory check its DNA procedures annually or whenever substantial changes are made to the protocol(s) against an appropriate and available NIST standard reference material (SRM) or standard traceable to a NIST standard? (CO 9.4)	
9.6	Does the laboratory have and follow written general guidelines for the interpretation of data? (CO 9.5)	
9.6.1	Does the laboratory verify that all control results are within established tolerance ranges? (CO 9.5.1)	
9.6.2	Where appropriate, are visual matches supported by a numerical match criterion?	
9.6.3	Has the 1996 National Research Council report and/or a court directed method been used for the statistical interpretation of a DNA profile for a given population and/or hypothesis or relatedness and are these calculations derived from an established population data base appropriate for the calculation?	

EQUIPMENT CALIBRATION AND MAINTENANCE		
10.1	Does the laboratory use equipment which is suitable for the methods employed?	
10.2	Does the laboratory have a documented program for calibration of equipment and instruments?	
10.2.1	Where available and appropriate, are standards traceable to national or international standards used in the calibration of equipment?	
10.2.1.1	Where traceability to national standard of measurement is not applicable, does the laboratory provide satisfactory evidence of correlation of results?	
10.2.2	For each instrument requiring calibration, has the frequency of calibration been documented and has such documentation been retained in accordance with applicable Federal or state law?	
10.3	Does the laboratory have a documented program to ensure that instruments and equipment or properly maintained?	
10.3.1	Have new instruments and equipment, or instruments and equipment that have undergone repair or maintenance, been calibrated before being used in casework analysis?	
10.3.2	Have written records or logs been maintained for maintenance service performed on instrument and equipment and has such documentation been retained in accordance with applicable Federal or state law?	

REPORTS		
11.1	Does the laboratory have and follow written procedures for taking and maintaining case notes to support the conclusions drawn in laboratory requests?	
11.1 (CO)	Does the laboratory have and follow written procedures for generating and maintaining documentation for database samples?	
11.1.1 (FO)	Does the laboratory maintain in a case record, all documentation generated by examiners related to case analyses?	
11.1.1 (CO)	Does the laboratory have written procedures for the release of database sample information?	
a	Case identifier	
b	Description of evidence examined	
c	A description of methodology	
d	Locus	

e	Results and/or conclusions	
f	An interpretative statement (either quantitative or qualitative)	
g	Date issued	
h	Disposition of evidence	
i	A signature and title or equivalent identification of the person(s) accepting responsibility for the content of the report	
11.1.3 (FO)	Does the laboratory have written procedures for the release of case report information?	

REVIEW		
12.1 (FO)	Does the laboratory conduct administrative and technical reviews of all case files and reports to ensure conclusions and supporting data are reasonable and within the constraints of scientific knowledge?	
12.1 (CO)	Does the laboratory have and follow written procedures for reviewing database sample information, results and matches?	
12.1.1	Does the laboratory have a mechanism in place to address unresolved discrepant conclusions between analysts and reviewers?	
12.2	Does the laboratory have and follow a written program that documents the annual monitoring of the testimony of each examiner?	
12.2 (CO)	Does the laboratory have and follow a written program that documents the annual monitoring of the testimony of laboratory personnel?	

PROFICIENCY TESTING		
13.1	Do examiners and other personnel designated by the technical manager or leader who are actively engaged in DNA analysis undergo open external proficiency tests at regular intervals not to exceed 180 days?	
13.1.1 Does the laboratory maintain the following records for proficiency tests and is such documentation retained in accordance with applicable Federal or state law?		
a	The test set identifier	
b	Identity of the examiner	
c	Date of analysis and completion	
d	Copies of all data and notes supporting the conclusions	
e	The proficiency test results	
f	Any discrepancies noted	
g	Corrective action taken	

13.1.2 Has the laboratory established at a minimum the following criteria for evaluation of proficiency tests?		
a	All reported inclusions are correct or incorrect.	
b	All reported exclusions are correct or incorrect.	
c	All reported genotypes and/or phenotypes are correct or incorrect according to consensus genotypes/phenotypes or within established empirically determined ranges.	
d	All results reported as inconclusive or uninterpretable are consistent with written laboratory guidelines. The basis for inconclusive interpretations in proficiency tests must be documented.	
e	All discrepancies/errors and subsequent corrective actions must be documented.	
f	All final reports are graded as satisfactory or unsatisfactory. A satisfactory grade is attained when there are no analytical errors for the DNA profile typing data. Administrative errors shall be documented and corrective actions taken to minimize the error in the future.	
g	All proficiency test participants shall be informed of the final test results.	

CORRECTIVE ACTION		
14.1	Does the laboratory have and follow written procedures for taking corrective action whenever proficiency testing discrepancies and/or case work errors are detected?	
14.1 (CO)	Does the laboratory have and follow written procedures for taking corrective action whenever proficiency testing discrepancies and/or analytical errors are detected?	
14.1.1	Does the laboratory maintain documentation retained in accordance with applicable Federal or state law?	

AUDITS		
15.1	Are audits of the laboratory completed and documented annually?	
15.1.1 Did the audit procedures address the following?		
a	Quality assurance program	
b	Organization and management	
c	Personnel	
d	Facilities	
e	Evidence control	
f	Validation	
g	Analytical procedures	
h	Calibration and maintenance	

i	Proficiency testing	
j	Corrective action	
k	Reports	
l	Review	
m	Safety	
n	Previous audits	
15.1.2	Has the laboratory retained all documentation pertaining to audits in accordance with relevant legal, agency, and state requirements?	
15.2	Did a second agency (external) participate in an annual audit of the laboratory at least once every two years?	

SAFETY		
16.1	Does the laboratory have and follow a documented environmental health and safety program?	

SUBCONTRACTORS OF ANALYTICAL TESTING FOR WHICH VALIDATED PROCEDURES EXIST		
17.1	Does the laboratory require certification of compliance with these standards when a subcontractor performs forensic DNA analyses for the laboratory?	
17.1.1	Has the laboratory established and does the laboratory use appropriate review procedures to verify the integrity of the data received from the subcontractor?	
17.1.1.A (CO)	Has the laboratory established and used review procedures which include (but are not limited to) each of the following?	
a	Random re-analysis of samples	
b	Visual inspection and evaluation of results/data	
c	Inclusion of QC samples	
d	On-site visits	

The signatures below recognize the above Administrative Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director Date

Mary Doe, Quality Assurance Manager Date

End of Document

Policy/Procedure Association

Doc. #	Rev. #	Description	Status	Related Policy	Related Forms

MANAGEMENT AND ORGANIZATION

Definition of Terms

1 PURPOSE

This document defines the terms utilized in **AGENCY NAME's** policy, procedure and technical manuals.

2 SCOPE

This policy applies to all policy, procedure and technical manuals utilized by the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-S015 will be utilized to define terms used in all policy, procedure and technical manuals published by the **AGENCY NAME**.

4 POLICY

The **AGENCY NAME** will establish and maintain a list of terms used in all policy, procedure and technical manuals published by the **AGENCY NAME**.

5 PROCEDURE

There are no procedures that are directly applicable to this policy.

6 APPROVAL

The signatures below recognize the above Administrative Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

MANAGEMENT AND ORGANIZATION

Legal Authority

1 PURPOSE

This document establishes the **AGENCY NAME's** legal authority.

2 SCOPE

This policy applies to all factions of the AGENCY NAME.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

The **AGENCY NAME** operates under the legal authority of **INSERT LEGAL CITATION AND LINK TO STATUTE'S TEXT OR LINK TO THE ORGANIZATION'S ARTICLES OF INCORPORATION**.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

The signatures below recognize the above Administrative Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

MANAGEMENT AND ORGANIZATION

Mission Statement

1 PURPOSE

This document defines **AGENCY NAME's** Mission Statement.

2 SCOPE

This policy applies to all factions of the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

The mission of the **AGENCY NAME** is to provide its users a sustainable level of quality scientific examination services based upon international standards of quality and dedication to continual self improvement if its analytical and management systems.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

The signatures below recognize the above Administrative Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

MANAGEMENT AND ORGANIZATION

Goals and Objectives

1 PURPOSE

This document establishes the **AGENCY NAME's** Goals and Objectives.

2 SCOPE

This policy applies to all factions of the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

The **AGENCY NAME** will establish and maintain a documented set of goals and objectives that are relevant to the needs of the community they sever.

AGENCY NAME employees will be advised of the **AGENCY NAME** goals and objectives and any changes there of.

All employees agree to support the documented goals and objectives of the **AGENCY NAME** by virtue of their employment.

4.1 GOAL ONE

4.1.1 Goal

Goal one of the **AGENCY NAME** is to utilize accepted and validated scientific examination techniques.

4.1.2 Objectives

The **AGENCY NAME** will achieve or maintain Goal One through:

- Identifying and utilizing examination techniques that will satisfy the analytical needs of the **AGENCY NAME's** customers.
- Identifying funding sources that will enable the **AGENCY NAME** to increase their level of technology.
- Increase the level of sustainable technology as funding permits.

4.2 GOAL TWO

4.2.1 Goal

Goal two of the **AGENCY NAME** is to provide quality scientific examinations.

4.2.2 Objectives

The **AGENCY NAME** will achieve or maintain Goal Two through:

- Utilizing examiners with the knowledge skills and abilities required to competently execute the examination.
- Utilizing analytical methods that have been validated and accepted by the scientific community.
- Establishing and maintaining a quality assurance program.
- Obtaining and maintaining laboratory accreditation through a recognized accreditation body.

4.3 GOAL THREE

4.3.1 Goal

Goal three of the **AGENCY NAME** is to continually evaluate and improve the services provided.

4.3.2 Objectives

The **AGENCY NAME** will achieve or maintain Goal Three through:

- Seeking client input and implementing their recommendations within their financial ability.
- Seeking employee input and implementing their recommendations within their financial ability.
- Performing quality systems audits and implement the recommendations within their financial ability.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

The signatures below recognize the above Administrative Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

MANAGEMENT AND ORGANIZATION

Services and Functions

1 PURPOSE

This document defines the services and functions provided by the **AGENCY NAME**.

2 SCOPE

This policy applies to all factions of the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

4.1 GENERAL SERVICES

The **AGENCY NAME** will provide the following analytical services:

- Crime scene response
- Forensic chemistry
  - Controlled substance examinations
  - Toxicology
  - Trace evidence
  - Arson and explosives examinations

- Forensic biology
  - Biological stain identification
  - DNA examinations

- Comparative analysis
  - Fingerprints
  - Firearms examinations
  - Firearms Test Fire Program
  - Tool mark examinations
  - Questioned document examinations

- Digital evidence examinations
  - Photography and video
  - Voice Print analysis
  - Forensic computer examinations

- Laboratory Support
  - Administrative support
  - Technical support
  - Property and Evidence Receipt and Storage

4.2 REGIONAL SERVICES

The **AGENCY NAME** will establish regional facilities to provide services specifically require by the customers in that regional area.

4.2.1 Region 1

The **AGENCY NAME** will provide the following analytical services in Region 1:

- Crime scene response
- Forensic chemistry
  - Controlled substance examinations
  - Toxicology
  - Trace evidence
  - Arson and explosives examinations

- Forensic biology
  - Biological stain identification
  - DNA examinations

- Comparative analysis
  - Fingerprints
  - Firearms examinations
  - Firearms Test Fire Program
  - Tool mark examinations
  - Questioned document examinations

- Digital evidence examinations
  - Photography and video
  - Voice Print analysis
  - Forensic computer examinations

- Laboratory Support
  - Administrative support
  - Technical support
  - Property and Evidence Receipt and Storage

4.2.2 Region X

The **AGENCY NAME** will provide the following analytical services in Region X:

- Crime scene response
- Forensic chemistry
  - Controlled substance examinations
  - Toxicology
  - Trace evidence
  - Arson and explosives examinations
- Forensic biology
  - Biological stain identification
  - DNA examinations
- Comparative analysis
  - Fingerprints
  - Firearms examinations
  - Firearms Test Fire Program
  - Tool mark examinations
  - Questioned document examinations
- Digital evidence examinations
  - Photography and video
  - Voice Print analysis
  - Forensic computer examinations
- Laboratory Support
  - Administrative support
  - Technical support
  - Property and Evidence Receipt and Storage

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

The signatures below recognize the above Administrative Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

MANAGEMENT AND ORGANIZATION

Budget

1 PURPOSE

This document establishes the **AGENCY NAME's** budget policy.

2 SCOPE

This policy applies to all fiscal policies of the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

The senior management of the **AGENCY NAME** will establish and maintain an annual written budget adequate to meet written objectives.

Each section will annually provide the senior management with information concerning their future chemical, equipment and consumable items needs adequate to meet their objectives.

The senior management of the **AGENCY NAWME** will utilize historical budgets, future needs and current financial allocations in developing the current year's budget.

The final written budgets will be filed in accordance with the **AGENCY NAME** document retention policy (Insert Relevant Document Number).

5 PROCEDURE

Budget Development Procedure is defined in the following procedures:
Insert an outline of the budget procedure utilized by your agency.

6 APPROVAL

The signatures below recognize the above Administrative Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

MANAGEMENT AND ORGANIZATION

Policy and Procedure Development and Distribution

1 PURPOSE

This policy establishes the **AGENCY NAME's** policy concerning the development and distribution of policies and procedures.

2 SCOPE

This policy applies to all factions of the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

The **AGENCY NAME** will develop, document and maintain the policies procedures and analytical methods required to operate an analytical laboratory.

All employees of the **AGENCY NAME** will be provided a copy of the most recent revision of the policies, procedures and analytical methods they would be responsible for compliance.

5 PROCEDURE

5.1 DEVELOPMENT

5.1.1 Document Need

The **AGENCY NAME** will develop a new or modify an existing policy or procedure when:

- The Director, senior management or Quality Assurance Manager identifies the need for a new or change of an existing policy or procedure; or
- An employee suggests the need for a new or change of an existing policy or procedure, or
- Changes in legal statutes or applicable case law requires a new or change of an existing policy or procedure; or
- Changes of the administrative regulations within the **AGENCY NAME's** parent organization requires a new or change of an existing policy or procedure.

5.1.2 Document Draft

The Quality Assurance Manager, or his designate, will research and draft a new or change an existing policy or procedure to address the needs identified through one of the above mechanisms.

5.1.3 Document Review

All policy and procedure changes or drafts will be submitted to the Director, or his designee, for review and comment.

The review process for all policy and procedure changes or new drafts is as follows:

- The Quality Assurance Manager will review and submit with comment any policy and procedure change or draft to the Director.
- The Director will distribute the suggested policy and procedure change or draft to the senior management staff for review and comment.
- Comments and suggestions are incorporated into the proposed policy and procedure change or draft.
- The Director and the senior staff will review and comment on the amended policy and procedure change or draft.
- Comments and suggestions are incorporated into the amended policy and procedure change or draft.

Final revision of the policy and procedure change or draft is submitted to the Director for final approval.

5.1.4 Document Approval

The approval process for all administrative policy and procedure changes or new drafts is as follows:

- The Director and the Quality Assurance Manager perform a final administrative review of the proposed new or changes to an existing administrative policy or procedure.
- The Director and the Quality Assurance Manager each sign and date the APPROVAL section of the original document.
- The effective date of the approved document will be the date of the Director's signature
- The Quality Assurance Manager, or his designee, will distribute the new or modified policy or procedure in accordance with dissemination procedure.

5.2 DISSEMINATION

5.2.1 Operational Manuals

The Quality Assurance Manager will:

- Compile the current electronic or print revisions of all operational policies and procedures to create a year's master Operational Manual.
- Create print copies of the Operational Manual for:
  - Each **AGENCY NAME** facility
  - Each **AGENCY NAME** employee

    - Each print copy of the Operational Manual will be placed in a loose leaf binder of sufficient size to accommodate the current manual with room for additional pages as additions and updates occur.
- Number each copy of the **AGENCY NAME** Operational Manual created.
- Distribute copies of the Operational Manual.
    - Operational Manual Distribution will be documented using the Operational Manual Distribution Log.
- Update the master Operational Manual as required.
- Distribute print copies of the approved Operational Manual updates as required.
    - The Quality Assurance Manager may create and distribute electronic copies of the Operational Manual in lieu of, or in addition to, the print copies.

5.2.2 Technical Manuals

The Quality Assurance Manager will:

- Compile the current electronic or print revisions of the technical policies and procedures of each discipline.
- Create print copies of each Technical Manual for:
    - Each AGENCY NAME facility.
    - Each employee with responsibilities in that discipline.
    - Each print copy of the Technical Manual will be placed in a loose leaf binder of sufficient size to accommodate the current manual with room for additional pages as additions and updates occur.
- Number each copy of the Technical Manuals created.
- Distribute copies of the Technical Manual.
- Technical Manual distribution will be documented using the Technical Manual Distribution Log.
- Update the master Technical Manuals as required.
- Distribute print copies of the approved Technical Manual updates as required.
    - The Quality Assurance Manager may create and distribute electronic copies of Technical Manuals in lieu of, or in addition to, the print copies.

5.2.3 Updates

The Quality Assurance Manager will provide all holders of Operational and Technical Manuals copies of the approved updates to their respective manuals, as soon as they are available.

- Update format (print or electronic) will depend upon the format the holder possesses.
- Changes in the document shall be easily identified.
- The distribution of updates to Operational and Technical manuals will be documented by the Quality Assurance Manager.
- The holders of Operational and Technical Manuals are responsible for inserting updated and removing obsolete copies of policies, procedures and methods.
- Holders are responsible for printing electronic files and inserting the printed version into appropriate printed manual, when required.

6 APPROVAL

The signatures below recognize the above Administrative Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

MANAGEMENT AND ORGANIZATION

Policy and Procedure Understanding

1 PURPOSE

This document establishes the **AGENCY NAME's** procedure for documenting an employee's understanding of the official policies and procedures.

2 SCOPE

This procedure applies to all policies and procedures of the **AGENCY NAME** policies and procedures.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

The **AGENCY NAME** will establish procedures to ensure that each employee understands the policies, procedures and analytical methods they are responsible for compliance.

5 PROCEDURE

5.1 OPERATIONAL MANUAL

- Each employee will be issued an Operational Manual to include:
  - Administrative Policy and Procedure Manual.
  - Health and Safety Manual.
  - Property and Evidence Manual.
  - Quality Assurance Manual.
- Each employee will be provided time to review all components of the Operational Manual.
- Each employee will review the contents of all components of the Operational Manual with the Quality Assurance Manager, or his designee.
- Operational Manual review and understanding will be documented using the following forms:
  - Insert Form Number: Administrative Policy Orientation.
  - Insert Form Number: Health and Safety Orientation.
  - Insert Form Number: Health and Safety Review.
  - Insert Form Number: Quality Assurance Orientation.
  - Insert Form Number: Sample Control Orientation.

5.2 TECHNICAL MANUALS

- Each employee will be issued a Technical Manual for each discipline they have analytical responsibility.
- Each employee will be provided time to review all components of the Technical Manual
- Each employee will review the contents of all components of the Technical Manual with the Quality Assurance Manager, or his designee.
- Technical Manual review and understanding will be documented using competency and proficiency testing mechanisms outlined in each Technical Manual.

6 APPROVAL

The signatures below recognize the above Administrative Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

MANAGEMENT AND ORGANIZATION

Long Range Planning

1 PURPOSE

This document establishes the **AGENCY NAME's** long range planning policies.

2 SCOPE

This policy applies to the planning process of the **AGENCY NAME**.

3. DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

The **AGENCY NAME** will establish a long range planning committee.

The long range planning committee will use previous budgets, case load statistics and projected chemical and equipment needs to prepare a 3, 5 and 10 year plans.

The long range planning committee will modify the 3, 5 and 10 year plans as necessary to meet the needs of the **AGENCY NAME**.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

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John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

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MANAGEMENT AND ORGANIZATION

Organizational Structure

1 PURPOSE

This policy establishes the organizational structure of the **AGENCY NAME**.

2 SCOPE

This policy applies to all factions of the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

The management structure shall cover work carried out in permanent facilities, at sites away from its permanent facilities, and in associated temporary or mobile facilities.

The responsibilities of management that have an involvement or influence on the testing and/or calibration activities of the laboratory shall be defined in separately from non-laboratory management managers in order to identify and eliminate potential conflicts of interest.

The organizational structure shall group the work and personnel in a manner that allows for efficiency of operation, taking into account the interrelation of various forensic disciplines.

The Director will consider and taken appropriate action to correct any discrepancies with regard to numbers of personnel when grouping work and resources.

The following documents define the organizational structure that allows for efficiency of operation, taking into account the interrelation of various forensic disciplines.

- APP-S001: General Organization
- APP-S002: Comparative Analysis Section
- APP-S003: Forensic Chemistry
- APP-S004: Forensic Biology
- APP-S005: Digital Evidence
- APP-S006: Crime Scene Investigations
- APP-S007: Laboratory Support
- APP-S008: Management

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

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John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

MANAGEMENT AND ORGANIZATION

Work Content

1 PURPOSE

This document establishes the work content policy of the **AGENCY NAME**.

2 SCOPE

This policy applies to the work performed by employees of the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

The **AGENCY NAME** will avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgment or operational integrity.

Each analytical section will only perform examinations under its jurisdiction.

Cases with multiple analytical requirements will be triaged based and examination sequence will be established based upon the requested examinations probative value.

5 PROCEDURE

5.1 SINGLE EXAM TYPE SUBMISSIONS:

Single exam type cases will be assigned using the following procedure:

- The Sample Control Section receives samples and forwards the Request for Examination Form to the Deputy Director's Office for distribution.
- The Deputy Director, or his designee, will review the Request for Examination Form and determines which analytical section will perform the examination.
- The Deputy Director will place the 3 letter section code of the assigned analytical section in the upper right corner of the PEM-F005.
  - The letters will be written in red ink.
  - The three letter section code will be as follows:
    - AEX Arson and explosives examinations.
    - CSR Crime scene response.
    - DIG Digital evidence examinations.
    - DNA DNA examinations.
    - DRG Controlled substance examinations.
    - FAT Firearms and Toolmark examinations.
    - FCE Forensic computer examinations.
    - LAT Latent fingerprint examination.

        - PHO Photography and video.
        - QDE Questioned document examinations.
        - TFS Test Fire Section.
        - TOX Toxicology.
        - TRA Trace evidence.
        - VPA Voice Print analysis.
- The Deputy Director's clerical staff will enter the case information into the Laboratory Information Management System.
- The Deputy Director's clerical staff will sort and forward the Request of Examination Forms to the appropriate Section Chief for examiner assignment and distribution.
- Each Section Chief will assign and distribute cases based upon:
    - The complexity of the case.
    - The experience of the examiner.
    - The examiner's backlog.

5.2 MULTIPLE EXAM TYPE SUBMISSIONS

Multiple exam type cases will be assigned using the following procedure:

- The Sample Control Section receives samples and forwards the Request for Examination Form to the Deputy Director's Office for distribution.
- The Deputy Director, or his designee, will review the Request for Examination Form and determine which analytical sections will be required to perform examinations.
    - The Deputy Director will prioritize the examinations required and establish the order in which the examinations will take place.
    - The Deputy Director may consult with the Section Chiefs involve to assist in the decision process.
- The Deputy Director will, in the upper right corner of the Request for Examination Form, place the 3 letter section code for each of the assigned analytical section.
    - The letters will be written in red ink.
    - The codes will be stacked, one on top of the others, in descending order of priority.
        - First examination on top.
        - Last examination on the bottom.
    - The three letter section code will be the same as listed in section 5.1 of this procedure.
- The Deputy Director's clerical staff will enter the case information into the Laboratory Information Management System.
- The Deputy Director's clerical staff will sort and forward the Request for Examination Form's to the appropriate Section Chief for examiner assignment and distribution.
    - The clerical staff will make one copy of the Request for Examination Form for each analytical section participating in the examination process.
        - The original copy will be sent to the analytical section that will perform the first examination(s).
        - Copies will be sent to the other sections for informational purposes.

- The original will be passed to the next Section Chief when the previous examination has been completed.
- Each Section Chief will assign and distribute cases based upon:
  - The complexity of the case.
  - The experience of the examiner.
  - The examiner's backlog.

5.2.1 Out of Sequence Examinations

Exhibits that require a single examination type may be processed out of sequence, if the exhibit is packaged separately and its examination will not effect the examination of other exhibits in the case.

6 APPROVAL

The signatures below recognize the above Administrative Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

MANAGEMENT AND ORGANIZATION

Delegation of Authority

1 PURPOSE

This document establishes the **AGENCY NAME** delegation of authority policy.

2 SCOPE

This policy applies to all employees of the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

Management and supervisory personnel will have authority commensurate with their responsibilities.

The authority to address issues will be delegated to the lowest possible lowest level of supervision or management.

The **AGENCY NAME** will establish, maintain and distribute a roster of personnel with decision making authority in the absence of a management or supervisory personnel.

- An updated Acting Authority Roster will de distributed to all employees within one business day of permanent change.
- A memorandum or electronic–mail may be used to advise effected personnel of temporary changes to the Acting Authority Roster.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

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John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

MANAGEMENT AND ORGANIZATION

Supervision

1 PURPOSE

This policy establishes the **AGENCY NAME** supervisory span of control.

2 SCOPE

This policy applies to all employees of the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

The **AGENCY NAME** will provide adequate supervision of staff, including trainees, by persons familiar with methods, procedures, and purpose of each examination, and with the assessment of the examination results.

Supervisors shall have the authority and resources needed to carry out their duties and to identify the occurrence of departures from the quality system or from the procedures for performing tests and/or calibrations, and to initiate actions to prevent or minimize such departures.

Supervisors shall encourage creative, objective thinking & recognize meritorious performance.

Each subordinate shall be accountable to only one immediate supervisor per function.

5 PROCEDURE

There are currently no procedures that are directly affecting the implementation of this policy.

6 APPROVAL

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John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

MANAGEMENT AND ORGANIZATION

Communication

1 PURPOSE

This document establishes the **AGENCY NAME** communication policies.

2 SCOPE

This policy applies to all employees of the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

The **AGENCY NAME** management shall establish vertical and horizontal lines of communication within the laboratory and that communication takes place regarding the effectiveness of the management system.

The **AGENCY NAME** management will ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the objectives of the management system.

The **AGENCY NAME** management will ensure that its parent organization and funding authorities are aware of the importance of meeting customer requirements as well as statutory and regulatory requirements.

4.1 INTERNAL COMMUNICATION

The management team shall conduct regular meetings with Section Chiefs to disseminate information.

Section Chiefs shall Conduct regular meetings with subordinates to disseminate information.

Peer groups shall relay information to the management team.

4.2 EXTERNAL COMMUNICATION

The management team shall conduct user group meetings to establish a line of communication between the **AGENCY NAME** and it clients.

An examination satisfaction questionnaire shall sent to establish a line of communication between the **AGENCY NAME** and it clients.

- A Customer Satisfaction Questionnaire shall accompany every examination report issued by the **AGENCY NAME**.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

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John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

MANAGEMENT AND ORGANIZATION

Quality Assurance Program

1 PURPOSE

This document establishes the **AGENCY NAME's** quality assurance program policy.

2 SCOPE

This policy applies to all factions of the **AGENCY NAME** operation.

3 DEFINITIONS

The current revision of document APP-P001 will be used as a guide to define terms.

4 POLICY

The **AGENCY NAME** will establish and maintain a quality assurance program.

The policies and procedures of the quality assurance program are outlined in the Quality Assurance Manual.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

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John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

PHYSICAL PLANT

Space

1 PURPOSE

This document establishes the **AGENCY NAME's** use of space policy.

2 SCOPE

This policy applies to all facilities of the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

Each employee shall have adequate work space to accomplish their assigned tasks.

There shall be effective separation between neighboring areas in which there are incompatible activities to prevent cross-contamination.

Examiners shall have adequate space for writing reports & other official communications separate from the area examinations are performed.

There shall sufficient space provided for storage of supplies, equipment & tools.

There shall be adequate & appropriate space available for records, reference works & other necessary documents.

There shall be adequate space available for each instrument/equipment to facilitate its operation.

Accessories shall be stored near instrumentation or equipment to facilitate its use & operation.

5 PROCEDURE

There are currently no procedures that are directly affect the implementation of this policy.

6 APPROVAL

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John Smith, Laboratory Director	Date
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End of Document

PHYSICAL PLANT

Design

1 PURPOSE

This document establishes the **AGENCY NAME's** facility design policy.

2 SCOPE

This policy applies to all facilities of the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

The physical design of the facilities shall permit the efficient flow of evidence from the time of its acceptance until its proper disposal.

The relative locations of functional areas shall facilitate the efficient use of equipment & instruments.

The facilities shall have adequate & proper lighting for personnel to carry out assigned tasks.

The facilities shall have adequate & proper plumbing & wiring available & accessible to carry out assigned tasks.

The facilities shall have proper general ventilation.

The facilities shall have adequate heating, cooling, & humidity controls.

The facilities shall be designed to secure the facility from unauthorized entry.

5 PROCEDURE

The U.S. Department of Justice, National Institute of Justice's Lab Design Guide (APP-S009) will be used to define the general design requirements for **AGENCY NAME** facilities.

6 APPROVAL

The signatures below recognize the above Administrative Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

PHYSICAL PLANT

Construction

1 PURPOSE

This document establishes the **AGENCY NAME's** physical plant construction guidelines.

2 SCOPE

This policy applies to all employees of the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

AGENCY NAME facilities shall be constructed of materials to secure the facility from unauthorized entry.

5 PROCEDURE

The U.S. Department of Justice, National Institute of Justice's Lab Design Guide (APP-S009) will be used to define the general construction requirements for **AGENCY NAME** facilities.

6 APPROVAL

The signatures below recognize the above Administrative Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

PHYSICAL PLANT

Access Control

1 PURPOSE

This document establishes the **AGENCY NAME's** facility access control policy.

2 SCOPE

This policy applies to all employees of the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

Access to the operational area of the laboratory shall be controllable and limited.

All exterior entrance and exit points shall have adequate security controls.

All internal areas requiring limited or controlled access shall have a lock system.

Distribution of all keys, magnetic cards, etc., shall be documented and is distribution limited to those individuals designated by the laboratory director to have access.

5 PROCEDURE

There are no procedures that directly effect the implementation of this policy.

6 APPROVAL

The signatures below recognize the above Administrative Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

PHYSICAL PLANT

Key Control

1 PURPOSE

This policy establishes the **AGENCY NAME's** key control policy.

2 SCOPE

This policy applies to all facilities and personnel of the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

4.1 KEY CONTROL

Only **AGENCY NAME** personnel will possess keys to the secure offices, laboratories and storage facilities.

All keys will have an individual identification number imprinted upon the key.

The Director will authorize one or more individual authorized to duplicate keys.

The Director will designate and individual to issue keys as required.

Individuals authorized unrestricted access to AGENCY NAME facilities will be issued general access keys and limited access keys.

4.2 GENERAL ACCESS

General access keys will be issued to all individuals who are authorized to have access to AGENCY NAME facilities.
The following areas will each be keyed for general access:

- Chemical and equipment storage areas
- Secure doors to common office areas
- Secure doors to Administrative and Technical Support section offices

The **AGENCY NAME** will establish and maintain a record of individuals that are issued general access keys (APP-F006).

4.3 LIMITED ACCESS

Limited access keys will be issued individuals who require unregulated access to specific parts of AGENCY NAME facilities.

- Each limited access area will have a separate and distinct key system.

The following areas will each be keyed for limited access:

- Laboratory areas used to examine physical evidence.
- Evidence storage areas within individual examination laboratories.
- Office areas used by examiners.
- Office areas used by technical and administrative support staff.
- Document and records storage areas.
- Chemical and equipment storage.
- Property and Evidence Section office space.
- Property and Evidence Section storage facilities.
- Property and Evidence Section currency and valuable storage vault.
- Property and Evidence Section firearms storage vault.
- Other areas designated by the Director of the AGENCY NAME.

The **AGENCY NAME** will establish and maintain a record of individuals that are issued limited access keys (APP-F006).

5 PROCEDURE

There are currently no procedures that directly apply to the implementation of this policy.

6 APPROVAL

The signatures below recognize the above Administrative Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

PHYSICAL PLANT

Alarm Systems

1 PURPOSE

This document establishes the **AGENCY NAME's** alarm system policy.

2 SCOPE

This policy applies to all facilities of the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

Facilities shall be secured during vacant hours by means of electronic alarms or by security personnel.

The Director will determine the number of alarm systems required to ensure the security and integrity of the offices, laboratories and storage facilities.

Alarm systems shall include but not limited to:

- Intrusion alarms
- Fire and smoke detection alarms
- Duress alarms
- Video surveillance cameras

The Director will determine the number of security personnel required to augment electronic alarms used to ensure the security and integrity of the offices, laboratories and storage facilities.

Administrative Policy APP-P601 defines additional Alarm Systems requirements.

5 PROCEDURE

There are currently no procedures that are directly affect the implementation of this policy.

6 APPROVAL

The signatures below recognize the above Administrative Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

PHYSICAL PLANT

Housekeeping

1 PURPOSE

This document establishes the **AGENCY NAME's** housekeeping policy.

2 SCOPE

This policy applies to all facilities of the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

Laboratory areas will be maintained sufficiently clean and orderly to prevent contamination of samples and to facilitate the efficiency of laboratory operations.

Housekeeping, as a minimum, includes the following activities:

- Sweeping or mopping floors, including walk-in refrigerators
- Cleaning up spills immediately
- Adequately decontaminating and cleansing glassware
- Cleaning contaminated equipment, removing all chemicals upon completion of analysis, removing all contaminants when the equipment is placed in surplus
- Disposing of radioactive, infectious, DEA- controlled, select agent, hazardous, and universal wastes properly
- Controlling pests
- Emptying trash cans
- Vacuuming carpet
- Cleaning restrooms
- Monitoring storage areas to ensure storage conditions are clean and dry, there is no leakage of product, timely disposition of materials, and proper containment offensive materials

Contractors may be employed perform a portion of the housekeeping responsibilities under the direction of the immediate supervisor or the principal analyst. Contractors are not allowed in certain laboratories without escort and guidance.

5 PROCEDURE

There are currently no procedures that are directly affect the implementation of this policy.

6 APPROVAL

The signatures below recognize the above Administrative Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

PERSONNEL

Job Descriptions and Minimum Qualifications

1 PURPOSE

This document establishes the **AGENCY NAME's** job description and minimum qualifications policy.

2 SCOPE

This policy applies to all employees of the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

The **AGENCY NAME** will establish job descriptions and minimum qualifications for each position.

- All job descriptions and minimum qualifications will be approved by the **PARENT ORGANIZATION** prior to adoption by the **AGENCY NAME**.

All employees will meet the minimum qualification for the position they hold.

- A position may be temporarily filled by an individual who does not meet all of the minimum qualifications utilizing the mechanism outlined by the **PARENT ORGANIZATION'S** personnel selection rules.

5 PROCEDURE

The following Position Descriptions define the job descriptions and minimum qualifications for each of the positions within the **AGENCY NAME**:

- APP-PD01 Director
- APP-PD02 Deputy Director
- APP-PD03 Assistant Director
- APP-PD04 Section Chief

- APP-PD05 Quality Assurance Manager
- APP-PD06 Supervising Examiner
- APP-PD07 Master Examiner
- APP-PD08 Journeyman Examiner
- APP-PD09 Apprentice Examiner
- APP-PD10 Journeyman Technician
- APP-PD11 Apprentice Technician
- APP-PD12 Administrative Assistant
- APP-PD13 Secretary
- APP-PD14 Clerk/Typist
- APP-PD15 Office Assistant
- APP-PD16 Senior Property Custodian
- APP-PD17 Property Custodian
- APP-PD18 Property Courier
- APP-PD19 Legal Advisor
- APP-PD20 Forensic Pathologist
- APP-PD21 Forensic Psychiatrist
- APP-PD22 Security Guard
- APP-PD23 Supervising Crime Scene Investigator
- APP-PD24 Master Crime Scene Investigator
- APP-PD25 Journeyman Crime Scene Investigator
- APP-PD26 Apprentice Crime Scene Investigator

6 APPROVAL

The signatures below recognize the above Administrative Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

PERSONNEL

Selection and Promotion

1 PURPOSE

This document establishes the **AGENCY NAME's** personnel selection and promotion policy.

2 SCOPE

This policy applies to all employees of the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

4.1 New Employee Selection

The **AGENCY NAME** will establish a selection process to choose the most qualified candidate for each new employee vacancy.

- The selection process will be approved by the **PARENT ORGANIZATION** prior to adoption.

4.2 In-Classification Promotion

The **AGENCY NAME** will establish a promotional process which will allow an employee to advance through a position classification.

- The promotional process will be approved by the **PARENT ORGANIZATION** prior to adoption.

4.3 Staff to Management Promotion

The **AGENCY NAME** will establish a promotional process which will allow an employee to advance from a staff position to a management/supervision position.

- The promotional process will be approved by the **PARENT ORGANIZATION** prior to adoption.

4.4 Within Management Promotion

The **AGENCY NAME** will establish a promotional process which will allow an employee to advance through the management classifications.

- The promotional process will be approved by the **UMBRELLA ORGANIZATION** prior to adoption.

5 PROCEDURE

5.1 New Employee Selection

The following steps will encompass the process used to select new employees:

- Review of application, resume' and curriculum vita to establish the candidate meets the minimum educational and experience requirements.
- Written examination to establish that the candidate possesses a minimum level of theoretical knowledge.
- An oral interview by a Qualifications Appraisal Board (QAB) to allow the managers the opportunity to personally evaluate each qualified candidate.
- Verification of information provided during the application process.

Employment offers will be provided to the individual with the highest aggregate score achieved during the selection process.

5.2 In-Classification Promotion

The following steps will encompass the In-Classification promotion process:

- Review of the employee's application, resume', curriculum vita and personnel records to establish the candidate meets the minimum requirements for promotion.
- Written examination to establish that the candidate possesses a minimum level of theoretical knowledge.
- An oral interview by a Qualifications Appraisal Board (QAB) to allow the managers the opportunity to personally evaluate each qualified candidate.

In-classification promotions are granted to individuals who successful complete the above requirements.

5.3 Staff to Management Promotion

The following steps will encompass the Staff to Management promotion process:

- Review of the employee's application, resume', curriculum vita and personnel records to establish the candidate meets the minimum requirements for promotion.
- Written examination to establish that the candidate possesses a minimum level of theoretical knowledge.

- An oral interview by a Qualifications Appraisal Board (QAB) to allow the senior managers the opportunity to personally evaluate each qualified candidate.

Promotion offer will be provided to the individual with the highest aggregate score achieved during the selection process.

5.4 In-Management Promotion

The following steps will encompass the In-Management promotion process:

- Review of the employee's application, resume', curriculum vita and personnel records to establish the candidate meets the minimum requirements for promotion.
- An oral interview by a Qualifications Appraisal Board (QAB) to allow the senior managers the opportunity to personally evaluate each qualified candidate.

Promotion offer will be provided to the individual with the highest aggregate score achieved during the selection process.

6 APPROVAL

The signatures below recognize the above Administrative Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

PERSONNEL

Evaluations

1 PURPOSE

This document establishes the **AGENCY NAME's** evaluation policy.

2 SCOPE

This policy applies to all employees of the AGENCY NAME.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

The **AGENCY NAME** will ensure that employee performance expectations established and are understood.

All employees will receive a minimum of one performance evaluation per year.

Employee performance expectations established during the annual performance evaluation.

Employees receiving substandard performance evaluations will be evaluated more frequently, until their performance issues have been corrected.

All employees with examination responsibilities will annually receive a minimum of one proficiency test per analytical discipline.

Employees who provide unsatisfactory results on proficiency tests will receive remedial training and additional proficiency tests until the performance issue has been corrected.

All employees with testimony responsibilities will annually have their testimony evaluated.

Employees receiving substandard rating on their testimony will receive remedial training and additional evaluations until the performance issue has been corrected.

Employees will be reassigned or terminated if the corrective actions taken to address substandard or unsatisfactory performance do not corrected the issues.

Termination actions will be in compliance with the **PARENT AGENCY'S** employee termination policies and procedures.

4.1 EVLAUATION CRITERIA

4.1.1 General Rating

The following define the rating levels used to evaluate non managerial employees

*Exceptional (**5**):*

This is the highest level of performance that always exceeds goals or standards. This rating should be used when the employee always shows extra drive and devotes efforts above and beyond expected job requirements. They model and display performance and behavior in a way that all employees should strive for.

*Very Good (**4**):*

This is performance that always meets, and sometimes exceeds, expectations. This rating should be used when the employee takes the initiative and dedication to go above and beyond expected job requirements. Employees in this group may often be called upon to train and assist others.

*Standard (**3**):*

A score of "Standard" is the baseline on which employees should be rated when they are valued and integral members of the team. This is good performance on the level expected of a trained staff member with experience who succeeds in their work. Performance always meets expectations.

*Needs Improvement (**2**):*

Performance falls somewhat short of what is expected of a trained, experienced employee. Improvement is expected, performance cannot continue at this level indefinitely. If improvement to the successful level is not demonstrated on a consistent basis, performance at this level will at some point be considered unacceptable.

*Substandard (**1**):*

Performance falls very short of what is expected of a trained employee with experience, either due to poor job fit or disciplinary issues. Performance at this level should prompt the manager to think about using measures of discipline, up to, and including termination.

4.1.2 Management Specific

ADMINISTRATION

PLANNING: Develops short and long range plans and goals to meet department objectives consistent with established priorities; sets appropriate priorities of needs and resulting services to be provided; anticipates and prepares for future requirements and devises contingencies; devises realistic plans.

BUDGETING AND ECONOMIC MANAGEMENT: Prepares an appropriate budget and subsequently adheres to it; utilizes finances, budgets, facilities, equipment, materials and products to minimize costs; actively practices cost containment.

ORGANIZATION OF WORK: Structures work in order to avoid crisis, promotes productivity, attains cost effectiveness, and delivers work on time. Involved in this process are the tasks of allocating work, delineating responsibilities, scheduling activities, and adequately preparing for meetings and presentations.

COMPLIANCE: Complies with established policies, procedures and directives; conducts department functions in accordance with applicable laws, statutes, and regulations.

PROBLEM SOLVING AND DECISION-MAKING: Identifies problem and acts to rectify them by employing analytical thinking and sound judgment.

EVALUATION AND CONTROL: Practices regular and systematic review of department operations to evaluate progress towards established goals; evaluates strategies employed in seeking those goals; implements remedial measures when necessary.

RISK (LIABILITY) MANAGEMENT: Ensures that liability risk exposures are identified and treated when proposing new programs and services; evaluates and monitors established programs and services to identify areas which need revision due to changes in operation, legislation, policies and procedures; implements changes where needed to facilitate favorable loss experience; manages employee safety program, including appropriate training and corrective action when necessary.

INTERPERSONAL

ORAL COMMUNICATION: Effectively communicates orally with individuals and groups, including public presentations; presents ideas in an organized, clear and concise manner, employs tact and discretion; listens well; offers appropriate feedback.

WRITTEN COMMUNICATION: Prepares organized, clear, concise, accurate and informative letters, memos, reports and other documents which effectively fulfill content and timeliness requirements.

COORDINATION/COLLABORATION: Works well with others at various levels; keeps information flowing to the appropriate parties vertically (down as well as up) and horizontally; facilitates communication and problems solving among parties when necessary.

SUPERVISORY CONTROL: Effectively hires, assigns, directs, controls, evaluates performance, counsels and disciplines all other functions necessary or incidental to supervision; practices compliance with employment law guidelines and mandates.

LEADERSHIP: Promotes cooperation and team work among employees; establishes high standards of conduct and job performance for subordinates; maintains open communication channels; delegates work; leads by example.

STAFF APPRAISAL AND DEVELOPMENT: Provides good record of subordinate performance; reviews appraisal information with subordinates; aides subordinates in improving performance on current job; helps subordinates in setting up and implementing development plans and objectives; cross-trains employees; encourages subordinates to participate in training.

INDIVIDUAL

EFFORT AND INITIATIVE: Requires little work direction; exhibits persistence an initiative; puts forth a consistent, energetic effort; assumes full and complete responsibility for accomplishment of department functions.

PROFESSIONAL/TECHNICAL COMPETENCE: Realistic knowledge and competence of the field and applies up-to-date technical/professional principles, practices, and standards appropriate to the functions of the department; acts as a resource person upon whom others can draw; professional demeanor maintained on a consistent basis.

INNOVATION: Displays original and novel thought in creative efforts to improve on the status quo.

OBJECTIVITY: Assesses issues, problems and decision situations based on the merits of the case presented; personal loyalties, biases, etc., does not influence department decisions; personnel decisions made on the basis of equal opportunity and objective job-related criteria.

CREDIBILITY: Through successful performance, instills the feeling of trust and dependability.

FLEXIBILITY: Adapts well to change, both internally and externally.

LEADERSHIP

COACHING: Communicates a positive attitude; serves as a catalyst for action and encourages employees to try new things and to take calculated risks; provides honest feedback; minimizes tension and defensiveness; creates an environment for success; teaches and guides employees rather than controls.

EMPOWERING: Creates an awareness in others of their powers and self worth; involves others and shares powers in planning and decision-making; fosters leadership in others; challenges others to assume leadership roles and provides support by allowing them to risk, fail and learn; creates an environment in which others feel ownership for results and feel comfortable to take action to achieve desired results.

MODELING: Believes in public service; treats all with respect and dignity and creates an atmosphere of mutual respect and trust. Serves as a catalyst for action and is a team player, believes in oneself and looks at problem as opportunities; uses powers in a positive way; keeps one's work: accepts responsibility for mistakes; insists on excellence (not perfection); communicates and reinforces by what they do - not what they say; adapts to changes as conditions and situations warrant.

TEAM BUILDING: Builds group cohesiveness and pride; encourages cooperation; fosters and practices good communication, recognizes and rewards individuals and team accomplishments and contributions; shares success and rewards; manages conflict, which is inevitable.

VISIONING: Establishes and articulates a vision of what could be; looks to and plans for the future; accepts new challenges, keeps an open mind.

SELF-DEVELOPMENT: Is not static; prepares for the future; has the courage to identify and address shortcomings; is committed to self-improvement manages personal stress in positive ways.

5 PROCEDURE

5.1 PERFORMANCE EVALUATIONS

The following procedure will be used to evaluate employee performance:

The evaluators will review the evaluation criteria with the subordinates they will be evaluating at the beginning of each rating period and document any expectations that are outside the evaluation criteria defined in section 4.1 or 4.2 of this policy.

Evaluators will rate each employee under their supervision using the Employee Evaluation form or Management Evaluation form for the evaluation period.

The evaluator will insert a comment for ratings in excess of standard.

The evaluator will complete a Corrective Action Report (QAM-F003) for every evaluation criterion that is rated sub-standard.

The evaluator will sign the evaluation form and provide it to the employee for review.

The evaluator will provide the employee a copy of any Corrective Action Report form generated during the rating period for review.

The evaluator and employee will meet privately and discuss the evaluation and the next rating period's expectations.

The employee will sign the evaluation at the conclusion of the meeting.

The employee may insert comments in any section of the evaluation in which he disagrees or feels the need to interject comments.

The employee may insert comments in any section of the evaluation of the corrective action report if necessary.

The evaluation form will be forwarded to the Deputy Director for review and comment.

The corrective action report form will be forwarded to the Quality Assurance Manager for appropriate action.

The original evaluation form will be filed in the employee's personnel file.

The employee will be provided a copy of the signed evaluation form upon request.

5.2 PROFICIENCY TESTING

The Quality Assurance Manual will outline the procedures used to administer the proficiency testing program.

5.3 TESTIMONY MONITORING

The Quality Assurance Manual will outline the procedures used to administer the testimony monitoring program.

6 APPROVAL

The signatures below recognize the above Administrative Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

PERSONNEL

Code of Conduct

1 PURPOSE

This document establishes the **AGENCY NAME's** code of conduct policy.

2 SCOPE

This policy applies to all employees of the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

All employees will be provided a copy of the **PARENT AGENCY** code of conduct.
All employees will be provided a copy of the **AGENCY NAME** code of conduct.
All employees agree to abide by the **PARENT AGENCY'S** and the **AGENCY NAME'S** code of conduct, by virtue of their employment.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

The signatures below recognize the above Administrative Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

PERSONNEL

Statement of Qualifications

1 PURPOSE

This document establishes the **AGENCY NAME's** statement of qualifications policy.

2 SCOPE

This policy applies to all employees of the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

The **AGENCY NAME** will create and maintain a file containing the statement of qualifications forms of all current employees.

- The statement of qualification forms of former employees will be maintained in a separate fill in accordance with document retention policy.

Each employee will complete and maintain a statement of qualifications form (APP-F010).

- Employees will update their statement of qualifications annually.

The **AGENCY NAME** will create and maintain a list of the types of analysis each employee is authorized to perform.

- The **AGENCY NAME** will update the list of types of analysis each employee is authorized to perform annually.

5 PROCEDURE

5.1 INITIAL FORMS

- The Quality Assurance Manager will provide each employee a paper or electronic copy of the statement of qualifications form (APP-F003).
- Each employee will complete and return the form within the time frame established by the Quality Assurance Manager.
- The Quality Assurance Manager will place the completed forms in the master statement of qualifications file.

5.2 ANNUAL UPDATE

- On or about the first week in January the Quality Assurance Manager will distribute copies of the completed Statement of Qualifications forms to all employees who have them on file.
- Each employee will review and update the information on their form.
  - Employees will initial and date the copy of their current form if no additions are required.
  - Employees will insert additions or prepare a new form if additions are required.
- The employees will return their form with the appropriate modifications to the Quality Assurance Manager by the last business day of January.
- The Quality Assurance Manager will replace the old forms with the modified forms in the master Statement of Qualifications file.

6 APPROVAL

The signatures below recognize the above Administrative Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

PERSONNEL

Grievances and Complaints

1 PURPOSE

This document establishes the **AGENCY NAME's** grievance policy.

2 SCOPE

This policy applies to all employees of the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

The **AGENCY NAME** will establish procedures in which employees can file complaints concerning personnel and administrative actions.

The **AGENCY NAME** will establish procedures in which non-employees can file complaints concerning personnel and administrative actions of AGENCY NAME personnel.

The **AGENCY NAME** will establish procedures in which employees can file complaints concerning the quality system.

The **AGENCY NAME** will establish procedures in which non-employees can file complaints concerning the quality system.

The **AGENCY NAME** will establish procedures in which non-employees can file complaints concerning personnel and administrative actions of **AGENCY NAME** personnel.

The Deputy Director, or his designee, will take corrective action when a grievance or complaint concerning personnel and administrative actions of **AGENCY NAME** personnel has been identified.

The Quality Assurance Manager, or his designee, will take corrective action when a quality assurance issue has been identified.

All formally filed grievances and complaints and the actions taken to address the issue(s) will be documented.

- Grievance-/Complaint Report form will be used to document administrative and personnel issues.
- Corrective Action Report forms will be used to document quality issues.

The **AGENCY NAME** will create and maintain a record of all grievances and complaints filed with the Deputy Director or Quality Assurance Manager.

5 PROCEDURE

The following Administrative Policy and Procedure method will be used to address grievances and complaints concerning personnel actions:

5.1 EMPLOYEE GRIEVANCE/COMPLAINTS

5.1.1 Level 1

- Employee will present his grievance or complaint to his immediate supervisor.
- The supervisor and employee discuss a successful resolution to the grievance or complaint.
  - The supervisor and employee implement the resolution, if their discussion generates a acceptable solution, or
  - The employee proceeds to Level 2, if an acceptable resolution to the grievance or complaint cannot be obtained.

5.1.2 Level 2

- The employee completes a Grievance/Complaint Report form.
  - The employee will:
    - Describe the grievance or complaint
    - Describe his ideal resolution
    - Sign the form
    - Present it to his Supervisor

- The Supervisor will review and sign the form and forwards it to the Deputy Director's office.
- The Deputy Director is responsible for ensuring all Grievance/Complaint Reports are resolved in a timely manner.
- The Deputy Director's office will establish and maintain a file for each Grievance/Complaint Reports initiated.
  - The Deputy Director's office will assign a unique file number to each Grievance/Complaint Report.
  - The Deputy Director's office will create and maintain a log of Grievance/Complaint Report to monitor the resolution status each Grievance/Complaint Report.

- The Deputy Director will assign and individual or group to investigate the merits of the grievance or complaint and propose a resolution.
- The investigator or investigative group will issue a report containing the following sections:
  - Background
  - Applicable Policies and Procedures
  - Interviews and Investigative
  - Proposed Resolution

- The Deputy Director will state a resolution to the grievance or complaint based upon:
  - The investigation report.
  - Personal interview with the employee who initiated the grievance or complaint.
- The Employee can accept the Deputy Director decision, or
- Proceed to Level 3

5.1.3 Level Three

- The Grievance/Complaint file is forwarded to the Director's Office.
- The Director:
  - Reviews the file.
  - Interviews the employee.
  - State a resolution to the grievance or complaint.
- The Director's decision is final.

5.2 NON-EMPLOYEE GRIEVANCE/COMPLAINTS

5.2.1 Level 1

- NON-employees will present their grievances or complaints to the Deputy Director's office.
- The Deputy Director or his designee will discuss a successful resolution to the grievance or complaint.
  - The Deputy Director will implement the resolution, if their discussion generates a acceptable solution; or
  - The non-employee will proceed to Level 2, if an acceptable resolution to the grievance or complaint cannot be obtained.

5.2.2 Level 2

- The non-employee completes a Grievance/Complaint Report form.
  - The non-employee will:
    - Describe the grievance or complaint
    - Describe his ideal resolution
    - Sign the form
    - Present it to the Deputy Director's office
- The Deputy Director's representative will review and sign the and forwards it for processing.
- The Deputy Director is responsible for ensuring all Grievance / Complaint Reports are resolved in a timely manner.
- The Deputy Director's office will establish and maintain a file for each Grievance/ Complaint Reports initiated.
  - The Deputy Director's office will assign a unique file number to each Grievance/ Complaint Report.
  - The Deputy Director's office will create and maintain a log of Grievance/Complaint Report to monitor the resolution status each Grievance/Complaint Report.

- The Deputy Director will assign and individual or group to investigate the merits of the grievance or complaint and propose a resolution.
- The investigator or investigative group will issue a report containing the following sections:
  - Background.
  - Applicable Policies and Procedures.
  - Interviews and Investigative.
  - Proposed Resolution.
- The Deputy Director will state a resolution to the grievance or complaint based upon:
  - The investigation report.
  - Personal interview with the Non-Employee who initiated the grievance or complaint.
- The Non-Employee can accept the Deputy Director decision; or
- Proceed to Level 3.

5.2.3 Level Three

- The Grievance/Complaint file is forwarded to the Director's Office.
- The Director:
  - Reviews the file.
  - Interviews the Non-Employee.
  - Documents a resolution to the grievance or complaint.
- The Director's decision is final.

The Quality Assurance Manual contains additional procedures that will be used to address grievances and complaints concerning personnel actions.

6 APPROVAL

The signatures below recognize the above Administrative Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

PERSONNEL

Duty Hours

1 PURPOSE

This document establishes the **AGENCY NAME's** duty hour policy.

2 SCOPE

This policy applies to all employees of the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

Employee duty hours will be established and adjusted in a manner that allows the **AGENCY NAME's** to accomplish its mission.

The employee duty hour policy will be in compliance with the **PARENT AGENCY'S** duty hour policy as well as all applicable federal, state and local labor laws or regulations.

5 PROCEDURE

There are currently no procedures that are directly affect the implementation of this policy.

6 APPROVAL

The signatures below recognize the above Administrative Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

PERSONNEL

Overtime

1 PURPOSE

This document establishes the **AGENCY NAME's** overtime policy.

2 SCOPE

This policy applies to all employees of the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

Employees may be required to work hours in excess of their normal duty hours (overtime) to meet deadlines or otherwise accomplish the **AGENCY NAME's** mission.

The **AGENCY NAME's** overtime policy will be in compliance with the **PARENT AGENCY's** overtime policy as well as all applicable federal, state and local labor laws or regulations.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

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John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

PERSONNEL

Sick Leave

1 PURPOSE

This document establishes the **AGENCY NAME's** sick leave policy.

2 SCOPE

This policy applies to all employees of the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

Employees will be provided sick leave in compliance with the **UMBRELLA AGENCY's** sick leave policy.

Employees will notify their immediate supervisor of their intention to utilize sick leave as soon as reasonably possible.

- An employee's failure to notify their supervisor may result in denial of sick leave.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

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John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

PERSONNEL

Annual Leave

1 PURPOSE

This document establishes the **AGENCY NAME's** annual leave policy.

2 SCOPE

This policy applies to all employees of the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

Employees will be provided annual leave in compliance with the **UMBRELLA AGENCY's** annual leave policy.

Employees will notify their immediate supervisor of their intention to utilize annual leave as soon as reasonably possible.

- An employee's failure to notify their supervisor may result in denial of annual leave.

The use of annual leave may be revoked or denied based upon the **AGENCY NAME's** needs.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

The signatures below recognize the above Administrative Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

PROFESSIONAL DEVELOPMENT

Training

1 PURPOSE

This document establishes the **AGENCY NAME's** training program policy.

2 SCOPE

This policy applies to all employees of the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

4.1 GENERAL

All employees will be provided training in their respective job which will allow them to competently perform their assigned duties.

The Quality Assurance Manager will create and maintain a training file for every **AGENCY NAME** employee to document all training provided or obtained during the employee's tenure.

4.2 NEW EMPLOYEE

All new employees will receive basic training and orientation concerning the policies and procedures associated with operation of the **AGENCY NAME**.

New employee training will include, but not be limited to:

- Administrative policy and procedure orientation
- Property and evidence section orientation
- Health and safety orientation
- Quality assurance program orientation

4.3 TECHNICAL TRAINING

All employees will be provided basic technical training in their respective job to allow them to competently perform their assigned duties.

The content and duration of the technical training an employee receives is outlined in the Technical Methods Manual of the section the employee is assigned.

4.4 IN-SERVICE TRAINING

All employees will be provided in-service training opportunities that will allow them to enhance their technical skills.

The content and duration of the in-service training an employee receives may be outlined in the Technical Methods Manual of the section the employee is assigned.

In-service training may be provided through one or more of the following venues:

- In-house training program
- Professional Association
- College/University
- Vendor
- Law Enforcement Agency

All employees will be provided an annual review of the Health and Safety Manual.

4.5 REMEDIAL TRAINING

Remedial training will be provided to employees whose performance has been identified to be below standard.

Below standard performance can be identified through one or more of the following methods:

- Below standard performance in written and practical training exercises
- Administrative or technical review of reports and case files
- Proficiency test deficiency report
- Corrective Action Report
- Testimony monitoring
- Supervisory evaluation
- Peer review

Every effort will be made to remediate an employee's substandard performance to an acceptable level.

The **AGENCY NAME** may transfer an employee with substandard performance to a position that is better suited to the employee's knowledge skills and abilities, after three (3) months of documented unsuccessful remediation training.

5 PROCEDURE

The following policies and procedures will be used to address grievances and training issues:

5.1 GENERAL

- The Chief of the Personnel Section or his designee will provide new employees an orientation concerning the general operation of the **AGENCY NAME**.
- New employee orientation will be documented.

5.2 OPERATIONAL POLICIES

New employees will be issued a copy of the Operational Policies and Procedures.

5.2.1 Administrative Policy and Procedure Orientation

- New employees will be provided time to read the administrative policies and procedures.
- The new employee will review the administrative policies and procedures with his supervisor or his designee.
- This review will be documented.

5.2.2 Sample Control Section Orientation

- New employees will be provided time to read the sample control manual.
- The new employee will review the property and evidence manual with the Chief of the Sample Control Section or his designee.
- This review will be documented.

5.2.3 Health and Safety Orientation

- New employees will be provided time to read the health and safety manual.
- The new employee will review the health and safety manual with the Health and Safety Program Manager or his designee.
- This review will be documented.

5.2.4 Quality Assurance Program Orientation

- New employees will be provided time to read the quality assurance manual.
- The new employee will review the quality assurance manual with the Quality Assurance Manager or his designee.
- This review will be documented.

5.3 TECHNICAL TRAINING

- The new employee's Section Chief or his designee will be responsible for the new employee's technical training.
- New employees with examination responsibilities will be provided technical manuals for every area in which they will perform examinations.
- New employees will be provided time to read all technical manuals and associated training materials.
- New employees with examination responsibilities will be provided training in their respective examination areas as outlined in the training section of the individual technical manual.
- Technical proficiency will be documented using written and practical examinations outlined in the individual technical manuals.

6 APPROVAL

The signatures below recognize the above Administrative Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

PERSONNEL

Professional Development

1 PURPOSE

This document establishes the **AGENCY NAME's** professional development program policy.

2 SCOPE

This policy applies to all employees of the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

The **AGENCY NAME** will establish and implement a professional development plan for each employee based upon the employee's knowledge, skills, abilities and the needs of the AGENCY NAME.

The **AGENCY NAME** will provide the resources necessary to implement employee development plans, within the funding limitations.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

The signatures below recognize the above Administrative Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

PROFESSIONAL DEVELOPMENT

Literature Resources

1 PURPOSE

This document establishes the **AGENCY NAME's** literature resources policy.

2 SCOPE

This policy applies to all employees of the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

The **AGENCY NAME** will establish and maintain a library containing current and historical reference material of general interest forensic science topics.

Each analytical section will establish and maintain a library containing current and historical reference material on topics specific to that analytical discipline.

Employees are encouraged to establish and maintain a personal library containing current and historical reference material of general and discipline specific forensic science topics.

The **AGENCY NAME** will dedicate a portion of it annual budget for acquiring and maintaining literature resources.

The Director will designate an individual to act as the librarian, to maintain the general interest library.

Each Section Chief will designate an individual to act as the section's librarian, to maintain the section's discipline specific library.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

The signatures below recognize the above Administrative Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

PERSONNEL

Periodical Circulation

1 PURPOSE

This document establishes the **AGENCY NAME's** periodical circulation policy.

2 SCOPE

This policy applies to all employees of the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

The **AGENCY NAME** will acquire and maintain copies of the periodicals of general and discipline specific forensic interest.

The Librarian will ensure that each employee is provided the opportunity to review a copy of the table of contents of each periodical received.

5 PROCEDURE

5.1 LIBRARIAN

Each month the Librarian will:

- Reproduce the table of contents of all periodicals received during the previous month.
  - The number of copies will be equal to the number of analytical sections.
- Prepare circulation packets containing one copy of each table of contents reproduction made.
  - One packet will be circulated through each analytical section.
- Attach a distribution list to each packet.
  - Each Section will have a unique distribution list.
- Distribute individual packets to Section Chiefs for circulation.
- Collect packet of periodical table of contents from the last person to complete packet review.
- File completed distribution lists in a file created to document circulation of the periodical table of contents.

5.2 SECTION CHIEF

Each month each Section Chief will:

- Receive a packet of periodical table of contents from the Librarian.
- Review each table of contents for relevant articles.
- Initial and date the distribution list upon completion of the review.
- Transfer the packet of periodical table of contents to an individual on the distribution list, who has not reviewed the packet.

5.3 EMPLOYEES

Each month each employee will:

- Receive a packet of periodical table of contents.
- Review each table of contents for relevant articles.
- Initial and date the distribution list upon completion of the review.
- Transfer the packet of periodical table of contents to an individual on the distribution list, who has not reviewed the packet.
    - The last individual on the distribution list will return the month's packet of periodical table of contents to the Librarian.

6 APPROVAL

The signatures below recognize the above Administrative Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

END OF DOCUMENT

PERSONNEL

Training Records

1 PURPOSE

This document establishes the **AGENCY NAME's** training records policy.

2 SCOPE

This policy applies to all employees of the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

The **AGENCY NAME** will establish and maintain a training file for each employee to document the training provided.

Each employee will submit an evaluation of each training session attended.

Employee training records will be maintained in accordance with the **AGENCY NAME** document retention policy.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

The signatures below recognize the above Administrative Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

PERSONNEL

Dress Code

1 PURPOSE

This document establishes the **AGENCY NAME's** dress code.

2 SCOPE

This policy applies to all **AGENCY NAME** employees.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

4.1 GROOMING

4.1.1 Men

Men will maintain a clean and well maintained appearance using the following guidelines:

- Hairstyles should be clean and neat.
  - Extreme styles or colors will be avoided.
- Sideburns should not extend below the earlobe or onto the cheek.
- Men are expected to be clean shaven; beards are not acceptable.
  - If worn, mustaches should be neatly trimmed and may not extend beyond or below the corners of the mouth.
- Earrings and other exposed body piercing jewelry are unacceptable.

4.1.2 Women

Women will maintain a clean and well maintained appearance using the following guidelines:

- Hairstyles should be clean and neat, avoiding extreme styles and colors.
- A clean and well-cared-for appearance should be maintained.
- Two pair of earrings are acceptable.
  - All other exposed body piercing jewelry is inappropriate.

4.2 BUSINESS ATTIRE

All employees will wear or have immediate access to appropriate business attire if they will be publicly representing the AGENCY NAME.
Business attire is to be worn during the following situations:

- All court appearances.
- All depositions.
- All professional presentations as a representative of the AGENCY NAME.
- All situations in which the employee represents the AGENCY NAME in a public forum.

4.2.1 Men

Appropriate business attire for male employees includes the following:

- Blazers, suits, or sport coats
- Dress slacks
- Dress shirts with buttons and collars
- Ties
- Dress shoes

4.2.2 Women

Appropriate business attire for female employees includes the following:

- Dresses.
  - Dresses must be knee length or longer.
- Skirts.
  - Skirts must be knee length or longer.
- Dress slacks.
- Blouses.
- Dress shoes.
- Sweaters.
- Nylons or stocking.

4.3 CASUAL BUSINESS ATTIRE

Employees may wear casual business attire in situations in which they will not represent the AGENCY NAME in an official capacity.

- Employees will have immediate access to appropriate business attire if they will be publicly representing the AGENCY NAME for a limited period of time during the business day.

Casual business attire may be worn during the following situations:

- Performing routine duties that do not require interaction with the public in an official capacity.
- In service training sessions.
- Professional meetings in which the employee is not making a presentation.
- Travel to or from professional meetings or in service training sessions.
- Other situations as required.

4.3.1 Men

Appropriate casual business attire for male employees includes:

- Sport coats or blazers
- Slacks, Chinos or Dockers
- Pull over shirts with collars
- Oxford button-down shirts
- Sweaters and cardigans
- Casual shoes
- Sweaters

4.3.2 Women

Appropriate casual business attire for female employees includes:

- Dresses.
  - Dresses must be knee length or longer.
- Skirts.
  - Skirts must be knee length or longer.
- Slacks.
- Stirrup pants.
- Walking shorts.
- Pull over shirts with collars.
- Casual shoes.
- Sweaters.

4.4 LABORATORY ATTIRE

Employees with laboratory duties will wear attire that promotes personal safety while working in a laboratory environment.

Laboratory attire includes:

- Long sleeved shirt
- Long pants

- Loose fitting clothing should be avoided
- Long hair should be secured with a tie (rubber band), pins or barrette
- Open-toed shoes should not be worn in the laboratory
- Ties or long jewelry which could dangle should be removed or tied back
- Wearing rings, bracelets or watches is discouraged in the laboratory
- Synthetic fingernails should not be worn in laboratories

4.5 UNACCEPTABLE ATTIRE

Unacceptable attire for employees includes:

- Shirts
- T-shirts of any kind
- Shirts or blouses that are sleeveless, strapless, backless, or revealing
- Underwear as outerwear
- Athletic wear
- Beach wear
- Provocative attire
- Workout clothes, except when required by duties
- Evening wear
- Cutoff pants
- Blue denim jeans
- Sandals of any kind
- Athletic shoes
- Deck shoes
- Work shoes, except when required by duties
- Skirts that have slits above the knee or are formfitting

5 PROCEDURE

Section Chiefs and supervisors are responsible for monitoring and enforcing this policy.
The policy will be administered according to the following action steps:

- If questionable attire is worn in the office, the respective department Section Chief or Supervisor will hold a personal, private discussion with the employee to advise and counsel the employee regarding the inappropriateness of the attire.
- If an obvious policy violation occurs, the Section Chief or Supervisor will hold a private discussion with the employee and ask the employee to go home and change their attire immediately.
- Repeated policy violations will result in disciplinary action, up to and including termination.

6 APPROVAL

The signatures below recognize the above Administrative Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

PERSONNEL

Signature/Initial Exemplar

1 PURPOSE

This document establishes the **AGENCY NAME's** signature/initial record policy.

2 SCOPE

This policy applies to all employees of the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

The **AGENCY NAME** will establish and maintain a record containing exemplars of the signatures and initials of all employees.

The Quality Assurance Manager will annually update the signature and initial exemplars.

The signature and initials exemplars of new employees will be added to the record as part of the new employee orientation.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

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John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

PERSONNEL

Outside Work Permits

1 PURPOSE

This document establishes the **AGENCY NAME's** outside work permint policy.

2 SCOPE

This policy applies to all employees of the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

Employees may hold jobs in addition to their position with the **AGENCY NAME**.

Outside employment may not conflict with the employee's duties and responsibilities to the **AGENCY NAME**.

All outside employment will be pre-approved by the Director.

5 PROCEDURE

The employee will submit a memorandum to the Director, through his supervisor, requesting permission to obtain outside employment.
The memorandum will include:

- The employer's name
- The employer's business activities
- The employee's responsibilities and duties
- Prospective work schedule

Within five (5) days of receipt the request the Director will review and sign the request memorandum with a notation indicating is approval or denial.

The original request memorandum will be placed into the employee's personnel file and with a copy forwarded to the requesting employee.

6 APPROVAL

The signatures below recognize the above Administrative Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

CASE MANAGEMENT

Case Numbering

1 PURPOSE

This document establishes the **AGENCY NAME's** case numbering policy.

2 SCOPE

This policy applies to all employees of the **AGENCY NAME.**

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

4.1 CASE NUMBERING

Each case submitted for examination will be assigned a unique record number.

The Sample Control Section will be responsible for the assignment of record numbers to cases submitted for examination.

Record numbers will be assigned in sequential order without a break in the numbering sequence.

Record numbers will utilize the following format: XX-R-YYYYY.

- XX
  - The last 2 digits of the year the record was created
- R
  - Facility Code
    - 1: Headquarters/Laboratory
    - 2: Regional Facility 1
    - 3: Regional Facility 2
    - 4: Regional Facility …
    - F: Firearms Database Program
- YYYYY
  - Unique identification number.
  - Numbers begin with 00001
  - Numbering restarts on 0000 hour of 1 January

An existing record number may be utilized if the submission contains additional exhibits for the same case.

4.2 SAMPLE NUMBERING

Each sample within a case submission will be assigned a unique identification number.

Examiners will assign a unique sample number to unnumbered items.

Examiners will assign a unique exhibit number to items or sub items created during the course of the examination.

5 PROCEDURE

5.1 CASE NUMBERING

There are currently no administrative procedures that directly affect the implementation of this policy.

6 APPROVAL

The signatures below recognize the above Administrative Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

CASE MANAGEMENT

Sample Submission

1 PURPOSE

This document establishes the **AGENCY NAME's** evidence submission policy.

2 SCOPE

This policy applies to all samples submitted to the **AGENCY NAME.**

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

All evidentiary and non-evidentiary samples submitted to the **AGENCY NAME** for examination or temporary storage will be logged into the Sample Control Section prior to transfer to the laboratory for examination.

Sample Control Section personnel will only accept items that are properly packaged, sealed and labeled.

- Sample Control Section personnel will not package or repackage any item(s) prior to acceptance.
- Sample Control Section personnel may provide the necessary packaging materials, as required.
- Sample Control Section personnel may provide advice concerning proper packaging techniques, as required.

Sample Control Section personnel will document the exchange or transfer of all evidentiary and non-evidentiary items using the appropriate forms.

The Sample Control database will be updated within 24 hours of case submission.

5 PROCEDURE

The Sample Control Manual contains specific polices and procedures related to the implementation of this administrative policy.

6 APPROVAL

The signatures below recognize the above Administrative Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

CASE MANAGEMENT

Sample Return

1 PURPOSE

This document establishes the **AGENCY NAME's** evidence submission policy.

2 SCOPE

This policy applies to all employees of the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

The AGENCY NAME does not provide long-term storage of evidentiary or non-evidentiary items.

- The Chief of the Sample Control Section may grant long-term storage privileges on a case by case basis.

The Sample Control Section will return evidentiary and non-evidentiary items to the submitting agency or individual as soon as the examination process has been completed.

Sample Control Section personnel will document the exchange or transfer of all evidentiary and non-evidentiary items using the appropriate forms.

5 PROCEDURE

The Sample Control Manual contains specific polices and procedures related to the implementation of this administrative policy.

6 APPROVAL

The signatures below recognize the above Administrative Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

CASE MANAGEMENT

Sample Database

1 PURPOSE

This document establishes the **AGENCY NAME's** sample database policy.

2 SCOPE

This policy applies to all factions of the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

The Sample Control Section will establish and maintain a database of all evidentiary and non-evidentiary items submitted to the **AGENCY NAME** for examination or temporary storage.

The sample database will contain the following information:

- Laboratory Record Number (RN)
- Submitting Agency Name
- Submitting Agency File #
- Date Submitted
- Date Returned
- Storage Location
- Date to Lab
- Examiner
- Date From Lab
- Examination Completed (YES/NO)
- Exam Completion Notice Sent
- Destruction Require (YES/NO)
- Date Destroyed

All property and evidence transaction information will be entered into the database within 24 hours of the transaction.

The Director and the senior managers will have unrestricted access to the Sample Database.

5 PROCEDURE

The Sample Control Manual contains specific polices and procedures related to the implementation of this administrative policy.

6 APPROVAL

The signatures below recognize the above Administrative Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

CASE MANAGEMENT

Case Assignment

1 PURPOSE

This document establishes the **AGENCY NAME's** case assignment policy.

2 SCOPE

This policy applies to all employees of the **AGENCY NAME.**

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

Cases submitted to the **AGENCY NAME** will be worked in the order they are received.

- The Section Chief may authorize the analysis of a case to be worked out of order.

Cases will be triaged by the Deputy Director and distributed to the appropriate Section Chief for distribution.

Cases requiring multiple examination types will be triaged by the Deputy Director to determine the sequence of examinations.

The following criteria will be utilized in determining the examination sequence:

- The destructive nature of the requested examinations
- The probative value of the requested examinations
- Analytical section case backlog
- Cases involving crimes against people take priority over crimes against property cases

5 PROCEDURE

5.1 SINGLE EXAM TYPE SUBMISSIONS:

Single exam type cases will be assigned using the following procedure:

- The Property and Evidence Section receives evidence and forwards the Evidence Submission Form (PEM-F005) to the Deputy Director's Office for distribution.
- The Deputy Director, or his designee, will review the PEM-F005 and determine which analytical section will perform the examination.

- The Deputy Director will place the 3 letter section code of the assigned analytical section in the upper right corner of the PEM-F005.
  - The letters will be written in red ink.
  - The three letter section code will be as follows:
    - AEX Arson and explosives examinations.
    - CSR Crime scene response.
    - DIG Digital evidence examinations.
    - DNA DNA examinations.
    - DRG Controlled substance examinations.
    - FAT Firearms and Toolmark examinations.
    - FCE Forensic computer examinations.
    - LAT Latent fingerprint examination.
    - PHO Photography and video.
    - QDE Questioned document examinations.
    - TFS Test Fire Section.
    - TOX Toxicology.
    - TRA Trace evidence.
    - VPA Voice Print analysis.
- The Deputy Director's clerical staff will enter the case information into the Laboratory Information Management System.
- The Deputy Director's clerical staff will sort and forward the PEF-F005's to the appropriate Section Chief for examiner assignment and distribution.
- Each Section Chief will assign and distribute cases based upon:
  - The complexity of the case.
  - The experience of the examiner.
  - The examiner's backlog.

5.2 MULTIPLE EXAM TYPE SUBMISSIONS

Multiple exam type cases will be assigned using the following procedure:

- The Property and Evidence Section receives evidence and forwards the Evidence Submission Form (PEM-F005) to the Deputy Director's Office for distribution.
- The Deputy Director, or his designee, will review the PEM-F005 and determine which analytical sections will be required to perform examinations.
  - The Deputy Director will prioritize the examinations required and establish the order in which the examinations will take place.
  - The Deputy Director may consult with the Section Chiefs involve to assist in the decision process.
- The Deputy Director will, in the upper right corner of the PEM-F005, place the 3 letter section code for each of the assigned analytical section.
  - The letters will be written in red ink.
  - The codes will be stacked, one on top of the others, in descending order of priority.
- First examination on top.

- Last examination on the bottom.
  - The three letter section code will be the same as listed in section 5.1 of this procedure.
- The Deputy Director's clerical staff will enter the case information into the Laboratory Information Management System.
- The Deputy Director's clerical staff will sort and forward the PEF-F005's to the appropriate Section Chief for examiner assignment and distribution.
  - The clerical staff will make one copy of the PEM-F005 for each analytical section participating in the examination process.
    - The original copy will be sent to the analytical section that will perform the first examination(s).
    - Copies will be sent to the other sections for informational purposes.
  - The original will be passed to the next Section Chief when the previous examination has been completed.
- Each Section Chief will assign and distribute cases based upon:
  - The complexity of the case.
  - The experience of the examiner.
  - The examiner's backlog.

5.3 OUT OF SEQUENCE EXAMINATIONS

Exhibits that require a single examination type may be processed out of sequence, if the exhibit is packaged separately and its examination will not effect the examination of other exhibits in the case.

6 APPROVAL

The signatures below recognize the above Administrative Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

END OF DOCUMENT

CASE MANAGEMENT

Backlog Management

1 PURPOSE

This document establishes the **AGENCY NAME's** backlog management policy.

2 SCOPE

This policy applies to all employees of the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

The Director will review and take account of changes in the volume and type of the work and allocate resources accordingly to minimizing the examination time required.

Examiners will efficiently process each case to maximize the information obtained while minimizing the examination time required.

Examiners will process sufficient exhibits of probative value to establish the elements of the crime of each crime the suspect is charged with.

The examiners will utilize one or more of the following to determine the probative value of each exhibit submitted for examination:

- The police report
- Discussion with the investigator
- Discussion with the prosecutor
- The examiner's experience

5 PROCEDURE

5.1 DIRECTOR

By the 10th of each month the Director will receive the backlog report from the Deputy Director of Operations.

The Director will evaluate the Deputy Director of Operations' report and recommendations.

The Director will adjust funding requests to acquire the resource necessary to reduce backlogs.

5.2 DEPUTY DIRECTOR OF OPERATIONS

By the 5th of each month the Deputy Director of Operations will receive backlog reports form the following sections:

- Property and Evidence Section
- Examination Section Chiefs
  - Section Supervisors will provide summary reports to their respective section chief

The Deputy Director of Operations will evaluate the reports and compare the data to establish use patterns and identify areas which require additional resources.

The Deputy Director of Operations will reallocate personnel resources as required to reduce the backlog.

The Deputy Director of Operations will make recommendations to the Director concerning the need for additional resources.

5.3 SAMPLE CONTROL SECTION

By the 5th of each month the Sample Control Section will submit a report to the Deputy Director of Operations containing the following information:

- Number of cases received during the previous month
- Number of cases returned to the submitting agency during the previous month
- Number of cases waiting for examination
  - Total number of cases
  - Number of cases older than 30 days
  - Number of cases older than 60 days
  - Number of cases older than 90 days
- Number of cases issued to the laboratory of examination purposes
  - Total number of cases
  - Number of cases older than 30 days
  - Number of cases older than 60 days
  - Number of cases older than 90 days

5.4 SECTION CHIEF

By the 5th of each month each Section Chief will submit a report to the Deputy Director of Operations containing the following information:

- Number of cases received during the previous month
- Number of case reports issued during the previous month
- Number of cases, by examination type, under examination
  - Total number of cases
  - Number of cases older than 30 days

- Number of cases older than 60 days
- Number of cases older than 90 days

5.5 SECTION SUPERVISOR

By the 3rd of each month each Section Supervisor will submit a report to their Section Chief containing the following information:

- Number of cases received during the previous month
- Number of case reports issued during the previous month
- Number of cases under examination
  - Total number of cases
  - Number of cases older than 30 days
  - Number of cases older than 60 days
  - Number of cases older than 90 days

6 APPROVAL

The signatures below recognize the above Administrative Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

CASE MANAGEMENT

Laboratory Information Management System (LIMS)

1 PURPOSE

This document establishes the **AGENCY NAME's** laboratory information management system (LIMS) policy.

2 SCOPE

This policy applies to all employees of the AGENCY NAME.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

AGENCY NAME will establish and maintain a laboratory information management system (LIMS).

- This information may be collected and maintained on one or more databases.
- Databases may be in written or electronic format.
- Database information will be maintained in accordance with the document retention policy.

The Director will designate an individual to act as the LIMS administrator.

- The LIMS Administrator will compile and disseminate the information from the various databases to the management team.

Information captured by LIMS will include, but not be limited to:

- Record Number
- Submitting Agency Name
- Submitting Agency Case Number
- Evidence Submission Date
- Evidence Return Date
- Laboratory Receipt Date
- Laboratory Return Date
- Examiner Name
- Examination Code
- Examination Time Per Code
- Report Approval Date

The Sample Control Section will maintain a database of information concerning the status of items submitted to the **AGENCY NAME** for examination for use by the LIMS Administrator.

The Supervisor of each analytical section will establish and maintain a log of the cases it has processed for use by the LIMS Administrator.

Each Examiner will establish and maintain a log of the cases it has processed for use by the LIMS Administrator.

The management team will periodically review LIMS information to identify trends which will lead to an effective allocation of resources and better customer service.

5 PROCEDURE

The LIMS Manual contains specific polices and procedures related to the implementation of this administrative policy.

6 APPROVAL

The signatures below recognize the above Administrative Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

DOCUMENT CONTROL

Document Retention

1 PURPOSE

This document establishes the **AGENCY NAME's** document retention policy.

2 SCOPE

This policy applies to all controlled documents of the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

4.1 GENERAL

The **AGENCY NAME** will establish and maintain a variety of record categories.

All records shall be retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss.

All records shall be held secure manner that prevents unauthorized access or amendment of the records.

All electronically stored records shall be protected and backed up to prevent unauthorized access or amendment of the records.

The AGENCY NAME will file, archive and dispose of documents using the following schedule.

4.2 CASE FILES

Case files will be maintained in a secure section of the laboratory for a period of 5 years after the completion of the examination.

Case files in excess of 5 years old will be archived in a secure location for an indefinite period of time, but not less than 25 years after the completion of the examination.

4.3 SAMPLE CONTROL RECORDS

Sample control files will be maintained in a secure section of the Sample Control Section for a period of 5 years after the completion of the examination.

Sample control files in excess of 5 years old will be archived in a secure location for an indefinite period of time, but not less than 25 years after the completion of the examination.

4.4 POLICY AND PROCEDURE MANUALS

Each employee will retain a current revision of the AGENCY NAME's operational manuals, which include

- Administrative Polices and Procedures
- Health and Safety Manual
- Property and Evidence Manual
- Quality Assurance Manual

Obsolete polices and procedures will be suitably marked and promptly removed from all points of issue or use, or otherwise assured against unintended use and retained for either legal or knowledge preservation purposes are.

4.5 TECHNICAL METHODS MANUALS

Each employee will retain a current revision of the Technical Methods Manuals of the section to which they are assigned.

Obsolete polices and procedures will be suitably marked and promptly removed from all points of issue or use, or otherwise assured against unintended use and retained for either legal or knowledge preservation purposes are.

4.6 CORRESPONDENCE

4.6.1 Internal Correspondence

All internal correspondence documents will be filed and retained for a period of one year.

4.6.2 External Correspondence

All external correspondence documents will be filed and retained for a period of two years.

4.7 PERSONNEL RECORDS

Employee personnel records will be maintained for a period of 5 years after the employee terminates employment with the **AGENCY NAME**.

The **UMBRELLA AGENCY** will maintain employee personnel records of terminated employees according with their document retention policy.

4.8 TRAINING RECORDS

Employee training record files will be maintained for a period of 5 years after the employee terminates employment with the **AGENCY NAME**.

4.9 PROFICENCY TEST RECORDS

Employee proficiency test files will be maintained for a period of 5 years after the employee terminates employment with the **AGENCY NAME**.

4.10 QUALITY ASSURANCE RECORDS

Quality assurance records will be maintained in a secure section of the laboratory for a period of 5 years.

Quality assurance records in excess of 5 years old will be archived in a secure location for an indefinite period of time, but not less than 25.

4.11 AUDIT RECORDS

Audit records will be maintained in a secure section of the laboratory for a period of 5 years.

Audit records in excess of 5 years old will be archived in a secure location for an indefinite period of time, but not less than 25.

4.12 CORRECTIVE ACTION REPORTS

Corrective action reports will be maintained in a secure section of the laboratory for a period of 5 years.

Corrective action reports in excess of 5 years old will be archived in a secure location for an indefinite period of time, but not less than 25.

4.13 GRIEVANCE/COMPLAINT REPORTS

Grievance/Complaint reports will be maintained in a secure section of the laboratory for a period of 5 years.

Grievance/Complaint reports in excess of 5 years old will be archived in a secure location for an indefinite period of time, but not less than 25.

4.14 ADMINISTRATIVE RECORDS

Administrative records will be maintained in a secure section of the laboratory for a period of 5 years.

4.15 PROCUREMENT RECORDS

Procurement documentation will be maintained in a secure section of the laboratory for a period of 5 years.

4.16 GRANT DOCUMENTATION

Grant documentation will be maintained in a secure section of the laboratory for a period of 5 years after the completion of the grant obligations.

4.17 BUDGET DOCUMENTATION

Budget documentation will be maintained in a secure section of the laboratory for a period of 5 years.

5 PROCEDURE

On or about the first week of a calendar year all records in older than their prescribed retention time will be removed from their respective files and disposed of.

- E.g., the week of January 3–7, 2000 all records dated prior to January 1, 1999 will be removed and disposed of properly.

6 APPROVAL

The signatures below recognize the above Administrative Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

DOCUMENT CONTROL

Document Disposal

1 PURPOSE

This document establishes the **AGENCY NAME's** document disposal policy.

2 SCOPE

This policy applies to all **AGENCY NAME** documents.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

The **AGENCY NAME** will dispose of documents that require destruction in a manner which will ensure the confidential information is disseminated to unauthorized personnel.

Authorized disposal methods for documents containing confidential information include:

- Incineration
- Shredding
- Disposal by a certified document disposal company
- Other method authorized by the Director

Documents that do not contain confidential information may be disposed of with the non-hazardous waste.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

The signatures below recognize the above Administrative Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

DOCUMENT CONTROL

Document Inventory

1 PURPOSE

This document establishes the **AGENCY NAME's** document inventory policy.

2 SCOPE

This policy applies to all **AGENCY NAME** controlled documents.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

The **AGENCY NAME** will establish and maintain an inventory of all controlled documents used as part of its operational or quality system.

The document inventory will identify the current revision status and distribution of all operational and quality system documents and be readily available to preclude the use of invalid or obsolete documents.

The Quality Assurance Manager, or his designee, maintain the document inventory and update the status of a document within five days of original or revision approval.

- Policy Inventory Form will be used to inventory controlled documents.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

The signatures below recognize the above Administrative Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

DOCUMENT CONTROL

Document Approval

1 PURPOSE

This document establishes the **AGENCY NAME's** document approval policy.

2 SCOPE

This policy applies to controlled documents used by the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

All documents issued by the **AGENCY NAME** as part of its operational or quality system shall be reviewed and approved for use by an approving authority prior to issue.

Documents that require approval prior to issuance include:

- Operational policies, procedures and methods
- Quality system policies, procedures and methods
- Analytical policies, procedures and methods
- Forms, templates and worksheets designated by the Director Other documents designated by the Director

Originals or revisions of documents requiring approval shall become effective on the date of the signature of the Director.

All approved documents will contain the following signatures:

- The Director, or his designee
- The Quality Assurance Manager, or his designee
- Peer Group Technical Leader
    - Technical Documents Only

5 PROCEDURE

5.1 OPERATIONAL MANUALS

5.1.1 Document Review

The review process for all administrative policy and procedure changes or new drafts is as follows:

- The Quality Assurance Manager will review and submit with comment any administrative policy and procedure change or draft to the Director.
- The Director will distribute the suggested administrative policy and procedure change or draft to the senior management staff for review and comment.
- Comments and suggestions are incorporated into the proposed policy and procedure change or draft.
- The Director and the senior staff will review and comment on the amended policy and procedure change or draft.
- Comments and suggestions are incorporated into the amended policy and procedure change or draft.
- Final revision of the policy and procedure change or draft is submitted to the Director for approval.

5.1.2 Document Approval

The approval process for all administrative policy and procedure changes or new drafts is as follows:

- The Director of the AGENCY NAME and the Quality Assurance Manager perform a final administrative review of the proposed new or changes to an existing administrative policy or procedure.
- The Director and the Quality Assurance Manager each sign and date the APPROVAL section of the original document.
  - The effective date of the approved document will be the date of the Director's signature.
- The Quality Assurance Manager or his designee will distribute the new or modified policy or procedure in accordance with Policy and Procedure Dissemination Procedure.

5.2 TECHNICAL MANUALS

5.2.1 Document Review

The review process for all technical method, policy and procedure changes or new drafts is as follows:

- The Quality Assurance Manager will review the draft technical method, policy and procedure change or draft and submit it, along with the validation information, to the Technical Leader of the appropriate Peer Group.
- The Director will distribute the suggested analytical method, policy and procedure change or draft and associated validation information to Peer Group members for review and comment.

- Comments and suggestions are incorporated into the proposed technical method, policy and procedure change or draft.
- The Technical Leader and the Peer Group members will review and comment on the amended technical method, policy and procedure change or draft.
- Comments and suggestions are incorporated into the amended technical method, policy and procedure change or draft.
- Final revision of the technical method, policy and procedure change or draft is submitted to the Director for approval, through the Quality Assurance Manager.

5.3 DOCUMENT APPROVAL

The approval process for all technical method, policy and procedure changes or new drafts is as follows:

- The Director and the Quality Assurance Manager perform a final administrative review of the proposed new or changes to an existing administrative policy or procedure.
- The Director and the Quality Assurance Manager each sign and date the APPROVAL section of the original document.
  - The effective date of the approved document will be the date of the Director's signature.
- The Quality Assurance Manager or his designee will distribute the new or modified policy or procedure in accordance with Policy and Procedure Dissemination Procedure.

6 APPROVAL

The signatures below recognize the above Administrative Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

END OF DOCUMENT

DOCUMENT CONTROL

Document Format

1 PURPOSE

This document establishes the **AGENCY NAME's** document format policy.

2 SCOPE

This policy applies to all documents used by the **AGENCY NAME**.

3 DEFINITIONS

Administrative Policy APP-P101 will be used as a guide to define terms.

4 POLICY

All documents issued by the **AGENCY NAME** will be consistent in format and appearance.

4.1 GENERAL

All policies, procedures and methods will contain the following header and footer formats.

4.1.1 Header

The header of the first page of an approved controlled document will contain the AGENCY NAME logo.

The balance of the pages of an approved controlled document will be void of header information.

4.1.2 Footer

The footer of every page of an approved controlled document will contain the following information:

- The title and subtitle of the document
- The document number
- The document revision date and number
- The page number and total number of pages
- The due date of the next revision

The footer of every page of internal and external correspondence will contain the following information:

- The correspondence identification number
- The page number and total number of pages

4.2 POLICIES AND PROCEDURES

4.2.1 Policies

All policy documents will contain the following six sections

- 1 Purpose
- 2 Scope
- 3 Definitions
- 4 Policy
- 5 Procedure
- 6 Approval

4.2.2 Operational Procedures/Methods

All operational procedure and method documents will contain the following six sections

- 1 Purpose
- 2 Scope
- 3 Definitions
- 4 Policy
- 5 Procedure
- 6 Approval

4.2.3 Analytical Procedures/Methods

All analytical procedures and method documents will contain the following ten sections

- 1 Scope
- 2 Definitions
- 3 Reagents and Equipment
- 4 Procedure Summary
- 5 Precautions
- 6 Procedure
- 7 Conclusions
- 8 Precision and Bias
- 9 References
- 10 Approval

4.3 EXAMINATION REPORTS

Examination reports will contain the following information:

- Descriptive Information:
  - Laboratory Record Number.
  - The date the report was prepared.
  - The identity of each person who has rendered an opinion contained in the report.
  - The identity of the person or organization, or both, requesting the report.
  - Generic description of the item(s) examined together with specific data to uniquely identify the item(s).
  - Date and location of examination.
  - The scope of investigative activities performed in preparation for reaching conclusions and opinions.
- Pertinent Facts:
  - The report shall contain all facts that are pertinent to the opinion.
  - Identify other facts and data that the expert relies upon in rendering an opinion.
- Opinions and Conclusions:
  - The report shall contain all of the technical opinions and conclusions rendered by the expert concerning the purpose for which the expert was engaged.
  - The report shall contain the logic and reasoning of the expert by which each of the opinions and conclusions were reached.
- Signature:
  - The report shall contain the signature of each person who has rendered a joint or separate opinion contained in the report.
  - The signature(s) shall be at the end of the opinion.
  - A professional seal should be used, if applicable.
  - If an opinion rendered is that of two or more experts, a signature page may be used.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

The signatures below recognize the above Administrative Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

DOCUMENT CONTROL

Document Numbering

1 PURPOSE

This document establishes the **AGENCY NAME's** document numbering policy.

2 SCOPE

This policy applies to all documents used by the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

All controlled documents and correspondence issued by the **AGENCY NAME** will be assigned a unique identification number.

All pages of a controlled documents and correspondence issued by the **AGENCY NAME** will contain the document's unique identification number.

4.1 OPERATIONAL AND TECHNICAL MANUAL DOCUMENTS

Operational policy and procedure manual documents will contain a unique identification number using the following format:

- XXX-Y00x-0z.
  - XXX: Manual Identifier.
  - Y: Document Type.
    - P: Policy.
    - M: Method/Procedure.
    - F: Form.
    - S: Static Document.
    - PD: Position Description.
  - 00x: Document number.
    - Document numbers will be sequential.
    - There will be no break in the document numbering sequence.
  - 0z: Revision number.
    - Revision numbers will be sequential.
    - There will be no break in the revision numbering sequence.

4.1.1 Manual Identifier

The following abbreviations will be used to identify operational manuals:

- APP Administrative Policies and Procedures
- HAS Health and Safety
- PEM Property and Evidence
- QAM Quality Assurance

The following abbreviations will be used to identify technical manuals:

- AEX Arson and explosives examinations
- CSR Crime scene response
- DIG Digital evidence examinations
- DNA DNA examinations
- DRG Controlled substance examinations
- FAT Firearms and Toolmark examinations
- FCE Forensic computer examinations
- LAT Latent fingerprint examination
- PHO Photography and video
- QDE Questioned document examinations
- TFS Test Fire Section
- TOX Toxicology
- TRA Trace evidence
- VPA Voice Print analysis

4.2 CORRESPONDENCE

Internal and external correspondence subject to control will contain a unique identification number using the following format:

- ABC-YYYY-MM-DDa.
  - ABC: The initials of the individual generating the document.
  - YYYY: The year the document was generated.
  - MM: The month the document was generated.
  - DD: The day the document was generated.
  - a: An alpha designation of the document revision.

4.3 PROCUREMENT RECORDS

Each procurement actions will contain a unique procurement number using the following format:

- YY-MM-00x.
  - YY: The year the procurement was initiated.
  - MM: The month the procurement was initiated.
  - 00x: The procurement number.
    - Numbering begins with 001 on the first day of the month.

4.4 GRIEVANCE AND COMPLAINT RECORDS

Each Grievance / Complaint Record will contain a unique number using the following format:

- GCR-YY-00x.
  - GCR: Grievance/Complaint Record.
  - YY: The year the grievance/complaint was initiated.
  - 00x: The procurement number.
    - Numbering begins with 001 on 1 January.

4.5 CORRECTIVE ACTION REPORTS

Each Corrective Action Record will contain a unique number using the following format:

- CAR-YY-00x.
  - CAR: Corrective Action Report.
  - YY: The year the grievance/complaint was initiated.
  - 00x: The procurement number.
    - Numbering begins with 001 on 1 January.

4.6 CASE FILES

Case files will be numbered in accordance with Case Numbering Policy.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

The signatures below recognize the above Administrative Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

DOCUMENT CONTROL

Document Filing

1 PURPOSE

This document establishes the **AGENCY NAME's** document filing policy.

2 SCOPE

This policy applies to all documents filed by the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

All controlled documents and correspondence issued by the **AGENCY NAME** will be filled in a secure manner in which will enable efficient retrieval.

The **AGENCY NAME** will establish and maintain a filing system that will ensure the protection of its customers' confidential information and proprietary rights.

4.1 SAMPLE RECORDS

Sample records will be filed in a secure location designated by the Director.

Sample records will be filed using the **AGENCY NAME** record number in accordance to the document retention policy.

The Sample Control Section will establish and maintain a record of the dissemination of sample control files that have been filed and stored in the Sample Control Section.

4.2 EXAMINATION REPORTS

Examination reports will be filed in a secure location designated by the Director.

Examination reports will be filed using the **AGENCY NAME** record number in accordance to the document retention policy.

The Records Section will establish and maintain a record of the dissemination of case files that have been submitted for filing and storage.

4.3 CORRESPONDENCE

Internal and external communications will be filed in a location designated by the Director.

Internal and external communications will be filed using the document's identification number in accordance to the document retention policy.

4.4 PROCUREMENT RECORDS

Procurement records will be filed in a location designated by the Director.

Procurement records will be filed using the document's identification number in accordance to the document retention policy.

4.5 CORRECTIVE ACTION REPORTS

Corrective Action Reports will be filed in a location designated by the Quality Assurance Manager.

Corrective Action Reports will be filed by Corrective Action Report Number (APP-P036) in accordance to the document retention policy (APP-P044).

4.6 GRIEVANCE/COMPLAINT REPORTS

Grievance/Complaint Reports will be filed in a location designated by the Director.

Grievance/Complaint Reports will be filed by Grievance Complaint Number in accordance to the document retention policy.

5 PROCEDURE

There are no procedures that are directly applicable to this policy.

6 APPROVAL

The signatures below recognize the above Administrative Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

END OF DOCUMENT

DOCUMENT CONTROL

Report Dissemination

1 PURPOSE

This document establishes the **AGENCY NAME's** report dissemination policy.

2 SCOPE

This policy applies to all examination reports issued by the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

Examination reports will only be disseminated outside the **AGENCY NAME** after the completion of a technical and an administrative review.

Examination reports will only be disseminated to the individual or agency requesting the examination.

- It is the responsibility of the individual or agency requesting the examination to disseminate copies of examination reports to interested parties.
- The requesting individual or agency may provide written authorization to disseminate the examination report to specific individuals or organizations.

Examination reports will be disseminated to an individual or agency other than the one requesting the examination in response to a Duces Tatum subpoena from a court of record.

- Case notes and other items which are considered work product shall not be included with this dissemination.

Each case file will contain a record of the dates and means of transmission of examination report dissemination.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

The signatures below recognize the above Administrative Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

DOCUMENT CONTROL

Manual Dissemination

1 PURPOSE

This document establishes the **AGENCY NAME's** manual dissemination policy.

2 SCOPE

This policy applies to all operational and technical manuals issued by the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

An updated printed or electronic version of all operational and applicable technical manuals will be provided to each employee.

Revisions of individual polices, procedures or other documents associated with operational and technical manuals will be disseminated as soon as the revised document has been approved.

- Employees will remove outdated versions of individual polices, procedures or other documents from the associated with operational and technical manuals as soon as the current revision has been received.

All operational and technical manuals are for internal use.

The Director shall approve dissemination of non-controlled versions of operational or technical manuals outside the **AGENCY NAME**.

The AGENCY NAME will maintain a record of the dissemination of controlled and non-controlled versions of operational and technical manuals.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

The signatures below recognize the above Administrative Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

DOCUMENT CONTROL

Freedom of Information Act Requests

1 PURPOSE

This document establishes the **AGENCY NAME's** Freedom of Information Act policy.

2 SCOPE

This policy applies to all information requests under the Freedom of Information Act submitted to the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

The **AGENCY NAME** shall provide the information requested by legitimate Freedom of Information Act requests that meet the guidelines established by 5 U.S.C. § 552, As Amended by Public Law No. 104-231, 110 Stat. 3048 while maintaining the appropriate privacy of witnesses, victims and suspects.

5 PROCEDURE

All Freedom of Information Act requests will be forwarded, through the Director, to the **AGENCY NAME's** legal section for review and action.

6 APPROVAL

The signatures below recognize the above Administrative Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

DOCUMENT CONTROL

Document Retirement

1 PURPOSE

This document establishes the **AGENCY NAME's** document retirement policy.

2 SCOPE

This policy applies to all controlled operational and technical manuals used by the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

Invalid or obsolete documents will be promptly retired and removed from all points of issue or use, or otherwise assured against unintended use.

Invalid or obsolete documents will be retained for either legal or knowledge preservation purposes will be suitably marked.

Retired documents will maintain their original unique document identification number.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

The signatures below recognize the above Administrative Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

DOCUMENT CONTROL

Document Review

1 PURPOSE

This document establishes the **AGENCY NAME's** document review policy.

2 SCOPE

This policy applies to all controlled operational and technical manuals used by the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P001 will be used as a guide to define terms.

4 POLICY

Controlled documents will be periodically reviewed and, where necessary, revised to ensure continuing suitability and compliance with applicable requirements.

Controlled documents will be periodically reviewed and, where necessary, retired and removed from circulation if the document is no longer applicable.

The Quality Assurance Manager will establish and maintain a review schedule for controlled documents subject to review.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

The signatures below recognize the above Administrative Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

DOCUMENT CONTROL

File Removal

1 PURPOSE

This document establishes the **AGENCY NAME's** file removal policy.

2 SCOPE

This policy applies to all files containing controlled information maintained by the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

The AGENCY NAME will document the removal and return of all files containing controlled information.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

The signatures below recognize the above Administrative Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

DOCUMENT CONTROL

Electronic File Security

1 PURPOSE

This document establishes the **AGENCY NAME's** electronic file security policy.

2 SCOPE

This policy applies to all electronic files containing controlled information maintained by the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

The final revision of all controlled documents will be stored as a non-modifiable portable document format (pdf) file on a secure server and distributed in accordance with the document dissemination policy.

Controlled electronic document files will be routinely backed up to ensure their preservation.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

The signatures below recognize the above Administrative Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

SECURITY

Authorized Access

1 PURPOSE

This document establishes the **AGENCY NAME's** facility access policy.

2 SCOPE

This policy applies to all personnel who enter **AGENCY NAME** facilities.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

The **AGENCY NAME** will take the precautions necessary to ensure security and integrity of its facilities.

4.1 GENERAL ACCESS

Employees of the **AGENCY NAME** will have unrestricted access to common areas of the facility.

The Director may grant non-employee individuals general access privileges, as required.

All individuals granted general access privileges will wear identification credentials indicating their access status.

General access areas include:

- Conference Rooms and library
- Reception area
- Chemical and equipment storage areas
- Administrative and Technical Support section work areas
- Break rooms
- Other areas designated by the Director

4.2 LIMITED ACCESS

Individuals will be granted unrestricted access to limited access areas on an as needed basis.

Individuals granted unrestricted access to limited access areas will be provided keys to facilitate their unrestricted access to limited access area.

Individuals with general access privileges, but not limited access privileges to a specific area may enter a limited access area under the escort of an individual with access privileges.

All individuals granted access privileges to limited access areas will wear identification credentials indicating their access status.

Limited Access areas include:

- Laboratory areas used to examine samples
- Evidence storage areas within individual examination laboratories
- Office areas used by examiners
- Office areas used by technical and administrative support staff
- Document and records storage areas
- Sample Control Section office space
- Sample Control storage facilities
- Sample Control Currency and valuable storage vault
- Sample Control Firearms storage vault
- Other areas designated by the Director

5 PROCEDURE

There are no procedures directly related to the implementation of this policy.

6 APPROVAL

The signatures below recognize the above Administrative Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

SECURITY

Escort Policy

1 PURPOSE

This document establishes the **AGENCY NAME's** escort policy.

2 SCOPE

This policy applies to all personnel who enter **AGENCY NAME** facilities.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

Visitors and individuals with restricted access to the AGENCY NAME facilities will be required to be escorted at all times while in the facilities.

Upon entering the facility, visitors and individuals with restricted access will be issued identification credentials indicating the restricted nature of their access status.

Upon exiting the facility, visitors and individuals with restricted access will surrender their identification credentials indicating the restricted nature of their access status.

Individuals with unrestricted access to the AGENCY NAME facilities may freely enter and exit the facilities while wearing identification indicating the unrestricted nature of their access status.

- Unrestricted access individuals may obtain temporary identification in the event they do not have their issued credentials in their possession.

5 PROCEDURE

5.1 VISITOR ENTRANCE

- The individual requesting access to restricted areas:
  - Provides security personnel identification credentials with a photograph and laboratory point of contact information.
  - Completes the following sections of the Laboratory Entrance Log.
    - Date.
    - Name of the individual.
    - Reason for entry.
- Security personnel:
  - Compares the photograph on the identification credentials to the individual presenting them.
  - Places the identification credentials in a Visitor Badge storage container.

- Contacts the individual's point of contact.
- Completes the following sections of the APP-F007.
  - Badge #.
- Issues the individual a Visitor, Restricted Access badge.
  - The badge will be worn in a conspicuous location for the duration of the individual's stay within facilities.

- Visitor's Escort:
  - Completes the following sections of the Laboratory Entrance Log.
    - Escort's name.
    - Time in.
    - Reason for entry.
  - Accompanies the visitor to the destination(s) within the facility.

5.2 VISITOR EXIT

- The Escort.
  - Accompanies the visitor in his charge to the security station.
- The Visitor.
  - Returns the Visitor Access Badge to security personnel.
  - Visitors who require facility access for a continual period may retain their access badge for the duration of their stay.
- Security Personnel.
  - Retrieves and returns the visitor's identification credentials.
  - Completes the following sections of the Laboratory Entrance Log.
    - Time out.

6 APPROVAL

The signatures below recognize the above Administrative Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

END OF DOCUMENT

SECURITY

Facility Entry Log

1 PURPOSE

This document establishes the **AGENCY NAME's** facility entry log policy.

2 SCOPE

This policy applies to all personnel and vehicles that enter **AGENCY NAME** facilities.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

4.1 INDIVIDUALS

The **AGENCY NAME** will establish and maintain a record of all restricted access individuals who enter secure facilities.

The visitor entry log will contain the following information:

- Date
- Badge #
- Time in
- Time out
- Visitor's Name
- Escort's name
- Reason for entry

Visitors and individuals with restricted access to **AGENCY NAME** facilities will sign the visitor entry log prior to entering any facility.

Visitors and individuals with restricted access will be issued identification credentials indicating the restricted nature of their access status.

Upon exiting the facility, visitors and individuals with restricted access will sign the visitor entry log and surrender their identification credentials.

4.2 VEHICLES

The **AGENCY NAME** will establish and maintain a record of all restricted access vehicles that enter secure areas of **AGENCY NAME** facilities.

The vehicle entry log will contain the following information:

- Date
- Vehicle License Plate Number
- Time in
- Time out
- Visitor's Name(s)
- Badge Number(s)
- Reason for entry

Information about vehicles with restricted access to AGENCY NAME facilities will be entered into the vehicle entry log prior to entering any facility.

Individuals with restricted access will be issued identification credentials identifying the restricted nature of their access status.

Upon exiting the facility, individuals with restricted access will receive their identification credentials and vehicle exit time will be recorded.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

The signatures below recognize the above Administrative Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

SECURITY

Hours of Operation

1 PURPOSE

This document establishes the **AGENCY NAME's** hours of operation policy.

2 SCOPE

This policy applies to all personnel who enter **AGENCY NAME** facilities.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

4.1 BUSINESS HOURS

The **AGENCY NAME's** normal business hours will be open to the public Monday through Friday from 0800 hours to 1700 hours.

Authorized personnel may occupy **AGENCY NAME** facilities two (2) hours prior and two (2) hours after normal business hours.

- Security personnel are exempt from this time restriction.

Access to facilities outside normal business hours is prohibited, unless authorized by the Director.

4.2 AFTER HOURS ACCESS

The Director may allow authorized personnel access to facilities outside normal business hours to facilitate the agency's mission.

- The Director, or his designee, will provide security personnel a list of personnel authorized after hours access.

Security personnel will establish and maintain an after hours entry log of all individuals who enter facilities outside normal business hours.

The after hours entry log will contain the following information:

- Date
- Time in
- Time out
- Employee's Name
- Reason for entry

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

The signatures below recognize the above Administrative Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

SECURITY

Alarms

1 PURPOSE

This document establishes the **AGENCY NAME's** alarm policy.

2 SCOPE

This policy applies to all **AGENCY NAME** facilities.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

4.1 INTRUSION ALARMS

The Director will determine the number of intrusion alarms required to ensure the security and integrity of the offices, laboratories and storage facilities.

The security staff will monitor the intrusion alarms twenty-four (24) hours a day, seven (7) days a week basis, when required.

The security staff will test and document the functionality of intrusion alarms the first week of every month, using the Security Equipment Inspection Form.

4.2 VIDEO SURVEILLANCE

The Director will determine the number of video surveillance cameras required to ensure the security and integrity of the offices, laboratories and storage facilities.

The security staff will monitor the video surveillance cameras on twenty-four (24) hours a day, seven (7) days a week basis, when required.

The security staff will test and document the functionality of the video surveillance cameras the first week of every month, using the Security Equipment Inspection Form.

4.3 FIRE AND SMOKE ALARMS

The Director will determine the number of fire and smoke detection alarms required to ensure the security and integrity of the offices, laboratories and storage facilities.

The security staff will monitor the fire and smoke detection alarms on twenty-four (24) hours a day, seven (7) days a week basis.

The security staff will test and document the functionality of the fire and smoke detection alarms the first week of every month, using the Security Equipment Inspection Form.

4.4 DURESS ALARMS

The Director will determine the number of duress alarms required to ensure the security and integrity of the offices, laboratories and storage facilities.

The security staff will monitor the duress alarms on twenty-four (24) hours a day, seven (7) days a week basis, when required.

The security staff will test and document the functionality of the duress alarms the first week of every month, using the Security Equipment Inspection Form,

4.5 DOCUMENTATION

The **AGENCY NAME** will establish and maintain a file of the completed Security Equipment Inspection Forms.

The Security Equipment Inspection Forms will be maintained for a period no less than 36 months.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

The signatures below recognize the above Administrative Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

SECURITY

Security Staff

1 PURPOSE

This document establishes the **AGENCY NAME's** security staff policy.

2 SCOPE

This policy applies to all **AGENCY NAME** facilities.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

The Director will determine the number of security personnel required to augment electronic alarms used to ensure the security and integrity of the offices, laboratories and storage facilities.

The security staff will perform and document an hourly check on the security and safety status of the personnel, offices, laboratories and storage facilities.

- During business hours the security and safety status check may consist solely of telephone communication with section personnel.
- After hours security status check will involve the physical evaluation of the offices, laboratories and storage spaces as well as exterior windows and doors.

Hourly security and safety status evaluation will be documented using the Security and Safety Status form.

- The security staff employee will place his initials in the box corresponding to the time and location he evaluated.
- The security staff employee will indicate the type of evaluation performed by placing a number next to his initials.
  - 1: Personal observation.
  - 2: Telephone verification.

The security staff will operate and maintain the alarm and electronic security systems.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

The signatures below recognize the above Administrative Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

SECURITY

Security Breach

1 PURPOSE

This document establishes the **AGENCY NAME's** security breach policy.

2 SCOPE

This policy applies to all **AGENCY NAME** facilities.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

Security personnel will notify the Director and the appropriate Section Chief upon the detection of a security breach of any offices, laboratories or storage facility.

The Director and the appropriate Section Chief will confer to determine the nature of the security breach.

If criminal in nature:

- Law enforcement will be notified.
- A criminal investigation will ensue.
- The area involved will be treated as a crime scene.
- Identify the cause of the security breach.
- Implement changes necessary to ensure the security breach does not reoccur.
- A complete inventory of all property and evidence stored in the area of the security breach will be conducted.

If Non-criminal in nature the Section Chief will:

- Identify the cause of the security breach.
- Implement changes necessary to ensure the security breach does not reoccur.
- Authorize an inventory of all property and evidence stored in the area of the security breach, if necessary.

Security personnel will document all detected security breaches in the security log and on a Security Breach / Safety Violation Report form, which will be forwarded to the Section Chief with a copy sent to the Director.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

The signatures below recognize the above Administrative Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

SECURITY

Safety Violation

1 PURPOSE

This document establishes the **AGENCY NAME's** safety violation policy.

2 SCOPE

This policy applies to all **AGENCY NAME** facilities.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

Security personnel will identify and abate any safety violations detected during their routine security checks.

Security personnel will document all safety violations in the security log and on a Security Breach/Safety Violation Report form, which will be forwarded to the appropriate Section Chief with a copy sent to the Director.

The Section Chief will identify the source of the safety violation and take appropriate action to rectify the issue.

5 PROCEDURE

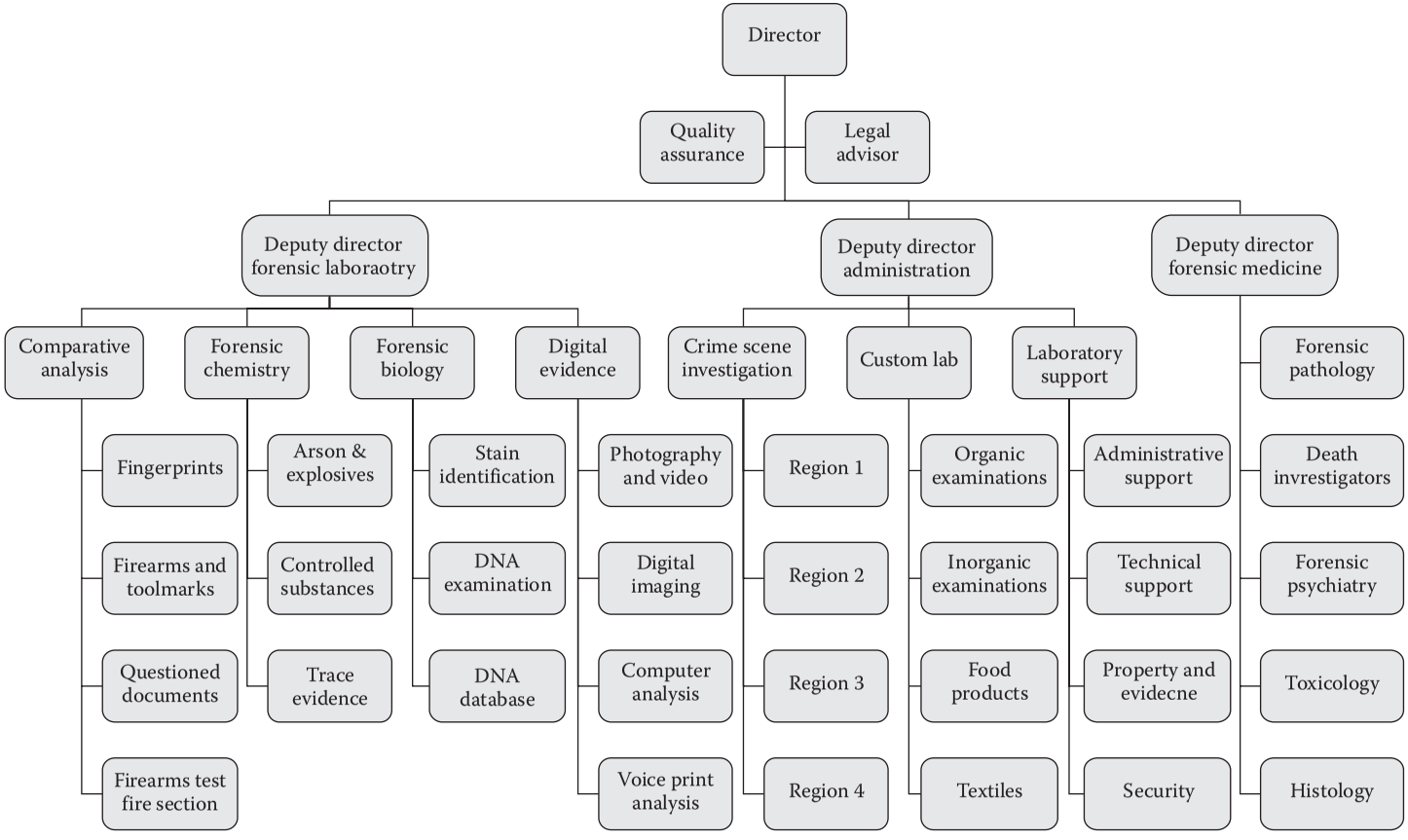
There are currently no procedures that directly affect the implementation of this policy.

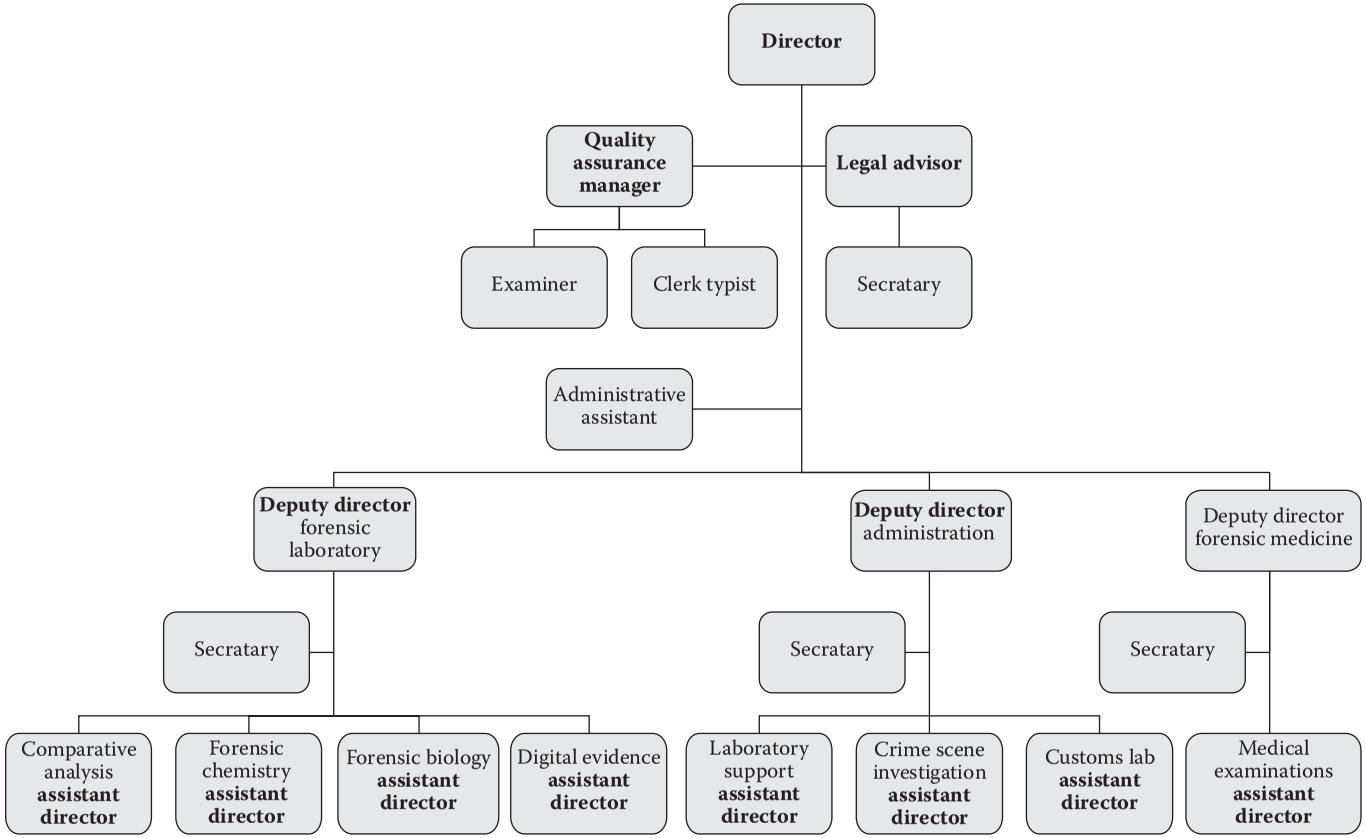
6 APPROVAL

The signatures below recognize the above Administrative Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document


Director
Quality assurance
Legal advisor
Deputy director forensic laboraotry
Deputy director administration
Deputy director forensic medicine
Comparative analysis
Forensic chemistry
Forensic biology
Digital evidence
Crime scene investigation
Custom lab
Laboratory support
Forensic pathology
Fingerprints
Firearms and toolmarks
Questioned documents
Firearms test fire section
Arson & explosives
Controlled substances
Trace evidence
Stain identification
DNA examination
DNA database
Photography and video
Digital imaging
Computer analysis
Voice print analysis
Region 1
Region 2
Region 3
Region 4
Organic examinations
Inorganic examinations
Food products
Textiles
Administrative support
Technical support
Property and evidecne
Security
Death invrestigators
Forensic psychiatry
Toxicology
Histology


Director
Quality assurance manager
Legal advisor
Examiner
Clerk typist
Secratary
Administrative assistant
Deputy director forensic laboratory
Deputy director administration
Deputy director forensic medicine
Secratary
Secratary
Secratary
Comparative analysis assistant director
Forensic chemistry assistant director
Forensic biology assistant director
Digital evidence assistant director
Laboratory support assistant director
Crime scene investigation assistant director
Customs lab assistant director
Medical examinations assistant director

MANAGEMENT AND ORGANIZATION

Staffing Levels

Section/Unit	Total	Supervisory	Examiners	Technicians	Clerical
Executive Staff	**11**	5	1	0	5
Medical Examination Sect.	**2**	1	0	0	1
Pathology	**9**	1	4	2	2
Death Investigation					
Histology					
Toxicology					
Psychiatry	**7**	1	4	0	2
Identification Section	**2**	1	0	0	1
Fingerprints	**12**	2	5	5	0
Firearms and Toolmarks	**6**	1	5	0	0
Firearms Test Fire Sec.	**11**	3	1	4	3
Questioned Documents	**7**	1	6	0	0
Forensic Biology Section	**2**	1	0	0	1
Stain Identification	**5**	1	4	0	0
DNA Identification	**8**	1	4	2	1
DNA Database	**5**	1	4	0	0
Forensic Chemistry Section	**2**	1	0	0	1
Drug Analysis	**7**	1	4	1	1
Trace Evidence	**7**	1	4	1	1
Arson/Explosives	**7**	1	4	1	1
Customs Lab	**2**	1	0	0	1
Organic Unit	**6**	1	4	0	1
Inorganic Unit	**6**	1	4	0	1
Food Unit	**6**	1	4	0	1
Textiles Unit	**6**	1	4	0	1
Digital Evidence	**2**	1	0	0	1
Photography / Video	**5**	1	4	0	0
Digital Imaging	**5**	1	4	0	0
Voice Prints	**5**	1	4	0	0
Computer Forensics	**5**	1	4	0	0
Crime Scene	**26**	5	0	16	5
Support Services	**2**	1	0	0	1
Adminstrative Support	**13**	1	0	0	12
Technical Support	**5**	1	0	0	4
Security	**11**	1	0	10	0
Property/Evidence	**6**	1	0	4	1

CODE OF CONDUCT

Agency Name

AGENCY NAME employee's role is to serve justice by using their expertise to further the doctrine of fairness. Therefore, they pledge:

- To maintain the highest standards of professional practice.
- To remain totally objective and to use their ability so that justice is served by accurate determination of the facts involved.
- To thoroughly examine and analyze the evidence in a case, to conduct examinations based on established scientific principles, and render opinions which have a demonstrably reasonable basis for my conclusion.
- Not to intentionally withhold or omit any findings or opinions discovered during a forensic examination that would cause the facts of a case to be misinterpreted or distorted.
- Never misrepresent their credentials, education, training, experience or employment status.
- To refrain from any conduct that would be adverse to the best interest and purpose of AGENCY NAME.
- To be forever vigilant of the importance of my role and to conduct myself only in the most professional manner at all times.

APPROVAL

The signatures below recognize the above as the approved Code of Conduct effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

PERSONNEL

Position Description
Job Title

1 PURPOSE

This document establishes the **AGENCY NAME'S** job description for the position of **INSERT JOB TITLE**.

2 SCOPE

This policy applies to all personnel applying for or holding the position of **INSERT JOB TITLE**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 DUTIES

- Duty 1
- Duty 2
- Duty 3
- Duty 4
- Duty 5
- Duty …..

5 KNOWLEDGE AND ABILITIES

5.1 KNOWLEDGE OF:

- Knowledge set 1
- Knowledge set 2
- Knowledge set 3
- Knowledge set 4
- Knowledge set 5
- Knowledge set …

5.2 ABILITY TO:

- Ability 1
- Ability 2
- Ability 3
- Ability 4
- Ability 5
- Ability …

6 MINIMUM QUALIFICATIONS

- Education Requirements
- General Experience Requirements
- Specific Experience Requirements
- Professional Training Requirements

7 APPROVAL

The signatures below recognize the above Administrative Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

Appendix C

Administrative Policy Manual

(Revision XX)

This document represents the administrative policies of the **AGENCY NAME**. All additions, deletions and modifications to this document are done in accordance with the policy preparation policy. This document is the property of the **AGENCY NAME** and cannot be reproduced without authorization.

Official revisions are incorporated annually. Interim modifications will be documented and implemented in accordance to the document modification policy. A copy of the interim modification will be distributed and inserted into the appropriate portion of each printed section of this manual.

The signatures below recognize the total volume as the official administrative policy of the **AGENCY NAME** effective **DATE**.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

CONTENTS

ADMINISTRATIVE POLICIES AND PROCEDURES

Management and Organization

Legal Authority

The **AGENCY NAME** operates under the legal authority of **INSERT LEGAL CITATION AND LINK TO STATUTE'S TEXT OR LINK TO THE ORGANIZATION'S ARTICLES OF INCORPORATION**.

Mission Statement

The mission of the **AGENCY NAME** is to provide its users a sustainable level of quality scientific examination services based upon international standards of quality and dedication to continual self improvement of its analytical and management systems.

Goals and Objectives

The **AGENCY NAME** will establish and maintain a documented set of goals and objectives that are relevant to the needs of the community they sever.

AGENCY NAME employees will be advised of the **AGENCY NAME** goals and objectives and any changes there of.

All employees agree to support the documented goals and objectives of the **AGENCY NAME** by virtue of their employment.

Goal One

Goal Goal one of the **AGENCY NAME** is to utilize accepted and validated scientific examination techniques.

Objectives The **AGENCY NAME** will achieve or maintain Goal One through:

- Identifying and utilizing examination techniques that will satisfy the analytical needs of the **AGENCY NAME's** customers.
- Identifying funding sources that will enable the **AGENCY NAME** to increase their level of technology.
- Increase the level of sustainable technology as funding permits.

Goal Two

Goal Goal two of the **AGENCY NAME** is to provide quality scientific examinations.

Objectives The **AGENCY NAME** will achieve or maintain Goal Two through:

- Utilizing examiners with the knowledge skills and abilities required to competently execute the examination.
- Utilizing analytical methods that have been validated and accepted by the scientific community.
- Establishing and maintaining a quality assurance program.
- Obtaining and maintaining laboratory accreditation through a recognized accreditation body.

Goal Three

Goal Goal three of the **AGENCY NAME** is to continually evaluate and improve the services provided.

Objectives The **AGENCY NAME** will achieve or maintain Goal Three through:

- Seeking client input and implementing their recommendations within their financial ability.
- Seeking employee input and implementing their recommendations within their financial ability.
- Performing quality systems audits and implement their recommendations within their financial ability.

Services and Functions

General Services

The **AGENCY NAME** will provide the following analytical services:

- Crime scene response
- Forensic chemistry
  - Controlled substance examinations
  - Toxicology
  - Trace evidence
  - Arson and explosives examinations
- Forensic biology
  - Biological stain identification
  - DNA examinations
- Comparative analysis
  - Fingerprints
  - Firearms examinations
  - Firearms Test Fire Program
  - Tool mark examinations
  - Questioned document examinations

- Digital evidence examinations
  - Photography and video
  - Voice Print analysis
  - Forensic computer examinations
- Laboratory Support
  - Administrative support
  - Technical support
- Property and Evidence Receipt and Storage

Regional Services

The **AGENCY NAME** will establish regional facilities to provide services specifically require by the customers in that regional area.

Region 1 The **AGENCY NAME** will provide the following analytical services in Region 1:

- Crime scene response
- Forensic chemistry
  - Controlled substance examinations
  - Toxicology
  - Trace evidence
  - Arson and explosives examinations
- Forensic biology
  - Biological stain identification
  - DNA examinations
- Comparative analysis
  - Fingerprints
  - Firearms examinations
  - Tool mark examinations
  - Questioned document examinations
- Digital evidence examinations
  - Photography and video
  - Voice Print analysis
  - Forensic computer examinations
- Laboratory Support
  - Administrative support
  - Technical support
  - Property and Evidence Receipt and Storage

Region X The **AGENCY NAME** will provide the following analytical services in Region X:

- Crime scene response
- Forensic chemistry
  - Controlled substance examinations
  - Toxicology
  - Trace evidence
  - Arson and explosives examinations

- Forensic biology
  - Biological stain identification
  - DNA examinations
- Comparative analysis
  - Fingerprints
  - Firearms examinations
  - Tool mark examinations
  - Questioned document examinations
- Digital evidence examinations
  - Photography and video
  - Voice Print analysis
  - Forensic computer examinations
- Laboratory Support
  - Administrative support
  - Technical support
  - Property and Evidence Receipt and Storage

Budget

The senior management of the **AGENCY NAME** will establish and maintain an annual written budget adequate to meet written objectives.

Each section will annually provide the senior management with information concerning their future chemical, equipment and consumable items needs adequate to meet their objectives.

The senior management of the **AGENCY NAME** will utilize historical budgets, future needs and current financial allocations in developing the current year's budget.

The final written budgets will be filed in accordance with the **AGENCY NAME** document retention policy (Insert Relevant Document Number).

Procedure

Budget Development Procedure is defined in the following procedures:

- Insert an outline of the budget procedure utilized by your agency.

Policy and Procedure Development and Distribution

The **AGENCY NAME** will develop, document and maintain the policies procedures and analytical methods required to operate an analytical laboratory.

All employees of the **AGENCY NAME** will be provided a copy of the most recent revision of the policies, procedures and analytical methods they would be responsible for compliance.

Procedure

Development

Document Need The **AGENCY NAME** will develop a new or modify an existing policy or procedure when:

- The Director, senior management or Quality Assurance Manager identifies the need for a new or change of an existing policy or procedure, or
- An employee suggests the need for a new or change of an existing policy or procedure, or
- Changes in legal statutes or applicable case law requires a new or change of an existing policy or procedure, or
- Changes of the administrative regulations within the **AGENCY NAME's** parent organization requires a new or change of an existing policy or procedure

Document Draft The Quality Assurance Manager, or his designate, will research and draft a new or change an existing policy or procedure to address the needs identified through one of the above mechanisms.

Document Review All policy and procedure changes or drafts will be submitted to the Director, or his designee, for review and comment.

The review process for all policy and procedure changes or new drafts is as follows:

- The Quality Assurance Manager will review and submit with comment any policy and procedure change or draft to the Director.
- The Director will distribute the suggested policy and procedure change or draft to the senior management staff for review and comment.
- Comments and suggestions are incorporated into the proposed policy and procedure change or draft.
- The Director and the senior staff will review and comment on the amended policy and procedure change or draft.
- Comments and suggestions are incorporated into the amended policy and procedure change or draft.
- Final revision of the policy and procedure change or draft is submitted to the Director for final approval.

Document Approval The approval process for all administrative policy and procedure changes or new drafts is as follows:

- The Director and the Quality Assurance Manager perform a final administrative review of the proposed new or changes to an existing administrative policy or procedure.
- The Director and the Quality Assurance Manager each sign and date the APPROVAL section of the original document.
    - The effective date of the approved document will be the date of the Director's signature.
- The Quality Assurance Manager, or his designee, will distribute the new or modified policy or procedure in accordance with dissemination procedure.

Dissemination

Operational Manuals The Quality Assurance Manager will:

- Compile the current electronic or print revisions of all operational policies and procedures to create a year's master Operational Manual.
- Create print copies of the Operational Manual for:

    - Each **AGENCY NAME** facility.
    - Each **AGENCY NAME** employee.
    - Each print copy of the Operational Manual will be placed in a loose leaf binder of sufficient size to accommodate the current manual with room for additional pages as additions and updates occur.
- Number each copy of the **AGENCY NAME** Operational Manual created.
- Distribute copies of the Operational Manual.
    - Operational Manual Distribution will be documented using the Operational Manual Distribution Log (Form APP-F002).
- Update the master Operational Manual as required.
- Distribute print copies of the approved Operational Manual updates as required.

The Quality Assurance Manager may create and distribute electronic copies of the Operational Manual in lieu of, or in addition to, the print copies.

Technical Manuals The Quality Assurance Manager will:

- Compile the current electronic or print revisions of the technical policies and procedures of each discipline.
- Create print copies of each Technical Manual for:
    - Each **AGENCY NAME** facility.
    - Each employee with responsibilities in that discipline.
    - Each print copy of the Technical Manual will be placed in a loose leaf binder of sufficient size to accommodate the current manual with room for additional pages as additions and updates occur.
- Number each copy of the Technical Manuals created.
- Distribute copies of the Technical Manual.
    - Technical Manual distribution will be documented using the Technical Manual Distribution Log (Form APP-F003).
- Update the master Technical Manuals as required.
- Distribute print copies of the approved Technical Manual updates as required.

The Quality Assurance Manager may create and distribute electronic copies of Technical Manuals in lieu of, or in addition to, the print copies.

Updates The Quality Assurance Manager will provide all holders of Operational and Technical Manuals copies of the approved updates to their respective manuals, as soon as they are available.

- Update format (print or electronic) will depend upon the format the holder possesses.
- Changes in the document shall be easily identified.
- The distribution of updates to Operational and Technical manuals will be documented by the Quality Assurance Manager.

The holders of Operational and Technical Manuals are responsible for inserting updated and removing obsolete copies of policies, procedures and methods.

- Holders are responsible for printing electronic files and inserting the printed version into appropriate printed manual, when required.

Policy and Procedure Review and Understanding

The **AGENCY NAME** will establish procedures to ensure that each employee understands the policies, procedures and analytical methods they are responsible for compliance.

Procedure

Operational Manual

- Each employee will be issued an Operational Manual to include:
  - Administrative Policy and Procedure Manual.
  - Health and Safety Manual.
  - Sample Control Manual.
  - Quality Assurance Manual.
- Each employee will be provided time to review all components of the Operational Manual.
- Each employee will review the contents of all components of the Operational Manual with the Quality Assurance Manager, or his designee.
- Operational Manual review and understanding will be documented using the following forms:
  - APP-F004: Administrative Policy Orientation.
  - HAS-F001: Health and Safety Orientation.
  - HAS-F002: Health and Safety Review.
  - QAM-F001: Quality Assurance Orientation.
  - SCM-F001: Sample Control Orientation.

Technical Manuals

- Each employee will be issued a Technical Manual for each discipline they have analytical responsibility.
- Each employee will be provided time to review all components of the Technical Manual
- Each employee will review the contents of all components of the Technical Manual with the Quality Assurance Manager, or his designee.
- Technical Manual review and understanding will be documented using competency and proficiency testing mechanisms outlined in each Technical Manual.

Long Range Planning

The **AGENCY NAME** will establish a long range planning committee.

The long range planning committee will use previous budgets, case load statistics and projected chemical and equipment needs to prepare a 3, 5 and 10 year plans.

The long range planning committee will modify the 3, 5 and 10 year plans as necessary to meet the needs of the **AGENCY NAME**.

Organizational Structure

The **AGENCY NAME** management structure shall cover work carried out in permanent facilities, at sites away from its permanent facilities, and in associated temporary or mobile facilities.

The responsibilities of **AGENCY NAME** management that have an involvement or influence on the testing and/or calibration activities of the laboratory shall be defined in separately from non-laboratory management managers in order to identify and eliminate potential conflicts of interest.

The organizational structure of the **AGENCY NAME** shall group the work and personnel in a manner that allows for efficiency of operation, taking into account the interrelation of various forensic disciplines.

The Director will consider and taken appropriate action to correct any discrepancies with regard to numbers of personnel when grouping work and resources.

The following documents define the organizational structure that allows for efficiency of operation, taking into account the interrelation of various forensic disciplines.

- APP-S001: General Organization
- APP-S002: Comparative Analysis Section
- APP-S003: Forensic Chemistry
- APP-S004: Forensic Biology
- APP-S005: Digital Evidence
- APP-S006: Crime Scene Investigations
- APP-S007: Laboratory Support
- APP-S008: Management

Work Content

The **AGENCY NAME** will avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgment or operational integrity.

Each analytical section will only perform examinations under its jurisdiction.

Cases with multiple analytical requirements will be triaged based and examination sequence will be established based upon the requested examinations probative value.

Procedure

Single Exam Type Submissions Single exam type cases will be assigned using the following procedure:

- The Sample Control Section receives samples and forwards the Request for Examination Form to the Deputy Director's Office for distribution.
- The Deputy Director, or his designee, will review the Request for Examination Form and determines which analytical section will perform the examination.
- The Deputy Director will place the 3 letter section code of the assigned analytical section in the upper right corner of the PEM-F005.
  - The letters will be written in red ink.
  - The three letter section code will be as follows:
    - AEX Arson and explosives examinations.
    - CSR Crime scene response.
    - DIG Digital evidence examinations.
    - DNA DNA examinations.
    - DRG Controlled substance examinations.
    - FAT Firearms and Toolmark examinations.
    - FCE Forensic computer examinations.

        - LAT Latent fingerprint examination.
        - PHO Photography and video.
        - QDE Questioned document examinations.
        - TFS Test Fire Section.
        - TOX Toxicology.
        - TRA Trace evidence.
        - VPA Voice Print analysis.
- The Deputy Director's clerical staff will enter the case information into the Laboratory Information Management System.
- The Deputy Director's clerical staff will sort and forward the Request of Examination Forms to the appropriate Section Chief for examiner assignment and distribution.
- Each Section Chief will assign and distribute cases based upon:
    - The complexity of the case.
    - The experience of the examiner.
    - The examiner's backlog.

Multiple Exam Type Submissions Multiple exam type cases will be assigned using the following procedure:

- The Sample Control Section receives samples and forwards the Request for Examination Form to the Deputy Director's Office for distribution.
- The Deputy Director, or his designee, will review the Request for Examination Form and determine which analytical sections will be required to perform examinations.
    - The Deputy Director will prioritize the examinations required and establish the order in which the examinations will take place.
    - The Deputy Director may consult with the Section Chiefs involve to assist in the decision process.
- The Deputy Director will, in the upper right corner of the Request for Examination Form, place the 3 letter section code for each of the assigned analytical section.
    - The letters will be written in red ink.
    - The codes will be stacked, one on top of the others, in descending order of priority.
        - First examination on top.
        - Last examination on the bottom.
    - The three letter section code will be the same as listed in section 5.1 of this procedure.
- The Deputy Director's clerical staff will enter the case information into the Laboratory Information Management System.
- The Deputy Director's clerical staff will sort and forward the Request for Examination Form's to the appropriate Section Chief for examiner assignment and distribution.
    - The clerical staff will make one copy of the Request for Examination Form for each analytical section participating in the examination process.
        - The original copy will be sent to the analytical section that will perform the first examination(s).
        - Copies will be sent to the other sections for informational purposes.
    - The original will be passed to the next Section Chief when the previous examination has been completed.

- Each Section Chief will assign and distribute cases based upon:
  - The complexity of the case.
  - The experience of the examiner.
  - The examiner's backlog.

Out of Sequence Examinations Exhibits that require a single examination type may be processed out of sequence, if the exhibit is packaged separately and its examination will not effect the examination of other exhibits in the case.

Delegation of Authority

Management and supervisory personnel will have authority commensurate with their responsibilities.

The authority to address issues will be delegated to the lowest possible lowest level of supervision or management.

The **AGENCY NAME** will establish, maintain and distribute a roster of personnel with decision making authority in the absence of a management or supervisory personnel.

- An updated Acting Authority Roster (APP-F017) will de distributed to all **AGENCY NAME** employees within one business day of permanent change.
- A memorandum or electronic–mail may be used to advise effected personnel of temporary changes to the Acting Authority Roster.

Supervision

The **AGENCY NAME** will provide adequate supervision of staff, including trainees, by persons familiar with methods, procedures, and purpose of each examination, and with the assessment of the examination results.

Supervisors shall have the authority and resources needed to carry out their duties and to identify the occurrence of departures from the quality system or from the procedures for performing tests and/or calibrations, and to initiate actions to prevent or minimize such departures.

Supervisors shall encourage creative, objective thinking & recognize meritorious performance.

Each subordinate shall be accountable to only one immediate supervisor per function.

Communication

The **AGENCY NAME** management shall establish vertical and horizontal lines of communication within the laboratory and that communication takes place regarding the effectiveness of the management system.

The **AGENCY NAME** management will ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the objectives of the management system.

The **AGENCY NAME** management will ensure that its parent organization and funding authorities are aware of the importance of meeting customer requirements as well as statutory and regulatory requirements.

Internal Communication

The management team shall conduct regular meetings with Section Chiefs to disseminate information.

Section Chiefs shall conduct regular meetings with subordinates to disseminate information.

Peer groups shall relay information to the management team.

External Communication

The management team shall conduct user group meetings to establish a line of communication between the **AGENCY NAME** and it clients.

An examination satisfaction questionnaire shall sent to establish a line of communication between the **AGENCY NAME** and it clients.

- A Customer Satisfaction Questionnaire (QAM-F002) shall accompany every examination report issued by the **AGENCY NAME**.

Quality Assurance Program

The **AGENCY NAME** will establish and maintain a quality assurance program.

The policies and procedures of the quality assurance program are outlined in the Quality Assurance Manual.

Physical Plant

Space

Each employee shall have adequate work space to accomplish their assigned tasks.

Examiners shall have adequate space for writing reports & other official communications separate from the area examinations are performed.

There shall sufficient space provided for storage of supplies, equipment & tools.

There shall be adequate & appropriate space available for records, reference works & other necessary documents.

There shall be adequate space available for each instrument/equipment to facilitate its operation.

Accessories shall be stored near instrumentation or equipment to facilitate its use & operation.

Design

The physical design of the facilities shall permit the efficient flow of evidence from the time of its acceptance until its proper disposal.

The relative locations of functional areas shall facilitate the efficient use of equipment & instruments.

The facilities shall have adequate & proper lighting for personnel to carry out assigned tasks.

The facilities shall have adequate & proper plumbing & wiring available & accessible to carry out assigned tasks.

The facilities shall have proper general ventilation.

The facilities shall have adequate heating, cooling & humidity controls.

The facilities shall be designed to secure the facility from unauthorized entry.

Procedure

The U.S. Department of Justice, National Institute of Justice's Lab Design Guide (APP-S009) will be used to define the general design requirements for **AGENCY NAME** facilities.

Construction

AGENCY NAME facilities shall be constructed of materials to secure the facility from unauthorized entry.

Procedure

The U.S. Department of Justice, National Institute of Justice's Lab Design Guide (APP-S009) will be used to define the general construction requirements for **AGENCY NAME** facilities.

Access Control

Access to the operational area of the laboratory shall be controllable and limited.

All exterior entrance and exit points shall have adequate security controls.

All internal areas requiring limited or controlled access shall have a lock system.

Distribution of all keys, magnetic cards, etc., shall be documented and is distribution limited to those individuals designated by the laboratory director to have access (See APP-P205).

Key Control

Only **AGENCY NAME** personnel will possess keys to the secure offices, laboratories and storage facilities.

All keys will have an individual identification number imprinted upon the key.

The Director will authorize one or more individual authorized to duplicate keys.

The Director will designate and individual to issue keys as required.

Individuals authorized unrestricted access to **AGENCY NAME** facilities will be issued general access keys and limited access keys.

General Access

General access keys will be issued to all individuals who are authorized to have access to **AGENCY NAME** facilities.

The following areas will each be keyed for general access:

- Chemical and equipment storage areas
- Secure doors to common office areas
- Secure doors to Administrative and Technical Support section offices

The **AGENCY NAME** will establish and maintain a record of individuals that are issued general access keys (APP-F006).

Limited Access

Limited access keys will be issued individuals who require unregulated access to specific parts of **AGENCY NAME** facilities.

- Each limited access area will have a separate and distinct key system.

The following areas will each be keyed for limited access:

- Laboratory areas used to examine physical evidence
- Evidence storage areas within individual examination laboratories
- Office areas used by examiners
- Office areas used by technical and administrative support staff
- Document and records storage areas
- Chemical and equipment storage
- Sample Control Section office space
- Sample Control Section storage facilities
- Sample Control Section currency and valuable storage vault
- Sample Control Section firearms storage vault
- Other areas designated by the Director of the **AGENCY NAME**

The **AGENCY NAME** will establish and maintain a record of individuals that are issued limited access keys.

Alarms

Facilities shall be secured during vacant hours by means of electronic alarms or by security personnel.

The Director will determine the number of alarm systems required to ensure the security and integrity of the offices, laboratories and storage facilities.

Alarm systems shall include but not limited to:

- Intrusion alarms
- Fire and smoke detection alarms
- Duress alarms
- Video surveillance cameras

The Director will determine the number of security personnel required to augment electronic alarms used to ensure the security and integrity of the offices, laboratories and storage facilities.

Personnel

Position Descriptions and Minimum Qualifications

The **AGENCY NAME** will establish job descriptions and minimum qualifications for each position.

- All job descriptions and minimum qualifications will be approved by the **UMBELLA ORGANIZATION** prior to adoption by the **AGENCY NAME**.

All employees will meet the minimum qualification for the position they hold.

- A position may be temporarily filled by an individual who does not meet all of the minimum qualifications utilizing the mechanism outlined by the **UMBRELLA ORGANIZATION'S** personnel selection rules.

Procedure

The following Position Descriptions define the job descriptions and minimum qualifications for each of the positions within the **AGENCY NAME**:

- APP-PD01 Director
- APP-PD02 Deputy Director
- APP-PD03 Assistant Director
- APP-PD04 Section Chief
- APP-PD05 Quality Assurance Manager
- APP-PD06 Supervising Examiner
- APP-PD07 Master Examiner
- APP-PD08 Journeyman Examiner
- APP-PD09 Apprentice Examiner
- APP-PD10 Journeyman Technician
- APP-PD11 Apprentice Technician
- APP-PD12 Administrative Assistant
- APP-PD13 Secretary
- APP-PD14 Clerk/Typist
- APP-PD15 Office Assistant
- APP-PD16 Senior Property Custodian
- APP-PD17 Property Custodian
- APP-PD18 Property Courier
- APP-PD19 Legal Advisor
- APP-PD20 Forensic Pathologist
- APP-PD21 Forensic Psychiatrist
- APP-PD22 Security Guard
- APP-PD23 Supervising Crime Scene Investigator
- APP-PD24 Master Crime Scene Investigator
- APP-PD25 Journeyman Crime Scene Investigator
- APP-PD26 Apprentice Crime Scene Investigator

Selection and Promotion

Policy

New Employee Selection The **AGENCY NAME** will establish a selection process to choose the most qualified candidate for each new employee vacancy.

- The selection process will be approved by the **PARENT ORGANIZATION** prior to adoption.

In-Classification Promotion The **AGENCY NAME** will establish a promotional process which will allow an employee to advance through a position classification.

- The promotional process will be approved by the **PARENT ORGANIZATION** prior to adoption.

Staff to Management Promotion The **AGENCY NAME** will establish a promotional process which will allow an employee to advance from a staff position to a management/supervision position.

- The promotional process will be approved by the **PARENT ORGANIZATION** prior to adoption.

Within Management Promotion The **AGENCY NAME** will establish a promotional process which will allow an employee to advance through the management classifications.

- The promotional process will be approved by the **PARENT ORGANIZATION** prior to adoption.

Procedure

New Employee Selection The following steps will encompass the process used to select new employees:

- Review of application, resume' and curriculum vita to establish the candidate meets the minimum educational and experience requirements.
- Written examination to establish that the candidate possesses a minimum level of theoretical knowledge.
- An oral interview by a Qualifications Appraisal Board (QAB) to allow the managers the opportunity to personally evaluate each qualified candidate.
- Verification of information provided during the application process.

Employment offers will be provided to the individual with the highest aggregate score achieved during the selection process.

In-Classification Promotion The following steps will encompass the In-Classification promotion process:

- Review of the employee's application, resume', curriculum vita and personnel records to establish the candidate meets the minimum requirements for promotion.
- Written examination to establish that the candidate possesses a minimum level of theoretical knowledge.
- An oral interview by a Qualifications Appraisal Board (QAB) to allow the managers the opportunity to personally evaluate each qualified candidate.

In-Classification promotions are granted to individuals who successful complete the above requirements.

Staff to Management Promotion The following steps will encompass the Staff to Management promotion process:

- Review of the employee's application, resume', curriculum vita and personnel records to establish the candidate meets the minimum requirements for promotion.
- Written examination to establish that the candidate possesses a minimum level of theoretical knowledge.
- An oral interview by a Qualifications Appraisal Board (QAB) to allow the senior managers the opportunity to personally evaluate each qualified candidate.

Promotion offer will be provided to the individual with the highest aggregate score achieved during the selection process.

In-Management Promotion The following steps will encompass the In-Management promotion process:

- Review of the employee's application, resume', curriculum vita and personnel records to establish the candidate meets the minimum requirements for promotion.
- An oral interview by a Qualifications Appraisal Board (QAB) to allow the senior managers the opportunity to personally evaluate each qualified candidate.

Promotion offer will be provided to the individual with the highest aggregate score achieved during the selection process.

Evaluations

The **AGENCY NAME** will ensure that employee performance expectations established and are understood.

All employees will receive a minimum of one performance evaluation per year.

- Employee performance expectations established during the annual performance evaluation.
- Employees receiving substandard performance evaluations will be evaluated more frequently, until their performance issues have been corrected.

All employees with examination responsibilities will annually receive a minimum of one proficiency test per analytical discipline.

- Employees who provide unsatisfactory results on proficiency tests will receive remedial training and additional proficiency tests until the performance issue has been corrected.

All employees with testimony responsibilities will annually have their testimony evaluated.

- Employees receiving substandard rating on their testimony will receive remedial training and additional evaluations until the performance issue has been corrected.

Employees will be reassigned or terminated if the corrective actions taken to address substandard or unsatisfactory performance do not corrected the issues.

- Termination actions will be in compliance with the **PARENT AGENCY'S** employee termination policies and procedures.

Evaluation Criteria

General Employee Criteria The following define the rating levels used to evaluate non managerial employees

- Exceptional (**5**):
  - This is the highest level of performance that always exceeds goals or standards. This rating should be used when the employee always shows extra drive and devotes efforts above and beyond expected job requirements. They model and display performance and behavior in a way that all employees should strive for.
- Very Good (**4**):
  - This is performance that always meets, and sometimes exceeds, expectations. This rating should be used when the employee takes the initiative and dedication to go above and beyond expected job requirements. Employees in this group may often be called upon to train and assist others.
- Standard (**3**):
  - A score of "Successful" is the baseline on which employees should be rated when they are valued and integral members of the team. This is good performance on the level expected of a trained staff member with experience who succeeds in their work. Performance always meets expectations.
- Needs Improvement (**2**):
  - Performance falls somewhat short of what is expected of a trained, experienced employee. Improvement is expected, performance cannot continue at this level indefinitely. If improvement to the successful level is not demonstrated on a consistent basis, performance at this level will at some point be considered unacceptable.
- Substandard (**1**):
  - Performance falls very short of what is expected of a trained employee with experience, either due to poor job fit or disciplinary issues. Performance at this level should prompt the manager to think about using measures of discipline, up to, and including termination.

Management Specific Criteria

- ADMINISTRATION
  - PLANNING: Develops short and long range plans and goals to meet department objectives consistent with established priorities; sets appropriate priorities of needs and resulting services to be provided; anticipates and prepares for future requirements and devises contingencies; devises realistic plans.
  - BUDGETING AND ECONOMIC MANAGEMENT: Prepares an appropriate budget and subsequently adheres to it; utilizes finances, budgets, facilities, equipment, materials and products to minimize costs; actively practices cost containment.

- ORGANIZATION OF WORK: Structures work in order to avoid crisis, promotes productivity, attains cost effectiveness, and delivers work on time. Involved in this process are the tasks of allocating work, delineating responsibilities, scheduling activities, and adequately preparing for meetings and presentations.
- COMPLIANCE: Complies with established policies, procedures and directives; conducts department functions in accordance with applicable laws, statutes, and regulations.
- PROBLEM SOLVING AND DECISION-MAKING: Identifies problem and acts to rectify them by employing analytical thinking and sound judgment.
- EVALUATION AND CONTROL: Practices regular and systematic review of department operations to evaluate progress towards established goals; evaluates strategies employed in seeking those goals; implements remedial measures when necessary.
- RISK (LIABILITY) MANAGEMENT: Ensures that liability risk exposures are identified and treated when proposing new programs and services; evaluates and monitors established programs and services to identify areas which need revision due to changes in operation, legislation, policies and procedures; implements changes where needed to facilitate favorable loss experience; manages employee safety program, including appropriate training and corrective action when necessary.

- INTERPERSONAL
  - ORAL COMMUNICATION: Effectively communicates orally with individuals and groups, including public presentations; presents ideas in an organized, clear and concise manner, employs tact and discretion; listens well; offers appropriate feedback.
  - WRITTEN COMMUNICATION: Prepares organized, clear, concise, accurate and informative letters, memos, reports and other documents which effectively fulfill content and timeliness requirements.
  - COORDINATION/COLLABORATION: Works well with others at various levels; keeps information flowing to the appropriate parties vertically (down as well as up) and horizontally; facilitates communication and problems solving among parties when necessary.
  - SUPERVISORY CONTROL: Effectively hires, assigns, directs, controls, evaluates performance, counsels and disciplines all other functions necessary or incidental to supervision; practices compliance with employment law guidelines and mandates.
  - LEADERSHIP: Promotes cooperation and team work among employees; establishes high standards of conduct and job performance for subordinates; maintains open communication channels; delegates work; leads by example.
  - STAFF APPRAISAL AND DEVELOPMENT: Provides good record of subordinate performance; reviews appraisal information with subordinates; aides subordinates in improving performance on current job; helps subordinates in setting up and implementing development plans and objectives; cross-trains employees; encourages subordinates to participate in training.
- INDIVIDUAL
  - EFFORT AND INITIATIVE: Requires little work direction; exhibits persistence an initiative; puts forth a consistent, energetic effort; assumes full and complete responsibility for accomplishment of department functions.

- PROFESSIONAL/TECHNICAL COMPETENCE: Realistic knowledge and competence of the field and applies up-to-date technical/professional principles, practices, and standards appropriate to the functions of the department; acts as a resource person upon whom others can draw; professional demeanor maintained on a consistent basis.
- INNOVATION: Displays original and novel thought in creative efforts to improve on the status quo.
- OBJECTIVITY: Assesses issues, problems and decision situations based on the merits of the case presented; personal loyalties, biases, etc., does not influence department decisions; personnel decisions made on the basis of equal opportunity and objective job-related criteria.
- CREDIBILITY: Through successful performance, instills the feeling of trust and dependability.
- FLEXIBILITY: Adapts well to change, both internally and externally.

- LEADERSHIP
  - COACHING: Communicates a positive attitude; serves as a catalyst for action and encourages employees to try new things and to take calculated risks; provides honest feedback; minimizes tension and defensiveness; creates an environment for success; teaches and guides employees rather than controls.
  - EMPOWERING: Creates an awareness in others of their powers and self worth; involves others and shares powers in planning and decision-making; fosters leadership in others; challenges others to assume leadership roles and provides support by allowing them to risk, fail and learn; creates an environment in which others feel ownership for results and feel comfortable to take action to achieve desired results.
  - MODELING: Believes in public service; treats all with respect and dignity and creates an atmosphere of mutual respect and trust. Serves as a catalyst for action and is a team player, believes in oneself and looks at problem as opportunities; uses powers in a positive way; keeps one's work: accepts responsibility for mistakes; insists on excellence (not perfection); communicates and reinforces by what they do - not what they say; adapts to changes as conditions and situations warrant.
  - TEAM BUILDING: Builds group cohesiveness and pride; encourages cooperation; fosters and practices good communication, recognizes and rewards individuals and team accomplishments and contributions; shares success and rewards; manages conflict, which is inevitable.
  - VISIONING: Establishes and articulates a vision of what could be; looks to and plans for the future; accepts new challenges, keeps an open mind.
  - SELF-DEVELOPMENT: Is not static; prepares for the future; has the courage to identify and address shortcomings; is committed to self-improvement manages personal stress in positive ways.

Procedure

Performance Evaluations The following procedure will be used to evaluate employee performance:

- The evaluators will review the evaluation criteria with the subordinates they will be evaluating at the beginning of each rating period and document any expectations that are outside the evaluation criteria defined in Section 4.1 or 4.2 of this policy.

- Evaluators will rate each employee under their supervision using the Employee Evaluation form or Management Evaluation form for the evaluation period.
  - The evaluator will insert a comment for ratings in excess of standard.
  - The evaluator will complete a Corrective Action Report for every evaluation criterion that is rated sub-standard.
- The evaluator will sign the evaluation form and provide it to the employee for review.
  - The evaluator will provide the employee a copy of any Corrective Action Report form generated during the rating period for review.
- The evaluator and employee will meet privately and discuss the evaluation and the next rating period's expectations.
- The employee will sign the evaluation at the conclusion of the meeting.
  - The employee may insert comments in any section of the evaluation in which he disagrees or feels the need to interject comments.
  - The employee may insert comments in any section of the evaluation of the corrective action report if necessary.
- The evaluation form will be forwarded to the Deputy Director for review and comment.
  - The corrective action report form will be forwarded to the Quality Assurance Manager for appropriate action.
- The original evaluation form will be filed in the employee's personnel file.
  - The employee will be provided a copy of the signed evaluation form upon request.

Proficiency Testing The Quality Assurance Manual will outline the procedures used to administer the proficiency testing program.

Testimony Monitoring The Quality Assurance Manual will outline the procedures used to administer the testimony monitoring program.

Code of Conduct

All employees will be provided a copy of the **PARENT AGENCY** code of conduct.

All employees will be provided a copy of the **AGENCY NAME** code of conduct (APP-S013).

All employees agree to abide by the **PARENT AGENCY'S** and the **AGENCY NAME'S** code of conduct, by virtue of their employment.

Statement of Qualifications

The **AGENCY NAME** will create and maintain a file containing the statement of qualifications forms of all current employees.

- The statement of qualification forms of former employees will be maintained in a separate fill in accordance with document retention policy.

Each employee will complete a statement of qualifications form.

The **AGENCY NAME** will annual update the statement of qualifications files.

Procedure

Initial Forms

- The Quality Assurance Manager will provide each employee a paper or electronic copy of the statement of qualifications form.
- Each employee will complete and return the form within the time frame established by the Quality Assurance Manager.
- The Quality Assurance Manager will place the completed forms in the master statement of qualifications file.

Annual Update

- On or about the first week in January the Quality Assurance Manager will distribute copies of the completed Statement of Qualifications forms to all employees who have them on file.
- Each employee will review and update the information on their form.
  - Employees will initial and date the copy of their current form if no additions are required.
  - Employees will insert additions or prepare a new form if additions are required.
- The employees will return their form with the appropriate modifications to the Quality Assurance Manager by the last business day of January.
- The Quality Assurance Manager will replace the old forms with the modified forms in the master Statement of Qualifications file.

Grievances and Complaints

The **AGENCY NAME** will establish procedures in which employees can file complaints concerning personnel and administrative actions.

The **AGENCY NAME** will establish procedures in which non-employees can file complaints concerning personnel and administrative actions of **AGENCY NAME** personnel.

The **AGENCY NAME** will establish procedures in which employees can file complaints concerning the quality system.

The **AGENCY NAME** will establish procedures in which non-employees can file complaints concerning the quality system.

The **AGENCY NAME** will establish procedures in which non-employees can file complaints concerning personnel and administrative actions of **AGENCY NAME** personnel.

The Deputy Director, or his designee, will take corrective action when a grievance or complaint concerning personnel and administrative actions of **AGENCY NAME** personnel has been identified.

The Quality Assurance Manager, or his designee, will take corrective action when a quality assurance issue has been identified.

All formally filed grievances and complaints and the actions taken to address the issue(s) will be documented.

- Grievance/Complaint Report form will be used to document administrative and personnel issues.
- Corrective Action Report forms will be used to document quality issues.

The **AGENCY NAME** will create and maintain a record of all grievances and complaints filed with the Deputy Director or Quality Assurance Manager.

Procedure

The following Administrative Policy and Procedure method will be used to address grievances and complaints concerning personnel actions:

Employee Grievance/Complaints

Level 1

- Employee will present his grievance or complaint to his immediate supervisor.
- The supervisor and employee discuss a successful resolution to the grievance or complaint.
  - The supervisor and employee implement the resolution, if their discussion generates a acceptable solution; or
  - The employee proceeds to Level 2, if an acceptable resolution to the grievance or complaint cannot be obtained.

Level 2

- The employee completes a Grievance/Complaint Report form.
  - The employee will:
    - Describe the grievance or complaint.
    - Describe his ideal resolution.
    - Sign the form.
    - Present it to his Supervisor.
- The Supervisor will review and sign the form and forwards it to the Deputy Director's office.
- The Deputy Director is responsible for ensuring all Grievance / Complaint Reports are resolved in a timely manner.
  - The Deputy Director's office will establish and maintain a file for each Grievance/Complaint Reports initiated.
  - The Deputy Director's office will assign a unique file number to each Grievance/Complaint Report.
  - The Deputy Director's office will create and maintain a log of Grievance/Complaint Report to monitor the resolution status each Grievance/Complaint Report.
- The Deputy Director will assign and individual or group to investigate the merits of the grievance or complaint and propose a resolution.
- The investigator or investigative group will issue a report containing the following sections:
  - Background.
  - Applicable Policies and Procedures.
  - Interviews and Investigative.
  - Proposed Resolution.
- The Deputy Director will state a resolution to the grievance or complaint based upon:
  - The investigation report.
  - Personal interview with the employee who initiated the grievance or complaint.
- The Employee can accept the Deputy Director decision; or
- Proceed to Level 3.

Level Three

- The Grievance/Complaint file is forwarded to the Director's Office.
- The Director:
  - Reviews the file.
  - Interviews the employee.
  - State a resolution to the grievance or complaint.
- The Directors decision is final.

Non-Employee Grievance/Complaints

Level 1

- Non-employees will present their grievances or complaints to the Deputy Director's office.
- The Deputy Director or his designee will discuss a successful resolution to the grievance or complaint.
  - The Deputy Director will implement the resolution, if their discussion generates a acceptable solution; or
  - The non-employee will proceed to Level 2, if an acceptable resolution to the grievance or complaint cannot be obtained.

Level 2

- The non-employee completes a Grievance/Complaint Report form.
  - The non-employee will:
    - Describe the grievance or complaint.
    - Describe his ideal resolution.
    - Sign the form.
    - Present it to the Deputy Director's office.
- The Deputy Director's representative will review and sign the Grievance/Complaint Report and forwards it for processing.
- The Deputy Director is responsible for ensuring all Grievance/Complaint Reports are resolved in a timely manner.
  - The Deputy Director's office will establish and maintain a file for each Grievance/Complaint Reports initiated.
  - The Deputy Director's office will assign a unique file number to each Grievance/Complaint Report.
  - The Deputy Director's office will create and maintain a log of Grievance/Complaint Report to monitor the resolution status each Grievance/Complaint Report.
- The Deputy Director will assign and individual or group to investigate the merits of the grievance or complaint and propose a resolution.
- The investigator or investigative group will issue a report containing the following sections:
  - Background.
  - Applicable Policies and Procedures.
  - Interviews and Investigative.
  - Proposed Resolution.

- The Deputy Director will state a resolution to the grievance or complaint based upon:
  - The investigation report.
  - Personal interview with the Non-Employee who initiated the grievance or complaint.
- The Non-Employee can accept the Deputy Director decision; or
- Proceed to Level 3.

Level Three

- The Grievance/Complaint file is forwarded to the Director's Office.
- The Director:
  - Reviews the file.
  - Interviews the Non-Employee.
  - Documents a resolution to the grievance or complaint.
- The Director's decision is final.

The Quality Assurance Manual contains additional procedures that will be used to address grievances and complaints concerning personnel actions.

Duty Hours

Employee duty hours will be established and adjusted in a manner that allows the **AGENCY NAME's** to accomplish its mission.

The employee duty hour policy will be in compliance with the **PARENT AGENCY'S** duty hour policy as well as all applicable federal, state and local labor laws or regulations.

Over Time

Employees may be required to work hours in excess of their normal duty hours (overtime) to meet deadlines or otherwise accomplish the **AGENCY NAME's** mission.

The **AGENCY NAME'S** overtime policy will be in compliance with the **PARENT AGENCY'S** overtime policy as well as all applicable federal, state and local labor laws or regulations.

Sick Leave

Employees will be provided sick leave in compliance with the **PARENT AGENCY'S** sick leave policy.

Employees will notify their immediate supervisor of their intention to utilize sick leave as soon as reasonably possible.

- An employee's failure to notify their supervisor may result in denial of sick leave.

Annual Leave

Employees will be provided annual leave in compliance with the **PARENT AGENCY'S** annual leave policy.

Employees will notify their immediate supervisor of their intention to utilize annual leave as soon as reasonably possible.

- An employee's failure to notify their supervisor may result in denial of annual leave.

The use of annual leave may be revoked or denied based upon the **PARENT NAME's** needs.

Training

General

All employees will be provided training in their respective job which will allow them to competently perform their assigned duties.

The Quality Assurance Manager will create and maintain a training file for every **AGENCY NAME** employee to document all training provided or obtained during the employee's tenure.

New Employee

All new employees will receive basic training and orientation concerning the policies and procedures associated with operation of the **AGENCY NAME**.

New employee training will include, but not be limited to:

- Administrative policy and procedure orientation
- Sample control section orientation
- Health and safety orientation
- Quality assurance program orientation

Technical Training

All employees will be provided basic technical training in their respective job to allow them to competently perform their assigned duties.

The content and duration of the technical training an employee receives is outlined in the Technical Methods Manual of the section the employee is assigned.

In-service Training

All employees will be provided in-service training opportunities that will allow them to enhance their technical skills.

The content and duration of the in-service training an employee receives may be outlined in the Technical Methods Manual of the section the employee is assigned.

In-service training may be provided through one or more of the following venues:

- In-house training program
- Professional Association
- College/University
- Vendor
- Law Enforcement Agency

All employees will be provided an annual review of the Health and Safety Manual.

Remedial Training

Remedial training will be provided to employees whose performance has been identified to be below standard.

Below standard performance can be identified through one or more of the following methods:

- Below standard performance in written and practical training exercises.
- Administrative or technical review of reports and case files.
- Proficiency test deficiency report.
- Corrective Action Report.
- Testimony monitoring.
- Supervisory evaluation.
- Peer review.

Every effort will be made to remediate an employee's substandard performance to an acceptable level.

The **AGENCY NAME** may transfer an employee with substandard performance to a position that is better suited to the employee's knowledge skills and abilities, after three (3) months of documented unsuccessful remediation training.

Procedure

The following policies and procedures will be used to address grievances and training issues:

General

- The Chief of the Personnel Section or his designee will provide new employees an orientation concerning the general operation of the **AGENCY NAME**.
- New employee orientation will be documented.

Operational Policies New employees will be issued a copy of the Operational Policies and Procedures.

Administrative Policy and Procedure Orientation

- New employees will be provided time to read the administrative policies and procedures.
- The new employee will review the administrative policies and procedures with his supervisor or his designee.
- This review will be documented.

Sample Control Section Orientation

- New employees will be provided time to read the sample control manual.
- The new employee will review the property and evidence manual with the Chief of the Sample Control Section or his designee.
- This review will be documented.

Health and Safety Orientation

- New employees will be provided time to read the health and safety manual.
- The new employee will review the health and safety manual with the Health and Safety Program Manager or his designee.
- This review will be documented.

Quality Assurance Program Orientation

- New employees will be provided time to read the quality assurance manual.
- The new employee will review the quality assurance manual with the Quality Assurance Manager or his designee.
- This review will be documented.

Technical Training

- The new employee's Section Chief or his designee will be responsible for the new employee's technical training.
- New employees with examination responsibilities will be provided technical manuals for every area in which they will perform examinations.
- New employees will be provided time to read all technical manuals and associated training materials.
- New employees with examination responsibilities will be provided training in their respective examination areas as outlined in the training section of the individual technical manual.
- Technical proficiency will be documented using written and practical examinations outlined in the individual technical manuals.

Professional Development

The **AGENCY NAME** will establish and implement a professional development plan for each employee based upon the employee's knowledge, skills, abilities and the needs of the **AGENCY NAME**.

The **AGENCY NAME** will provide the resources necessary to implement employee development plans, within the funding limitations.

Literature Resources

The **AGENCY NAME** will establish and maintain a library containing current and historical reference material of general interest forensic science topics.

Each analytical section will establish and maintain a library containing current and historical reference material on topics specific to that analytical discipline.

Employees are encouraged to establish and maintain a personal library containing current and historical reference material of general and discipline specific forensic science topics.

The **AGENCY NAME** will dedicate a portion of it annual budget for acquiring and maintaining literature resources.

The Director will designate an individual to act as the librarian, to maintain the general interest library.

Each Section Chief will designate an individual to act as the section's librarian, to maintain the section's discipline specific library.

Periodical Circulation

The **AGENCY NAME** will acquire and maintain copies of the periodicals of general and discipline specific forensic interest.

The librarian will ensure that each employee is provided the opportunity to review a copy of the table of contents of each periodical received.

Procedure

Librarian Each month the **AGENCY NAME** Librarian will:

- Reproduce the table of contents of all periodicals received during the previous month.
  - The number of copies will be equal to the number of analytical sections.
- Prepare circulation packets containing one copy of each table of contents reproduction made.
  - One packet will be circulated through each analytical section.
- Attach a distribution list to each packet.
  - Each Section will have a unique distribution list.
- Distribute individual packets to Section Chiefs for circulation.
- Collect packet of periodical table of contents from the last person to complete packet review.
- File completed distribution lists in a file created to document circulation of the periodical table of contents.

Section Chief Each month each Section Chief will:

- Receive a packet of periodical table of contents from the **AGENCY NAME** Librarian.
- Review each table of contents for relevant articles.
- Initial and date the distribution list upon completion of the review.
- Transfer the packet of periodical table of contents to an individual on the distribution list, who has not reviewed the packet.

Employees Each month each employee will:

- Receive a packet of periodical table of contents.
- Review each table of contents for relevant articles.
- Initial and date the distribution list upon completion of the review.
- Transfer the packet of periodical table of contents to an individual on the distribution list, who has not reviewed the packet.
  - The last individual on the distribution list will return the month's packet of periodical table of contents to the **AGENCY NAME** Librarian.

Training Records

The AGENCY NAME will create and maintain a training file for each employee to document the training provided.

Each employee will submit a critique of each training seminar attended.

Employee training records will be maintained in accordance with the **AGENCY NAME** document retention policy.

Dress Code

Grooming

Men Men will maintain a clean and well maintained appearance using the following guidelines:

- Hairstyles should be clean and neat.
  - Extreme styles or colors will be avoided.
- Sideburns should not extend below the earlobe or onto the cheek.
- Men are expected to be clean shaven; beards are not acceptable.
  - If worn, mustaches should be neatly trimmed and may not extend beyond or below the corners of the mouth.
- Earrings and other exposed body piercing jewelry are unacceptable.

Women Women will maintain a clean and well maintained appearance using the following guidelines:

- Hairstyles should be clean and neat, avoiding extreme styles and colors.
- A clean and well-cared-for appearance should be maintained.
- Two pair of earrings are acceptable.
  - All other exposed body piercing jewelry is inappropriate.

Business Attire

All employees will wear or have immediate access to appropriate business attire if they will be publicly representing the **AGENCY NAME**.

Business attire is to be worn during the following situations:

- All court appearances
- All depositions
- All professional presentations as a representative of the **AGENCY NAME**
- All situations in which the employee represents the **AGENCY NAME** in a public forum

Men Appropriate business attire for male employees includes the following:

- Blazers, suits, or sport coats
- Dress slacks
- Dress shirts with buttons and collars
- Ties
- Dress shoes

Women Appropriate business attire for female employees includes the following:

- Dresses.
  - Dresses must be knee length or longer.
- Skirts.
  - Skirts must be knee length or longer.
- Dress slacks.
- Blouses.
- Dress shoes.
- Sweaters.
- Nylons or stocking.

Casual Business Attire

Employees may wear casual business attire in situations in which they will not represent the **AGENCY NAME** in an official capacity.

- Employees will have immediate access to appropriate business attire if they will be publicly representing the **AGENCY NAME** for a limited period of time during the business day.

Casual business attire may be worn during the following situations:

- Performing routine duties that do not require interaction with the public in an official capacity.
- In service training sessions.
- Professional meetings in which the employee is not making a presentation.
- Travel to or from professional meetings or in service training sessions.
- Other situations as required.

Men Appropriate casual business attire for male employees includes:

- Sport coats or blazers
- Slacks, Chinos or Dockers
- Pull over shirts with collars
- Oxford button-down shirts
- Sweaters and cardigans
- Casual shoes
- Sweaters

Women Appropriate casual business attire for female employees includes:

- Dresses.
  - Dresses must be knee length or longer.
- Skirts.
  - Skirts must be knee length or longer.
- Slacks.
- Stirrup pants.
- Walking shorts.
- Pull over shirts with collar.
- Casual shoes.
- Sweaters.

Laboratory Attire

Employees with laboratory duties will wear attire that promotes personal safety while working in a laboratory environment.

Laboratory attire includes:

- Long sleeved shirt.
- Long pants.
- Loose fitting clothing should be avoided.
- Long hair should be secured with a tie (rubber band), pins or barrette.
- Open-toed shoes should not be worn in the laboratory.
- Ties or long jewelry which could dangle should be removed or tied back.
- Wearing rings, bracelets or watches is discouraged in the laboratory.
- Synthetic fingernails should not be worn in laboratories.

Unacceptable Attire

Unacceptable attire for employees includes:

- Shirts
- T-shirts of any kind
- Shirts or blouses that are sleeveless, strapless, backless, or revealing
- Underwear as outerwear
- Athletic wear
- Beach wear
- Provocative attire
- Workout clothes, except when required by duties
- Evening wear
- Cutoff pants
- Blue denim jeans
- Sandals of any kind
- Athletic shoes
- Deck shoes
- Work shoes, except when required by duties
- Skirts that have slits above the knee or are formfitting

Procedure

Section Chiefs and supervisors are responsible for monitoring and enforcing this policy.

The policy will be administered according to the following action steps:

- If questionable attire is worn in the office, the respective department Section Chief or Supervisor will hold a personal, private discussion with the employee to advise and counsel the employee regarding the inappropriateness of the attire.
- If an obvious policy violation occurs, the Section Chief or Supervisor will hold a private discussion with the employee and ask the employee to go home and change their attire immediately.

Repeated policy violations will result in disciplinary action, up to and including termination.

Signature/Initial Exemplars

The **AGENCY NAME** will establish and maintain a record containing exemplars of the signatures and initials of all employees.

The Quality Assurance Manager will annually update the signature and initial exemplars.

The signature and initials exemplars of new employees will be added to the record as part of the new employee orientation.

Outside Work Permits

Employees may hold jobs in addition to their position with the **AGENCY NAME**.

Outside employment may not conflict with the employee's duties and responsibilities to the **AGENCY NAME**.

All outside employment will be pre-approved by the Director.

Procedure

The employee will submit a memorandum to the Director, through his supervisor, requesting permission to obtain outside employment.

The memorandum will include:

- The employer's name
- The employer's business activities
- The employee's responsibilities and duties
- Prospective work schedule

Within five (5) days of receipt the request the Director will review and sign the request memorandum with a notation indicating is approval or denial.

The original request memorandum will be placed into the employee's personnel file and with a copy forwarded to the requesting employee.

Case Management

Case Numbering

Case Numbering

Each case submitted for examination will be assigned a unique record number.

The Sample Control Section will be responsible for the assignment of record numbers to cases submitted for examination.

Record numbers will be assigned in sequential order without a break in the numbering sequence.

Record numbers will utilize the following format: XX-R-YYYYY.

- XX
  - The last 2 digits of the year the record was created

- R
  - Facility Code
    - 1: Headquarters/Laboratory
    - 2: Regional Facility 1
    - 3: Regional Facility 2
    - 4: Regional Facility …
    - F: Firearms Database Program
- YYYYY
    - Unique identification number
    - Numbers begin with 00001
    - Numbering restarts on 0000 hour of 1 January

An existing record number may be utilized if the submission contains additional exhibits for the same case.

Sample Numbering

Each sample within a case submission will be assigned a unique identification number.

Examiners will assign a unique sample number to unnumbered items.

Examiners will assign a unique exhibit number to items or sub items created during the course of the examination.

Sample Submission

All evidentiary and non-evidentiary samples submitted to the **AGENCY NAME** for examination or temporary storage will be logged into the Sample Control Section prior to transfer to the laboratory for examination.

Sample Control Section personnel will only accept items that are properly packaged, sealed and labeled.

- Sample Control Section personnel will not package or repackage any item(s) prior to acceptance.
- Sample Control Section personnel may provide the necessary packaging materials, as required.
- Sample Control Section personnel may provide advice concerning proper packaging techniques, as required.

Sample Control Section personnel will document the exchange or transfer of all evidentiary and non-evidentiary items using the appropriate forms.

The Sample Control database will be updated within 24 hours of case submission.

Sample Return

The **AGENCY NAME** does not provide long term storage of evidentiary or non-evidentiary items.

- The Chief of the Sample Control Section may grant long term storage privileges on a case by case basis.

The Sample Control Section will return evidentiary and non-evidentiary items to the submitting agency or individual as soon as the examination process has been completed.

Sample Control Section personnel will document the exchange or transfer of all evidentiary and non-evidentiary items using the appropriate forms.

Sample Database

The Sample Control Section will establish and maintain a database of all evidentiary and non-evidentiary items submitted to the **AGENCY NAME** for examination or temporary storage.

The sample database will contain the following information:

- Laboratory Record Number (RN)
- Submitting Agency Name
- Submitting Agency File #
- Date Submitted
- Date Returned
- Storage Location
- Date to Lab
- Examiner
- Date From Lab
- Examination Completed (YES/NO)
- Exam Completion Notice Sent
- Destruction Require (YES/NO)
- Date Destroyed

All property and evidence transaction information will be entered into the database within 24 hours of the transaction.

The Director and the senior managers will have unrestricted access to the Sample Database.

Case Assignment

Cases submitted to the **AGENCY NAME** will be worked in the order they are received.

- The Section Chief may authorize the analysis of a case to be worked out of order.

Cases will be triaged by the Deputy Director and distributed to the appropriate Section Chief for distribution.

Cases requiring multiple examination types will be triaged by the Deputy Director to determine the sequence of examinations.

The following criteria will be utilized in determining the examination sequence:

- The destructive nature of the requested examinations.
- The probative value of the requested examinations.
- Analytical section case backlog.
- Cases involving crimes against people take priority over crimes against property cases.

Procedure

Single Exam Type Submissions Single exam type cases will be assigned using the following procedure:

- The Property and Evidence Section receives evidence and forwards the Evidence Submission Form to the Deputy Director's Office for distribution.
- The Deputy Director, or his designee, will review the Evidence Submission Form and determine which analytical section will perform the examination.
- The Deputy Director will place the 3 letter section code of the assigned analytical section in the upper right corner of the Evidence Submission Form.
  - The letters will be written in red ink.
  - The three letter section code will be as follows:
    - AEX Arson and explosives examinations.
    - CSR Crime scene response.
    - DIG Digital evidence examinations.
    - DNA DNA examinations.
    - DRG Controlled substance examinations.
    - FAT Firearms and Toolmark examinations.
    - FCE Forensic computer examinations.
    - LAT Latent fingerprint examination.
    - PHO Photography and video.
    - QDE Questioned document examinations.
    - TFS Test Fire Section.
    - TOX Toxicology.
    - TRA Trace evidence.
    - VPA Voice Print analysis.
- The Deputy Director's clerical staff will enter the case information into the Laboratory Information Management System.
- The Deputy Director's clerical staff will sort and forward the Evidence Submission Form's to the appropriate Section Chief for examiner assignment and distribution.
- Each Section Chief will assign and distribute cases based upon:
  - The complexity of the case.
  - The experience of the examiner.
  - The examiner's backlog.

Multiple Exam Type Submissions Multiple exam type cases will be assigned using the following procedure:

- The Property and Evidence Section receives evidence and forwards the Evidence Submission Form (PEM-F005) to the Deputy Director's Office for distribution.
- The Deputy Director, or his designee, will review the Evidence Submission Form and determine which analytical sections will be required to perform examinations.
  - The Deputy Director will prioritize the examinations required and establish the order in which the examinations will take place.
  - The Deputy Director may consult with the Section Chiefs involve to assist in the decision process.

- The Deputy Director will, in the upper right corner of the Evidence Submission Form, place the 3 letter section code for each of the assigned analytical section.
  - The letters will be written in red ink.
  - The codes will be stacked, one on top of the others, in descending order of priority.
    - First examination on top.
    - Last examination on the bottom.
  - The three letter section code will be the same as listed in Section 5.1 of this procedure.
- The Deputy Director's clerical staff will enter the case information into the Laboratory Information Management System.
- The Deputy Director's clerical staff will sort and forward the Evidence Submission Form's to the appropriate Section Chief for examiner assignment and distribution.
  - The clerical staff will make one copy of the Evidence Submission Form for each analytical section participating in the examination process.
    - The original copy will be sent to the analytical section that will perform the first examination(s).
    - Copies will be sent to the other sections for informational purposes.
  - The original will be passed to the next Section Chief when the previous examination has been completed.
- Each Section Chief will assign and distribute cases based upon:
  - The complexity of the case.
  - The experience of the examiner.
  - The examiner's backlog.

Out of Sequence Examinations Exhibits that require a single examination type may be processed out of sequence, if the exhibit is packaged separately and its examination will not affect the examination of other exhibits in the case.

Backlog Management

The Director will review and take account of changes in the volume and type of the work and allocate resources accordingly to minimizing the examination time required.

Examiners will efficiently process each case to maximize the information obtained while minimizing the examination time required.

Examiners will process sufficient exhibits of probative value to establish the elements of the crime of each crime the suspect is charged with.

The examiners will utilize one or more of the following to determine the probative value of each exhibit submitted for examination:

- The police report
- Discussion with the investigator
- Discussion with the prosecutor
- The examiner's experience

Procedure

Director By the 10th of each month the Director will receive the backlog report from the Deputy Director of Operations.

The Director will evaluate the Deputy Director of Operations' report and recommendations.

The Director will adjust funding requests to acquire the resource necessary to reduce backlogs.

Deputy Director of Operations By the 5th of each month the Deputy Director of Operations will receive backlog reports form the following sections:

- Property and Evidence Section.
- Examination Section Chiefs.
  - Section Supervisors will provide summary reports to their respective section chief.

The Deputy Director of Operations will evaluate the reports and compare the data to establish use patterns and identify areas which require additional resources.

The Deputy Director of Operations will reallocate personnel resources as required to reduce the backlog.

The Deputy Director of Operations will make recommendations to the Director concerning the need for additional resources.

Sample Control Section By the 5th of each month the Sample Control Section will submit a report to the Deputy Director of Operations containing the following information:

- Number of cases received during the previous month
- Number of cases returned to the submitting agency during the previous month
- Number of cases waiting for examination
  - Total number of cases
  - Number of cases older than 30 days
  - Number of cases older than 60 days
  - Number of cases older than 90 days
- Number of cases issued to the laboratory of examination purposes
  - Total number of cases
  - Number of cases older than 30 days
  - Number of cases older than 60 days
  - Number of cases older than 90 days

Section Chief By the fifth of each month each Section Chief will submit a report to the Deputy Director of Operations containing the following information:

- Number of cases received during the previous month
- Number of case reports issued during the previous month
- Number of cases, by examination type, under examination
  - Total number of cases
  - Number of cases older than 30 days
  - Number of cases older than 60 days
  - Number of cases older than 90 days

Section Supervisor By the 3rd of each month each Section Supervisor will submit a report to their Section Chief containing the following information:

- Number of cases received during the previous month
- Number of case reports issued during the previous month
- Number of cases under examination
  - Total number of cases
  - Number of cases older than 30 days
  - Number of cases older than 60 days
  - Number of cases older than 90 days

Document Control

Document Retention

General

The **AGENCY NAME** will establish and maintain a variety of record categories.

All records shall be retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss.

All records shall be held secure manner that prevents unauthorized access or amendment of the records.

All electronically stored records shall be protected and backed up to prevent unauthorized access or amendment of the records.

The **AGENCY NAME** will file, archive and dispose of documents using the following schedule.

Case Files

Case files will be maintained in a secure section of the laboratory for a period of 5 years after the completion of the examination.

Case files in excess of 5 years old will be archived in a secure location for an indefinite period of time, but not less than 25 years after the completion of the examination.

Sample Control Records

Sample control files will be maintained in a secure section of the Sample Control Section for a period of 5 years after the completion of the examination.

Sample control files in excess of 5 years old will be archived in a secure location for an indefinite period of time, but not less than 25 years after the completion of the examination.

Policy and Procedure Manuals

Each employee will retain a current revision of the **AGENCY NAME's** operational manuals, which include

- Administrative Policies and Procedures
- Health and Safety Manual
- Sample Control Manual
- Quality Assurance Manual

Obsolete polices and procedures will be suitably marked and promptly removed from all points of issue or use, or otherwise assured against unintended use and retained for either legal or knowledge preservation purposes are.

Technical Methods Manuals

Each employee will retain a current revision of the Technical Methods Manuals of the section to which they are assigned.

Obsolete policies and procedures will be suitably marked and promptly removed from all points of issue or use, or otherwise assured against unintended use and retained for either legal or knowledge preservation purposes are.

Correspondence

Internal Correspondence All internal correspondence documents will be filed and retained for a period of one year.

External Correspondence All external correspondence documents will be filed and retained for a period of two years.

Personnel Records

Employee personnel records will be maintained for a period of 5 years after the employee terminates employment with the **AGENCY NAME**.

The **PARENT AGENCY** will maintain employee personnel records of terminated employees according with their document retention policy.

Training Records

Employee training record files will be maintained for a period of 5 years after the employee terminates employment with the **AGENCY NAME**.

Proficency Test Records

Employee proficiency test files will be maintained for a period of 5 years after the employee terminates employment with the **AGENCY NAME**.

Quality Assurance Records

Quality assurance records will be maintained in a secure section of the laboratory for a period of 5 years.

Quality assurance records in excess of 5 years old will be archived in a secure location for an indefinite period of time, but not less than 25.

Audit Records

Audit records will be maintained in a secure section of the laboratory for a period of 5 years.

Audit records in excess of 5 years old will be archived in a secure location for an indefinite period of time, but not less than 25.

Corrective Action Reports

Corrective action reports will be maintained in a secure section of the laboratory for a period of 5 years.

Corrective action reports in excess of 5 years old will be archived in a secure location for an indefinite period of time, but not less than 25.

Grievance/Complaint Reports

Grievance/Complaint reports will be maintained in a secure section of the laboratory for a period of 5 years.

Grievance/Complaint reports in excess of 5 years old will be archived in a secure location for an indefinite period of time, but not less than 25.

Administrative Records

Administrative records will be maintained in a secure section of the laboratory for a period of 5 years.

Procurement Records

Procurement documentation will be maintained in a secure section of the laboratory for a period of 5 years.

Grant Documentation

Grant documentation will be maintained in a secure section of the laboratory for a period of 5 years after the completion of the grant obligations.

Budget Documentation

Budget documentation will be maintained in a secure section of the laboratory for a period of 5 years.

Procedure

On or about the first week of a calendar year all records in older than their prescribed retention time will be removed from their respective files and disposed of.

Document Disposal

The **AGENCY NAME** will dispose of documents that require destruction in a manner which will ensure the confidential information is disseminated to unauthorized personnel.

Authorized disposal methods for documents containing confidential information include:

- Incineration
- Shredding
- Disposal by a certified document disposal company
- Other method authorized by the Director of the **AGENCY NAME**

Documents that do not contain confidential information may be disposed of with the non-hazardous waste.

Document Inventory

The **AGENCY NAME** will establish and maintain an inventory of all controlled documents used as part of its operational or quality system.

The document inventory will identify the current revision status and distribution of all operational and quality system documents and be readily available to preclude the use of invalid or obsolete documents.

The Quality Assurance Manager, or his designee, maintain the document inventory and update the status of a document within five days of original or revision approval.

- Policy Inventory Form will be used to inventory controlled documents.

Document Approval

All documents issued by the **AGENCY NAME** as part of its operational or quality system shall be reviewed and approved for use by an approving authority prior to issue.

Documents that require approval prior to issuance include:

- Operational policies, procedures and methods
- Quality system policies, procedures and methods
- Analytical policies, procedures and methods
- Forms, templates and worksheets designated by the Director
- Other documents designated by the Director

Originals or revisions of documents requiring approval shall become effective on the date of the signature of the Director.

All approved documents will contain the following signatures:

- The Director, or his designee
- The Quality Assurance Manager, or his designee
- Peer Group Technical Leader
    - Technical Documents Only

Procedure

Operational Manuals

Document Review The review process for all administrative policy and procedure changes or new drafts is as follows:

- The Quality Assurance Manager will review and submit with comment any administrative policy and procedure change or draft to the Director.
- The Director will distribute the suggested administrative policy and procedure change or draft to the senior management staff for review and comment.
- Comments and suggestions are incorporated into the proposed policy and procedure change or draft.
- The Director and the senior staff will review and comment on the amended policy and procedure change or draft.
- Comments and suggestions are incorporated into the amended policy and procedure change or draft.
- Final revision of the policy and procedure change or draft is submitted to the Director for approval.

Document Approval The approval process for all administrative policy and procedure changes or new drafts is as follows:

- The Director and the Quality Assurance Manager perform a final administrative review of the proposed new or changes to an existing administrative policy or procedure.
- The Director and the Quality Assurance Manager each sign and date the APPROVAL section of the original document.
  - The effective date of the approved document will be the date of the Director's signature.
- The Quality Assurance Manager or his designee will distribute the new or modified policy or procedure in accordance with Policy and Procedure Dissemination Procedure.

Technical Manuals

Document Review The review process for all technical method, policy and procedure changes or new drafts is as follows:

- The Quality Assurance Manager will review the draft technical method, policy and procedure change or draft and submit it, along with the validation information, to the Technical Leader of the appropriate Peer Group.
- The Director will distribute the suggested analytical method, policy and procedure change or draft and associated validation information to Peer Group members for review and comment.
- Comments and suggestions are incorporated into the proposed technical method, policy and procedure change or draft.
- The Technical Leader and the Peer Group members will review and comment on the amended technical method, policy and procedure change or draft.
- Comments and suggestions are incorporated into the amended technical method, policy and procedure change or draft.
- Final revision of the technical method, policy and procedure change or draft is submitted to the Director for approval, through the Quality Assurance Manager.

Document Approval The approval process for all technical method, policy and procedure changes or new drafts is as follows:

- The Director and the Quality Assurance Manager perform a final administrative review of the proposed new or changes to an existing administrative policy or procedure.
- The Director and the Quality Assurance Manager each sign and date the APPROVAL section of the original document.
  - The effective date of the approved document will be the date of the Director's signature.
- The Quality Assurance Manager or his designee will distribute the new or modified policy or procedure in accordance with Policy and Procedure Dissemination Procedure.

Document Format

All documents issued by the **AGENCY NAME** will be consistent in format and appearance.

General

All policies, procedures and methods will contain the following header and footer formats.

Header The header of the first page of an approved controlled document will contain the **AGENCY NAME** logo.

The balance of the pages of an approved controlled document will be void of header information.

Footer The footer of every page of an approved controlled document will contain the following information:

- The title and subtitle of the document
- The document number
- The document revision date and number
- The page number and total number of pages
- The due date of the next revision

The footer of every page of internal and external correspondence will contain the following information:

- The correspondence identification number
- The page number and total number of pages

Policies and Procedures

Policies All policy documents will contain the following six sections

- 1 Purpose
- 2 Scope
- 3 Definitions
- 4 Policy
- 5 Procedure
- 6 Approval

Operational Procedures/Methods All operational procedure and method documents will contain the following six sections

- 1 Purpose
- 2 Scope
- 3 Definitions
- 4 Policy
- 5 Procedure
- 6 Approval

Analytical Procedures/methods All analytical procedures and method documents will contain the following six sections

- 1 Scope
- 2 Definitions
- 3 Reagents and Equipment
- 4 Procedure Summary
- 5 Precautions
- 6 Procedure
- 7 Conclusions
- 8 Precision and Bias
- 9 References
- 10 Approval

Examination Reports

Examination reports will contain the following information:

- Descriptive Information:
  - Laboratory Record Number.
  - The date the report was prepared.
  - The identity of each person who has rendered an opinion contained in the report.
  - The identity of the person or organization, or both, requesting the report.
  - Generic description of the item(s) examined together with specific data to uniquely identify the item(s).
  - Date and location of examination.
  - The scope of investigative activities performed in preparation for reaching conclusions and opinions.
- Pertinent Facts:
  - The report shall contain all facts that are pertinent to the opinion.
  - Identify other facts and data that the expert relies upon in rendering an opinion.
- Opinions and Conclusions:
  - The report shall contain all of the technical opinions and conclusions rendered by the expert concerning the purpose for which the expert was engaged.
  - The report shall contain the logic and reasoning of the expert by which each of the opinions and conclusions were reached.
- Signature:
  - The report shall contain the signature of each person who has rendered a joint or separate opinion contained in the report.
  - The signature(s) shall be at the end of the opinion.
  - A professional seal should be used, if applicable.
  - If an opinion rendered is that of two or more experts, a signature page may be used.

Document Numbering

All controlled documents and correspondence issued by the **AGENCY NAME** will be assigned a unique identification number.

All pages of a controlled documents and correspondence issued by the **AGENCY NAME** will contain the document's unique identification number.

Operational and Technical Manual Documents

Operational policy and procedure manual documents will contain a unique identification number using the following format:

- XXX-Y00x-0z.
  - XXX: Manual Identifier.
  - Y: Document Type.
    - P: Policy.
    - M: Method/Procedure.
    - F: Form.
    - S: Static Document.
    - PD: Position Description.
  - 00x: Document number.
    - Document numbers will be sequential.
    - There will be no break in the document numbering sequence.
  - 0z: Revision number.
    - Revision numbers will be sequential.
    - There will be no break in the revision numbering sequence.

Manual Identifier The following abbreviations will be used to identify operational manuals:

- APP Administrative Policies and Procedures
- HAS Health and Safety
- PEM Property and Evidence
- QAM Quality Assurance

The following abbreviations will be used to identify technical manuals:

- AEX Arson and explosives examinations
- CSR Crime scene response
- DIG Digital evidence examinations
- DNA DNA examinations
- DRG Controlled substance examinations
- FAT Firearms and Toolmark examinations
- FCE Forensic computer examinations
- LAT Latent fingerprint examination
- PHO Photography and video
- QDE Questioned document examinations
- TFS Test Fire Section
- TOX Toxicology
- TRA Trace evidence
- VPA Voice Print analysis

Correspondence
Internal and external correspondence subject to control will contain a unique identification number using the following format:

- ABC-YYYY-MM-DDa
  - ABC: The initials of the individual generating the document
  - YYYY: The year the document was generated
  - MM: The month the document was generated
  - DD: The day the document was generated
  - a: An alpha designation of the document revision

Procurement Records
Each procurement actions will contain a unique procurement number using the following format:

- YY-MM-00x.
  - YY: The year the procurement was initiated.
  - MM: The month the procurement was initiated.
  - 00x: The procurement number.
    - Numbering begins with 001 on the first day of the month.

Grievance and Complaint Records
Each Grievance / Complaint Record will contain a unique number using the following format:

- GCR-YY-00x.
  - GCR: Grievance/Complaint Record.
  - YY: The year the grievance/complaint was initiated.
  - 00x: The procurement number.
    - Numbering begins with 001 on 1 January.

Corrective Action Reports
Each Corrective Action Record will contain a unique number using the following format:

- CAR-YY-00x.
  - CAR: Corrective Action Report.
  - YY: The year the grievance/complaint was initiated.
  - 00x: The procurement number.
    - Numbering begins with 001 on 1 January.

Case Files
Case files will be numbered in accordance with Case Numbering Policy.

Document Filing

All controlled documents and correspondence issued by the **AGENCY NAME** will be filled in a secure manner in which will enable efficient retrieval.

The **AGENCY NAME** will establish and maintain a filing system that will ensure the protection of its customers' confidential information and proprietary rights.

Sample Records

Sample records will be filed in a secure location designated by the Director.

Sample records will be filed using the **AGENCY NAME** record number in accordance to the document retention policy.

The Sample Control Section will establish and maintain a record of the dissemination of sample control files that have been filed and stored in the Sample Control Section.

Examination Reports

Examination reports will be filed in a secure location designated by the Director.

Examination reports will be filed using the **AGENCY NAME** record number in accordance to the document retention policy.

The Records Section will establish and maintain a record of the dissemination of case files that have been submitted for filing and storage.

Correspondence

Internal and external communications will be filed in a location designated by the Director.

Internal and external communications will be filed using the document's identification number in accordance to the document retention policy.

Procurement Records

Procurement records will be filed in a location designated by the Director.

Procurement records will be filed using the document's identification number in accordance to the document retention policy.

Corrective Action Reports

Corrective Action Reports will be filed in a location designated by the Quality Assurance Manager.

Corrective Action Reports will be filed by Corrective Action Report Number (APP-P036) in accordance to the document retention policy.

Grievance/Complaint Reports

Grievance/Complaint Reports will be filed in a location designated by the Director.

Grievance/Complaint Reports will be filed by Grievance Complaint Number in accordance to the document retention policy.

Report Dissemination

Examination reports will only be disseminated outside the **AGENCY NAME** after the completion of a technical and an administrative review.

Examination reports will only be disseminated to the individual or agency requesting the examination.

- It is the responsibility of the individual or agency requesting the examination to disseminate copies of examination reports to interested parties.
- The requesting individual or agency may provide written authorization to disseminate the examination report to specific individuals or organizations.

Examination reports will be disseminated to an individual or agency other than the one requesting the examination in response to a Duces Tatum subpoena from a court of record.

- Case notes and other items which are considered work product shall not be included with this dissemination.

Each case file will contain a record of the dates and means of transmission of examination report dissemination.

Manual Dissemination

An updated printed or electronic version of all operational and applicable technical manuals will be provided to each employee.

Revisions of individual polices, procedures or other documents associated with operational and technical manuals will be disseminated as soon as the revised document has been approved.

- Employees will remove outdated versions of individual polices, procedures or other documents from the associated with operational and technical manuals as soon as the current revision has been received.

All operational and technical manuals are for internal use.

The Director shall approve dissemination of non-controlled versions of operational or technical manuals outside the **AGENCY NAME**.

The AGENCY NAME will maintain a record of the dissemination of controlled and non-controlled versions of operational and technical manuals.

Freedom of Information Act Requests

The **AGENCY NAME** shall provide the information requested by legitimate Freedom of Information Act requests that meet the guidelines established by 5 U.S.C. § 552, as Amended by Public Law No. 104-231, 110 Stat. 3048 while maintaining the appropriate privacy of witnesses, victims and suspects.

Document Retirement

Invalid or obsolete documents will be promptly retired and removed from all points of issue or use, or otherwise assured against unintended use.

Invalid or obsolete documents will be retained for either legal or knowledge preservation purposes will be suitably marked.

Retired documents will maintain their original unique document identification number.

Document Review

Controlled documents will be periodically reviewed and, where necessary, revised to ensure continuing suitability and compliance with applicable requirements.

Controlled documents will be periodically reviewed and, where necessary, retired and removed from circulation if the document is no longer applicable.

The Quality Assurance Manager will establish and maintain a review schedule for controlled documents subject to review.

File Removal

The AGENCY NAME will document the removal and return of all files containing controlled information.

Electronic File Security

The final revision of all controlled documents will be stored as a non-modifiable portable document format (pdf) file on a secure server and distributed in accordance with the document dissemination policy.

Controlled electronic document files will be routinely backed up to ensure their preservation.

Security

Authorized Access

The **AGENCY NAME** will take the precautions necessary to ensure security and integrity of its facilities.

General Access

Employees of the **AGENCY NAME** will have unrestricted access to common areas of the facility.

The Director may grant non-employee individuals general access privileges, as required.

All individuals granted general access privileges will wear identification credentials indicating their access status.

General access areas include:

- Conference Rooms and library
- Reception area
- Chemical and equipment storage areas
- Administrative and Technical Support section work areas
- Break rooms
- Other areas designated by the Director

Limited Access

Individuals will be granted unrestricted access to limited access areas on an as needed basis.

Individuals granted unrestricted access to limited access areas will be provided keys to facilitate their unrestricted access to limited access area.

Individuals with general access privileges, but not limited access privileges to a specific area may enter a limited access area under the escort of an individual with access privileges.

All individuals granted access privileges to limited access areas will wear identification credentials indicating their access status.

Limited Access areas include:

- Laboratory areas used to examine samples
- Evidence storage areas within individual examination laboratories
- Office areas used by examiners
- Office areas used by technical and administrative support staff
- Document and records storage areas
- Sample Control Section office space
- Sample Control storage facilities
- Sample Control Currency and valuable storage vault
- Sample Control Firearms storage vault
- Other areas designated by the Director

Escort Policy

Visitors and individuals with restricted access to the **AGENCY NAME** facilities will be required to be escorted at all times while in the facilities.

Upon entering the facility, visitors and individuals with restricted access will be issued identification credentials indicating the restricted nature of their access status.

Upon exiting the facility, visitors and individuals with restricted access will surrender their identification credentials indicating the restricted nature of their access status.

Individuals with unrestricted access to the **AGENCY NAME** facilities may freely enter and exit the facilities while wearing identification indicating the unrestricted nature of their access status.

- Unrestricted access individuals may obtain temporary identification in the event they do not have their issued credentials in their possession.

Procedure

Visitor Entrance

- The individual requesting access to restricted areas:
  - Provides security personnel identification credentials with a photograph and laboratory point of contact information.
  - Completes the following sections of the Laboratory Entrance Log.
    - Date.
    - Name of the individual.
    - Reason for entry.

- Security personnel:
  - Compares the photograph on the identification credentials to the individual presenting them.
  - Places the identification credentials in a Visitor Badge storage container.
  - Contacts the individual's point of contact.
  - Completes the following sections of the APP-F007.
    - Badge #.
  - Issues the individual a Visitor, Restricted Access badge.
    - The badge will be worn in a conspicuous location for the duration of the individual's stay within facilities.
- Visitor's Escort:
  - Completes the following sections of the Laboratory Entrance Log.
    - Escort's Name.
    - Time in.
    - Reason for entry.
  - Accompanies the visitor to the destination(s) within the facility.

Visitor Exit

- The Escort
  - Accompanies the visitor in his charge to the security station
- The Visitor:
  - Returns the Visitor Access Badge to security personnel
  - Visitors who require facility access for a continual period may retain their access badge for the duration of their stay
- Security Personnel
  - Retrieves and returns the visitor's identification credentials
  - Completes the following sections of the Laboratory Entrance Log
    - Time out

Entry Log

Individuals

The **AGENCY NAME** will establish and maintain a record of all restricted access individuals who enter secure facilities.

The visitor entry log will contain the following information:

- Date
- Badge #
- Time in
- Time out
- Visitor's Name
- Escort's name
- Reason for entry

Visitors and individuals with restricted access to **AGENCY NAME** facilities will sign the visitor entry log prior to entering any facility.

Visitors and individuals with restricted access will be issued identification credentials indicating the restricted nature of their access status.

Upon exiting the facility, visitors and individuals with restricted access will sign the visitor entry log and surrender their identification credentials.

Vehicles

The **AGENCY NAME** will establish and maintain a record of all restricted access vehicles that enter secure areas of **AGENCY NAME** facilities.

The vehicle entry log will contain the following information:

- Date
- Vehicle License Plate Number
- Time in
- Time out
- Visitor's Name(s)
- Badge Number(s)
- Reason for entry

Information about vehicles with restricted access to **AGENCY NAME** facilities will be entered into the vehicle entry log prior to entering any facility.

Individuals with restricted access will be issued identification credentials identifying the restricted nature of their access status.

Upon exiting the facility, individuals with restricted access will receive their identification credentials and vehicle exit time will be recorded.

Business Hours

Business Hours

The **AGENCY NAME's** normal business hours will be open to the public Monday through Friday from 0800 hours to 1700 hours.

Authorized personnel may occupy **AGENCY NAME** facilities two (2) hours prior and two (2) hours after normal business hours.

- Security personnel are exempt from this time restriction.

Access to facilities outside normal business hours is prohibited, unless authorized by the Director.

After Hours Access

The Director may allow authorized personnel access to facilities outside normal business hours to facilitate the agency's mission.

- The Director, or his designee, will provide security personnel a list of personnel authorized after hours access.

Security personnel will establish and maintain an afterhours entry log of all individuals who enter facilities outside normal business hours.

The afterhours entry log will contain the following information:

- Date
- Time in
- Time out
- Employee's Name
- Reason for entry

Alarms

Intrusion Alarms

The Director will determine the number of intrusion alarms required to ensure the security and integrity of the offices, laboratories and storage facilities.

The security staff will monitor the intrusion alarms twenty-four (24) hours a day, seven (7) days a week basis, when required.

The security staff will test and document the functionality of intrusion alarms the first week of every month, using the Security Equipment Inspection Form.

Video Surveillance

The Director will determine the number of video surveillance cameras required to ensure the security and integrity of the offices, laboratories and storage facilities.

The security staff will monitor the video surveillance cameras on twenty-four (24) hours a day, seven (7) days a week basis, when required.

The security staff will test and document the functionality of the video surveillance cameras the first week of every month, using the Security Equipment Inspection Form.

Fire and Smoke Alarms

The Director will determine the number of fire and smoke detection alarms required to ensure the security and integrity of the offices, laboratories and storage facilities.

The security staff will monitor the fire and smoke detection alarms on twenty-four (24) hours a day, seven (7) days a week basis.

The security staff will test and document the functionality of the fire and smoke detection alarms the first week of every month, using the Security Equipment Inspection Form.

Duress Alarms

The Director will determine the number of duress alarms required to ensure the security and integrity of the offices, laboratories and storage facilities.

The security staff will monitor the duress alarms on twenty-four (24) hours a day, seven (7) days a week basis, when required.

The security staff will test and document the functionality of the duress alarms the first week of every month, using the Security Equipment Inspection Form.

Documentation

The **AGENCY NAME** will establish and maintain a file of the completed Security Equipment Inspection Forms.

The Security Equipment Inspection Forms will be maintained for a period no less than 36 months.

Security Staff

The Director will determine the number of security personnel required to augment electronic alarms used to ensure the security and integrity of the offices, laboratories and storage facilities.

The security staff will perform and document an hourly check on the security and safety status of the personnel, offices, laboratories and storage facilities.

- During business hours the security and safety status check may consist solely of telephone communication with section personnel.
- After hours security status check will involve the physical evaluation of the offices, laboratories and storage spaces as well as exterior windows and doors.

Hourly security and safety status evaluation will be documented using the Security and Safety Status form.

- The security staff employee will place his initials in the box corresponding to the time and location he evaluated.
- The security staff employee will indicate the type of evaluation performed by placing a number next to his initials.
  - 1: Personal observation.
  - 2: Telephone verification.

The security staff will operate and maintain the alarm and electronic security systems.

Security Breach

Security personnel will notify the Director and the appropriate Section Chief upon the detection of a security breach of any offices, laboratories or storage facility.

The Director and the appropriate Section Chief will confer to determine the nature of the security breach.

If criminal in nature:

- Law enforcement will be notified.
- A criminal investigation will ensue.
- The area involved will be treated as a crime scene.
- Identify the cause of the security breach.
- Implement changes necessary to ensure the security breach does not reoccur.
- A complete inventory of all property and evidence stored in the area of the security breach will be conducted.

If non-criminal in nature the Section Chief will:

- Identify the cause of the security breach.
- Implement changes necessary to ensure the security breach does not reoccur.
- Authorize an inventory of all property and evidence stored in the area of the security breach, if necessary.

Security personnel will document all detected security breaches in the security log and on a Security Breach/Safety Violation Report form, which will be forwarded to the Section Chief with a copy sent to the Director.

Safety Violations

Security personnel will identify and abate any safety violations detected during their routine security checks.

Security personnel will document all safety violations in the security log and on a Security Breach/Safety Violation Report form, which will be forwarded to the appropriate Section Chief with a copy sent to the Director.

The Section Chief will identify the source of the safety violation and take appropriate action to rectify the issue.

DOCUMENT HISTORY

Rev. #	Issue Date	Description of Changes
01	01/01/2009	Original Document

End of Document

Appendix D

Name	Title

Quality Assurance Manual Orientation

Item	Trainee's Initials	Date Completed	Trainer's Initials	Date Reviewed
Quality Assurance Manual Issued				
Quality Assurance Program Overview (Read/Reviewed)				
Audits, Evaluations and Reviews (Read/Reviewed)				
Document Control (Read/ Reviewed)				
Equipment and Chemicals (Read/ Reviewed)				
Personnel (Read/Reviewed)				
Evidence (Read/Reviewed)				
Laboratory Information Management System (LIMS) (Read/Reviewed)				
Issue Management (Read/ Reviewed)				
Forms (Read/Reviewed)				

Orientation/Training Successfully Completed

Supervisor	**Date**
Quality Assurance Manager	**Date**

Date	**Customer Satisfaction Survey**		Record Number
Agency Name			Agency File Number
Type of Crime			Date of Occurrence
Investigator Name		ID number	Phone

Examination Types (Check all that apply)

☐ Fingerprint Records	☐ Latent Print	☐ Firearms/ Toolmarks	☐ Question Documents
☐ Arson/Explosives	☐ Controlled Substances	☐ Trace Evidence	☐ Toxicology
☐ Blood Stain Identification	☐ Forensic DNA	☐ DNA Database	☐ Photography
☐ Digital Imaging	☐ Voice Print	☐ Forensic Computer	☐ Crime Scene Investigation

Review

	POOR				BEST	
	1	2	3	4	5	N/A
Evidence submission process	☐	☐	☐	☐	☐	☐
Evidence return process	☐	☐	☐	☐	☐	☐
Property Custodian's assistance	☐	☐	☐	☐	☐	☐
Examination completed in a timely manner	☐	☐	☐	☐	☐	☐
Examination expedited to meet deadlines	☐	☐	☐	☐	☐	☐
Examiner's knowledge	☐	☐	☐	☐	☐	☐
Examiner's assistance	☐	☐	☐	☐	☐	☐
Examination report completeness	☐	☐	☐	☐	☐	☐
Examination report understandable.	☐	☐	☐	☐	☐	☐
Other:_____	☐	☐	☐	☐	☐	☐

Additional comments and suggestions are encouraged.

Return survey, comments and suggestions to:

AGENCY NAME
Attention Quality Assurance Manager
Address
City, STATE Postal Code

Corrective Action Report Form

Date	CAR #

Risk/Issue Source

☐ Employee Suggestion ☐ Peer Group ☐ User Group
☐ Audit ☐ Proficiency Test ☐ Employee Performance

Risk or Issue: Describe risk or issue
Resolution: Describe steps taken to address the risk or resolve the issue.
Results: Describe effect of the steps taken to address the risk or resolve the issue and any follow up action required.
Describe Follow Up Action Required:

Issue Successfully Resolved

Employee	**Date**
Supervisor	**Date**
Quality Assurance Manager	**Date**

Operational Manual Distribution Log

Manual #	Name	Signature	Date Issued	Date Return
001				
002				
003				
004				
005				
006				
007				
008				
009				
010				
011				
012				
013				
014				
015				
016				
017				
018				
019				
020				
021				
022				
023				
024				
025				

Technical Manual Distribution Log

Disipline _____

Manual #	Name	Signature	Date Issued	Date Return
001				
002				
003				
004				
005				
006				
007				
008				
009				
010				
011				
012				
013				
014				
015				
016				
017				
018				
019				
020				
021				
022				
023				
024				
025				
026				

DOCUMENT INVENTORY
POLICIES AND PROCEDURES

Doc. #	Rev. #	Description	Status	Date Approved	Review Date

FORMS

Doc. #	Rev. #	Description	Status	Date Approved	Review Date

STATIC DOCUMENTS

Doc. #	Rev. #	Description	Status	Date Approved	Review Date

ASCLD/LAB (2005) Audit Worksheet

http://www.ascld-lab.org/legacy/forms/word/legacyInteractiveCriteriaFileContentGuide2005revised52506.doc

Criteria	Description	Yes	No	NA	Comment
	OBJECTIVES				
(I) 1.1.1.1	Does the laboratory have a written statement of objectives?				
(I) 1.1.1.2	Do the objectives appear relevant to needs of community serviced by the laboratory?				
(D) 1.1.1.3	Does the laboratory staff understand and support the objectives?				
	ADMINISTRATIVE PRACTICES				
(I) 1.1.2.1	Does the laboratory or its parent organization have a formal written budget?				
(I) 1.1.2.2	Is budget adequate to meet written objectives?				
	Do clearly written and well understood procedures exist for the following:				
(E) 1.1.2.3	Handling and preserving the integrity of evidence?				
(E) 1.1.2.4	Laboratory security?				
(E) 1.1.2.5	Preparation, storage, security & disposition of case records or reports?				
(E) 1.1.2.6	Control of materials and supplies?				

Criteria	Description	Yes	No	NA	Comment
(E) 1.1.2.7	Maintenance and calibration of equipment and instruments?				
(E) 1.1.2.8	The operation of individual characteristic databases?				
(D) 1.1.2.9	Job requirements and descriptions?				
(D) 1.1.2.10	Personnel evaluations and objectives				
(D) 1.1.2.11	Employee complaints concerning the quality system?				
(I) 1.1.2.12	Does the laboratory have and use an information management system?				
	ORGANIZATIONAL STRUCTURE				
(D) 1.2.1.1	Does the organizational structure group the work and personnel in a manner that allows for efficiency of operation, taking into account the interrelation of various forensic disciplines?				
(D) 1.2.1.2	Has the laboratory director considered and taken appropriate action to correct any discrepancies with regard to numbers of personnel when grouping work and resources?				
	DELEGATION OF AUTHORITY				
(I) 1.2.2.1	Is the laboratory director's authority well defined?				
(I) 1.2.2.2	Does the laboratory director have authority commensurate with responsibilities?				

Criteria	Description	Yes	No	NA	Comment
(I) 1.2.2.3	Is there sufficient delegation of authority?				
(I) 1.2.2.4	Is the authority of supervisors commensurate with their responsibilities?				
(I) 1.2.2.5	Is each subordinate accountable to one and only one immediate supervisor per function?				
(I) 1.2.2.6	Are performance expectations established and are they understood by laboratory personnel?				
	SUPERVISION				
(D) 1.3.1.1	Is there constructive discussion between supervisors & subordinates?				
(I) 1.3.1.2	Do supervisors carefully & objectively review laboratory activities & personnel?				
(D) 1.3.1.3	Do supervisory techniques encourage creative, objective thinking & recognize meritorious performance?				
	COMMUNICATION				
(D) 1.3.2.1	Does and effective means of communication exist with the laboratory?				

Criteria	Description	Yes	No	NA	Comment
	TRAINING AND DEVELOPMENT				
(E) 1.3.3.1	Does the laboratory have and use a documented training program in each functional area for employees who are new, untrained or in need of remedial training?				
(I) 1.3.3.2	Does the laboratory have an employee development program?				
(I) 1.3.3.3	Does the forensic library contain current books, journals & other literature dealing with each functional area?				
(I) 1.3.3.4	Does a system exist to encourage each examiner to review appropriate new literature?				
	EVIDENCE CONTROL				
(E) 1.4.1.1	Does the laboratory have a written or secure electronic chain of custody record with all necessary data which provides for complete tracking of evidence?				
(E) 1.4.1.2	Is all evidence marked for identification?				
(E) 1.4.1.3	Is evidence stored under proper seal?				
(E) 1.4.1.4	Is evidence protected from loss, cross transfer, contamination and/or deleterious change?				
(E) 1.4.1.5	Is there a secure area for overnight and/or long term storage of evidence?				

Criteria	Description	Yes	No	NA	Comment
(E) 1.4.1.6	Has the laboratory established whether individual characteristic database samples are treated as evidence, reference materials, or examination documentation?				
(E) 1.4.1.7	Is each individual characteristic database sample under control of the laboratory uniquely identified?				
(E) 1.4.1.8	Are individual characteristic database samples protected from loss, cross transfer, contamination and/or deleterious change?				
(E) 1.4.1.9	Is access to characteristic database samples restricted to those persons authorized by the laboratory Director?				
	QUALITY SYSTEM				
(E) 1.4.2.1	Does the laboratory have a comprehensive Quality Manual?				
(E) 1.4.2.2	Is there an individual designated as Quality Manager?				
(E) 1.4.2.3	Did the laboratory conduct and document an annual audit of its operations and submit an annual accreditation audit report to ASCLD/LAB by the required deadline?				
(E) 1.4.2.4	Does the laboratory conduct and document an annual review of its quality system?				
(E) 1.4.2.5	Are the procedures used generally accepted in the field or supported by data gathered & recorded in a scientific manner?				

Criteria	Description	Yes	No	NA	Comment
(E) 1.4.2.6	Are new technical procedures scientifically validated before being used in casework and is the validation documentation available for review?				
(E) 1.4.2.7	Are the technical procedures used by the laboratory documented and available to laboratory personnel for review?				
(E) 1.4.2.8	Are appropriate controls & standards specified in the procedures & are they used and documented in the case record to ensure the validity of examination results?				
(E) 1.4.2.9	Is the quality of standard samples & reagents adequate for procedures used?				
(E) 1.4.2.10	Does the laboratory routinely check reliability of its reagents?				
(I) 1.4.2.11	Are the instruments/equipment adequate for procedure used?				
(I) 1.4.2.12	Are the instruments/equipment in proper working order?				
(E) 1.4.2.13	Are the instruments/equipment properly calibrated?				
(E) 1.4.2.14	Does the laboratory create and maintain a uniquely identified case record for all examination and administrative documentation generated and/or received by the laboratory for each case involving the analysis of evidence?				
(E) 1.4.2.15	Does the laboratory's unique case identifier appear on each page o the examination documentation and does the handwritten initials (or secure electronic equivalent) of the persons generating the examination documentation appear on each page generated by that person?				

Criteria	Description	Yes	No	NA	Comment
(E) 1.4.2.16	Are conclusions and opinions in reports supported by data available in the case record, and are the examination documents sufficiently detailed such that in the absence of the examiner(s) an other competent examiner or supervisor could evaluate what was done and interpret the data?				
(E) 1.4.2.17	Is examination documentation of a permanent nature and free of obliterations and erasures?				
(E) 1.4.2.18	Has each person(s) in the laboratory who issued findings based on the examination documentation generated by another person, completes a review of all relevant pages of examination documentation and documented the review in the case record?				
(E) 1.4.2.19	Does the laboratory generate written reports for all analytical work performed on evidence, and do the reports contain the conclusions and opinions that address the purpose for which the analytical work was undertaken?				
(E)1.4.2.20	Where associations are made, is the significance of the association communicated clearly and qualified properly in the report?				
(E)1.4.2.21	Does the name of the author(s) appear in the report?				
(E)1.4.2.22	Does the laboratory have, use and document a system of technical review of the reports to ensure that the conclusions of its examiners are reasonable and within the constraints of scientific knowledge?				
(E)1.4.2.23	Does the laboratory conduct and document administrative reviews of all reports issued?				

Criteria	Description	Yes	No	NA	Comment
(E)1.4.2.24	Does the laboratory monitor the testimony of each examiner at least annually and is the examiner given feedback from the evaluation?				
(E)1.4.2.25	If the laboratory has an indication of a significant technical problem, is there a procedure in writing and in use whereby the laboratory initiates a review and takes any corrective action required?				
	PROFICIENCY TESTING				
(E) 1.4.3.1	Does the laboratory have a documented program of proficiency testing?				
(E) 1.4.3.2	Does the laboratory participate in proficiency testing programs conducted by approved test providers, or by other external providers(s) when no approved provider is available?				
(I) 1.4.3.3	Was each examiner proficiency tested annually in each subdiscipline in which casework was performed?				
(I) 1.4.3.4	Does the laboratory conduct proficiency testing using re-examination or blind techniques?				

Criteria	Description	Yes	No	NA	Comment
	MANAGEMENT				
(I) 2.1.1	Does the laboratory director possess degree in a natural science, criminalistics or in a closely related field, or is the laboratory director supported by scientific personnel of sufficient managerial rank & authority?				
(D) 2.1.2	Does the laboratory director have at least 5 years of forensic science experience?				
(D) 2.1.3	Does the laboratory director have some formal training in management?				
(D) 2.1.4	Does the laboratory director have at least 2 years of managerial experience?				
	CONTROLLED SUBSTANCES				
(E) 2.2.1	Does each examiner have a Baccalaureate degree in a natural science, criminalistics, or in a closely related field & does each have experience/training commensurate with the examinations & testimony provided?				
(E) 2.2.2	Does each examiner understand the instruments & the methods & procedures used?				
(E) 2.2.3	Did each examiner successfully complete a competency test prior to assuming casework responsibility?				

Criteria	Description	Yes	No	NA	Comment
(E) 2.2.4	Did each examiner successfully complete an annual proficiency test?				
	TOXICOLOGY				
(E) 2.3.1	Does each examiner have a Baccalaureate degree in a natural science, toxicology, criminalistics, or in a closely related field & does each have experience/training commensurate with the examinations & testimony provided?				
(E) 2.3.2	Does each examiner understand the instruments & the methods & procedures used?				
(E) 2.3.3	Did each examiner successfully complete a competency test prior to assuming casework responsibility?				
(E) 2.3.4	Did each examiner successfully complete an annual proficiency test?				
	TRACE EVIDENCE				
(E) 2.4.1	Does each examiner have a Baccalaureate degree in a natural science, criminalistics, or in a closely related field & does each have experience/training commensurate with the examinations & testimony provided?				
(E) 2.4.2	Does each examiner understand the instruments & methods & procedures used?				

Criteria	Description	Yes	No	NA	Comment
(E) 2.4.3	Did each examiner successfully complete a competency test in each of the subdisciplines processed prior to assuming casework responsibility?				
(E) 2.4.4	Did each examiner successfully complete an annual proficiency test?				
	BIOLOGY				
(E) 2.5.1	Does each examiner have a Baccalaureate degree in a natural science, criminalistics, or in a closely related field & does each have experience/training commensurate with the examinations & testimony provided?				
(E) 2.5.2	Does each examiner performing DNA analysis have education, training and experience consistent with those required by the Quality Assurance Audit Document?				
(E) 2.5.3	Does each examiner understand the instruments & methods & procedures used?				
(E) 2.5.4	Did each examiner successfully complete a competency test prior to assuming casework responsibility?				
(E) 2.5.5	Did each examiner successfully complete an annual proficiency test?				
(E) 2.5.6	Did each examiner performing DNA analysis successfully complete two annual proficiency tests from an approved test provider?				

Criteria	Description	Yes	No	NA	Comment
	FIREARMS/TOOLMARKS				
(I) 2.6.1	Does each examiner have a Baccalaureate degree with science courses?				
(E) 2.6.2	Does each examiner understand the instruments and the methods & procedures used?				
(E) 2.6.3	Did each examiner have extensive training from a qualified examiner & does each have experience commensurate with the examinations & testimony provided?				
(E) 2.6.4	Did each examiner successfully complete a competency test prior to assuming casework responsibility?				
(E) 2.6.5	Did each examiner successfully complete an annual proficiency test?				
	QUESTIONED DOCUMENTS				
(I) 2.7.1	Does each examiner have a Baccalaureate degree with science courses?				
(E) 2.7.2	Does each examiner understand the instruments & the methods & procedures used?				

Criteria	Description	Yes	No	NA	Comment
(E) 2.7.3	Did each examiner have extensive training from a qualified examiner & does each have experience commensurate the examinations & testimony provided?				
(E) 2.7.4	Did each examiner successfully complete a competency test prior to assuming casework responsibility?				
(E) 2.7.5	Did each examiner successfully complete an annual proficiency test?				
	LATENT PRINTS				
(I) 2.8.1	Does each examiner have a Baccalaureate degree with science courses?				
(E) 2.8.2	Does each examiner understand the instruments & the methods & procedures used?				
(E) 2.8.3	Did each examiner have extensive training from a qualified examiner & does each have experience commensurate the examinations & testimony provided?				
(E) 2.8.4	Did each examiner successfully complete a competency test prior to assuming casework?				
(E) 2.8.5	Did each examiner successfully complete an annual proficiency test?				

Criteria	Description	Yes	No	NA	Comment
	TECHNICAL SUPPORT				
(E) 2.9.1	Do technical support personnel meet the requirements of their job descriptions?				
(E) 2.9.2	Are the job descriptions & the duties performed in agreement?				
(E) 2.9.3	Did each member of the technical support staff successfully complete an appropriate competency test prior to assuming casework responsibility?				
(E) 2.9.4	Did all technical support personnel complete an appropriate proficiency test, annually?				
(E) 2.9.5	Did DNA analytical support personnel successfully complete two annual proficiency tests from an approved test provider?				
	CRIME SCENE				
(E) 2.10.1	Do examiners meet the requirements of their job descriptions?				
(E) 2.10.2	Does each examiner understand the equipment, methods and procedures used?				
(E) 2.10.3	Did each examiner have extensive training and experience commensurate with their examinations?				
(E) 2.10.4	Did each examiner successfully complete a competency test prior to primary responsibility for the examination, documentation and processing of a crime scene?				

Criteria	Description	Yes	No	NA	Comment
(E) 2.10.5	Did each examiner successfully complete an annual proficiency test?				
	DIGITAL EVIDENCE				
(I) 2.11.1	Does each examiner have a Baccalaureate degree with science courses?				
(E) 2.11.2	Does each examiner understand the equipment, programs, methods and procedures used?				
(E) 2.11.3	Did each examiner have experience commensurate the examinations/ documentation & testimony provided?				
(E) 2.11.4	Did each examiner successfully complete a competency test in each sub-discipline prior to assuming casework?				
(E) 2.11.5	Did each examiner successfully complete an annual proficiency test?				
	SPACE				
(I) 3.1.1	Does each employee have adequate work space to accomplish assigned tasks?				
(D) 3.1.2	Is there sufficient space provided for storage of supplies, equipment & tools?				

Criteria	Description	Yes	No	NA	Comment
(I) 3.1.3	Is there adequate space available for examiners for writing reports & other official communications?				
(I) 3.1.4	Is there adequate & appropriate space available for records, reference works & other necessary documents?				
(I) 3.1.5	Is there adequate space available for each instrument/equipment to facilitate its operation?				
(D) 3.1.6	Are accessories stored near instrumentation/equipment to facilitate its use & operation?				
	DESIGN				
(I) 3.2.1	Does the physical design permit the efficient flow of evidence from the time of its acceptance until its proper disposal?				
(D) 3.2.2	Do the relative locations of functional areas facilitate the use of equipment & instruments?				
(I) 3.2.3	Is there adequate & proper lighting available for personnel to carry out assigned tasks?				
(I) 3.2.4	Is there adequate & proper plumbing & wiring available & accessible to carry out assigned tasks?				

Criteria	Description	Yes	No	NA	Comment
(I) 3.2.5	Does the laboratory have proper general ventilation?				
(I) 3.2.6	Is the heating, cooling & humidity control in the laboratory adequate?				
	SECURITY				
(E) 3.3.1	Is access to the operational area of the laboratory controllable & limited?				
(E) 3.3.2	Do all exterior entrance/exit points have adequate security control?				
(E) 3.3.3	Do all internal areas requiring limited/controlled access have a lock system?				
(E) 3.3.4	Is distribution of all keys, magnetic cards, etc., documented and is distribution limited to those individuals designated by the laboratory director to have access?				
(E) 3.3.5	Is the laboratory secured during vacant hours by means of an intrusion alarm or by security personnel?				
(I) 3.3.6	Does the laboratory have a fire detection system?				

Criteria	Description	Yes	No	NA	Comment
	HEALTH AND SAFETY				
(I) 3.4.1	Does the laboratory have an effective health & safety program documented in a manual?				
(I) 3.4.2	Is an individual designated as the Health & Safety Manager?				
(I) 3.4.3	Is the health & safety program monitored regularly & reviewed annually to ensure that its requirements are being?				
(I) 3.4.4	Does the laboratory have available & encourage the use of safety devices, particularly those required by its health & safety manual?				
(I) 3.4.5	Does the laboratory have proper equipment & material available for the handling of carcinogenic, toxic and/or other dangerous material spills?				
(I) 3.4.6	Does the laboratory have safety shower & eye wash equipment in appropriate locations & in good working condition?				
(I) 3.4.7	Are sufficient exhaust hoods available to maintain a safe work environment?				
(I) 3.4.8	Are sufficient first aid kits available & strategically located?				
(I) 3.4.9	Does the laboratory have an adequate number of personnel holding current certification in first aid?				
(I) 3.4.10	Is appropriate space provided for safe storage of volatile, flammable, explosive & other hazardous materials?				

Criteria	Description	Yes	No	NA	Comment
(I) 3.4.11	Are the emergency exits from the laboratory adequate for safe exit in an emergency?				
(D) 3.4.12	Is there general cleanliness & apparent good housekeeping in the laboratory?				

The signatures below recognize the above Quality Assurance Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director Date

Mary Doe, Quality Assurance Manager Date

End of Document

ISO17025 (2005) Audit Worksheet
(Rev. 2006-1)

Criteria	Description	Yes	No	NA	Comment
4.0	**MANAGEMENT REQUIREMENTS**				
4.1	**Organization**				
4.1.1	The laboratory or the organization of which it is part shall be an entity that can be held legally responsible.				
4.1.2	It is the responsibility of the laboratory to carry out its testing and calibration activities in such a way as to meet the requirements of this International Standard and to satisfy the needs of the customer, the regulatory authorities or organizations providing recognition.				
4.1.3	The laboratory management system shall cover work carried out in the laboratory's permanent facilities, at sites away from its permanent facilities, or in associated temporary or mobile facilities.				
4.1.4	If the laboratory is part of an organization performing activities other than testing and/or calibration, the responsibilities of key personnel in the organization that have an involvement or influence on the testing and/or calibration activities of the laboratory shall be defined in order to identify potential conflicts of interest.				

Criteria	Description	Yes	No	NA	Comment
	Note 1: Where a laboratory is part of a larger organization, the organizational arrangements should be such that departments having conflicting interests, such as production, commercial marketing or financing do not adversely influence the laboratory's compliance with the requirements of this International Standard. ***Note 2:*** If the laboratory wishes to be recognized as a third-party laboratory, it should be able to demonstrate that it is impartial and that it and its personnel are free from any undue commercial, financial and other pressures which might influence their technical judgment. The third-party testing or calibration laboratory should not engage in any activities that may endanger the trust in its independence of judgment and integrity in relation to its testing or calibration activities.				
4.1.5	The laboratory shall:				
a)	Have managerial and technical personnel with the authority and resources needed to carry out their duties and to identify the occurrence of departures from the quality system or from the procedures for performing tests and/or calibrations, and to initiate actions to prevent or minimize such departures (see also 5.2).				
b)	Have arrangements to ensure that its management and personnel are free from any undue internal and external commercial, financial and other pressures and influences that may adversely affect the quality of their work.				

Criteria	Description	Yes	No	NA	Comment
c)	Have policies and procedures to ensure the protection of its customers' confidential information and proprietary rights, including procedures for protecting the electronic storage and transmission of results.				
d)	Have policies and procedures to avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgement or operational integrity.				
e)	Define the organization and management structure of the laboratory, its place in any parent organization, and the relationships between quality management, technical operations and support services.				
f)	Specify the responsibility, authority and interrelationships of all personnel who manage, perform and verify work affecting the quality of the tests and/or calibrations.				
g)	Provide adequate supervision of testing and calibration staff, including trainees, by persons familiar with methods and procedures, purpose of each test and/or calibration, and with the assessment of the test or calibration results.				
h)	Have technical management which has overall responsibility for the technical operations and the provision of the resources needed to ensure the required quality of laboratory operations.				

Criteria	Description	Yes	No	NA	Comment
i)	Appoint a member of staff as quality manager (however named) who, irrespective of other duties and responsibilities, shall have defined responsibility and authority for ensuring that the quality system is implemented and followed at all times; the quality manager shall have direct access to the highest level of management at which decisions are made on laboratory policy or resources.				
j)	Appoint deputies for key managerial personnel.				
	Note: Individuals may have more than one function and it may be impractical to appoint deputies for every function.				
k)	Ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the objectives of the management system.				
4.1.6	Top management shall ensure that appropriate communication processes are established within the laboratory and that communication takes place regarding the effectiveness of the management system.				
4.2	**Quality System**				
4.2.1	The laboratory shall establish, implement and maintain a quality system appropriate to the scope of its activities. The laboratory shall document its policies, systems, programs, procedures and instructions to the extent necessary to assure the quality of the test and/or calibration results. The system's documentation shall be communicated to, understood by, available to, and implemented by the appropriate personnel.				

Criteria	Description	Yes	No	NA	Comment
4.2.2	The laboratory's quality system policies and objectives shall be defined in a quality manual (however named). The overall objectives shall be documented in a quality policy statement. The quality policy statement shall be issued under the authority of the chief executive. It shall include at least the following:				
a)	the laboratory management's commitment to good professional practice and to the quality of its testing and calibration in servicing its customers				
b)	the management's statement of the laboratory's standard of service				
c)	the purpose of the management system related to quality				
d)	a requirement that all personnel concerned with testing and calibration activities within the laboratory familiarize themselves with the quality documentation and implement the policies and procedures in their work				
e)	the laboratory management's commitment to comply with this International Standard and to continually improve the effectiveness of the management system				
	Note: The quality policy statement should be concise and may include the requirement that tests and/or calibrations shall always be carried out in accordance with stated methods and customers' requirements. When the test and/or calibration laboratory is pat of a larger organization, some quality policy elements may be in other documents.				

Criteria	Description	Yes	No	NA	Comment
4.2.3	Top management shall provide evidence of commitment to the development and implementation of the management system and to continually improving its effectiveness.				
4.2.4	Top management shall communicate to the organization the importance of meeting customer requirements as well as statutory and regulatory requirements.				
4.2.5.	The quality manual shall include or make reference to the supporting procedures including technical procedures. It shall outline the structure of the documentation used in the quality system.				
4.2.6.	The roles and responsibilities of technical management and the quality manager, including their responsibility for ensuring compliance with this International Standard, shall be defined in the quality manual.				
4.2.7.	Top management shall ensure that the integrity of the management system is maintained when changes to the management system are planned and implemented.				
4.3	**Document Control**				
4.3.1	General				
	The laboratory shall establish and maintain procedures to control all documents that form part of its quality system (internally generated or from external sources), such as regulations, standards, other normative documents, test and/or calibration methods, as well as drawings, software, specifications, instructions and manuals.				

Criteria	Description	Yes	No	NA	Comment
	Note 1: In this context "document" could be policy statements, procedures, specifications, calibration tables, charts, text books, posters, notices, memoranda, software, drawings, plans, etc. These may be on various media, whether hard copy or electronic, and they may be digital, analog, photographic or written. ***Note 2:*** The control of data related to testing and calibration is covered in 5.4.7. The control of records is covered in 4.13.				
4.3.2	Document Approval and Issue				
4.3.2.1	All documents issued to personnel in the laboratory as part of the quality system shall be reviewed and approved for use by authorized personnel prior to issue. A master list or an equivalent document control procedure identifying the current revision status and distribution of documents in the quality system shall be established and be readily available to preclude the use of invalid and/or obsolete documents.				
4.3.2.2	The procedure(s) adopted shall ensure that:				
a)	authorized editions of the appropriate documents are available at all locations where operations essential to the effective functioning of the laboratory are performed				
b)	documents are periodically reviewed and, where necessary, revised to ensure continuing suitability and compliance with applicable requirements				

Criteria	Description	Yes	No	NA	Comment
c)	invalid or obsolete documents are promptly removed from all points of issue or use, or otherwise assured against unintended use				
d)	obsolete documents retained for either legal or knowledge preservation purposes are suitably marked				
4.3.2.3	Management system documents generated by the laboratory shall be uniquely identified. Such identification shall include the date of issue and/or revision identification, page numbering, the total number of pages or a mark to signify the end of the document, and the issuing authority(ies).				
4.3.3	Document Change				
4.3.3.1	Changes to documents shall be reviewed and approved by the same function that performed the original review unless specifically designated otherwise. The designated personnel shall have access to pertinent background information upon which to base their review and approval.				
4.3.3.2	Where practicable, the altered or new test shall be identified in the document or the appropriate attachments.				
4.3.3.3	If the laboratory's documentation control system allows for the amendment of documents by hand pending the re-issue of the documents, the procedures and authorities for such amendments shall be defined. Amendments shall be clearly marked, initialed and dated. A revised document shall be formally re-issued as soon as practicable.				

Criteria	Description	Yes	No	NA	Comment
4.3.3.4	Procedures shall be established to describe how changes in documents maintained in computerized systems are made and controlled.				
4.4	**Removal of Requests, Tenders and Contracts**				
4.4.1	The laboratory shall establish and maintain procedures for the review of requests, lenders and contracts. The policies and procedures for these reviews leading to a contract for testing and/or calibration shall ensure that:				
a)	the requirements, including the methods to be used, are adequately defined, documented and understood (see 5.4.2)				
b)	the laboratory has the capability and resources to meet the requirements				
c)	the appropriate test and/or calibration method is selected and capable of meeting the customer's requirements; (see 5.4.2)				
	Any differences between the request or tender and the contract shall be resolved before any work commences. Each contract shall be acceptable both to the laboratory and the customer.				

Criteria	Description	Yes	No	NA	Comment
	Note 1: The request, tender and contract review shall be conducted in a practical and efficient manner, and the effect of financial, legal and time schedule aspects should be taken into account For internal customers, reviews of requests, tenders and contracts can be performed in a simplified way. ***Note 2:*** The review of capability should establish that the laboratory possesses the necessary physical, personnel and information resources, and that the laboratory's personnel have the skills and expertise necessary for the performance of the tests and/or calibrations in question. The review may also encompass results of earlier participation in inter laboratory comparisons or proficiency testing and/or the running of trial test or calibration programs using certified reference materials in order to determine uncertainties of measurement, limits of detection, confidence limits, etc. ***Note 3:*** A contract may be any written or oral agreement to provide a customer with testing and/or calibration services.				
4.4.2	Records of reviews, including any significant changes, shall be maintained. Records shall also be maintained of pertinent discussions with a customer relating to the customer's requirements or the results of the work during the period of execution of the contract.				

Criteria	Description	Yes	No	NA	Comment
	Note: For review of routine and other simple tasks, the date and the identification (e.g., the initials) of the person in the laboratory responsible for carrying out the contracted work are considered adequate. For repetitive routine tasks, the review need be made only at the initial enquiry stage or on granting of the contract for on-going routine work performed under a general agreement with the customer, provided that the customer's requirements remain unchanged. For new, complex or advanced testing and/or calibration tasks, a more comprehensive record should be maintained.				
4.4.3	The review shall also cover any work that is subcontracted by the laboratory.				
4.4.4	The customer shall be informed of any deviation from the contract.				
4.4.5	If a contract needs to be amended after work has commenced, the same contract review process shall be repeated and any amendments shall be communicated to all affected personnel.				
4.5	**Subcontracting of Tests and Calibrations**				
4.5.1	When a laboratory subcontracts work whether because of unforeseen reasons (e.g., workload, need for further expertise or temporary incapacity) or on a continuing basis (e.g., through permanent subcontracting, agency or franchising arrangements), this work shall be placed with a competent subcontractor. A competent subcontractor is one that, for example, complies with this International Standard for the work in question.				

Criteria	Description	Yes	No	NA	Comment
4.5.2	The laboratory shall advise the customer of the arrangement in writing and, when appropriate, gain the approval of the customer, preferably in writing.				
4.5.3	The laboratory is responsible to the customer for the subcontractor's work, except in the case where the customer or a regulatory authority specifies which subcontractor is to be used.				
4.5.4	The laboratory shall maintain a register of all subcontractors that it uses for tests and/or calibrations and a record of the evidence of compliance with this International Standard for the work in question.				
4.6	**Purchasing Services and Supplies**				
4.6.1	The laboratory shall have a policy and procedure(s) for the selection and purchasing of services and supplies it uses that affect the quality of the tests and/or calibrations. Procedures shall exist for the purchase, reception and storage of reagents and laboratory consumable materials relevant for the tests and calibrations.				
4.6.2	The laboratory shall ensure that purchased supplies and reagents and consumable materials that affect the quality of tests and/or calibrations are not used until they have been inspected or otherwise verified as complying with standard specifications or requirements defined in the methods for the tests and/or calibrations concerned. These services and supplies used shall comply with specified requirements. Records of actions taken to check compliance shall be maintained.				

Criteria	Description	Yes	No	NA	Comment
4.6.3	Purchasing documents for items affecting the quality of laboratory output shall contain data describing the services and supplies ordered. These purchasing documents shall be reviewed and approved for technical content prior to release.				
	Note: The description may include type, class, grade, precise identification, specifications, drawings, inspection instructions, other technical data including approval of test results, the quality required and the quality system standard under which they were made.				
4.6.4	The laboratory shall evaluate suppliers of critical consumables, supplies and services which affect the quality of testing and calibration, and shall maintain records of these evaluations and list those approved.				
4.7	**Service to the Customer**				
4.7.1	The laboratory shall afford customers or their representatives cooperation to clarify the customer's request and to monitor the laboratory's performance in relation to the work performed, provided that the laboratory ensures confidentiality to their customers.				

Criteria	Description	Yes	No	NA	Comment
	Note 1: Such cooperation may include: • providing the customer of the customer's representative reasonable access to relevant areas of the laboratory for the witnessing of tests and/or calibrations performed for the customer • preparation, packaging, and dispatch of test and/or calibration items needed by the customer for verification purposes ***Note 2:*** Customer's value the maintenance of good communication, advice and guidance in technical matters, and opinions and interpretations based on results. Communication with the customer, especially in large assignments, should be maintained throughout the work. The laboratory should inform the customer of any delays or major deviations in the performance of the tests and/or calibrations.				
4.7.2.	The laboratory shall seek feedback, both positive and negative, from its customers. The feedback shall be used and analyzed to improve the management system, testing and calibration activities and customer service.				
	NOTE: Examples of the types of feedback include customer satisfaction surveys and review of test or calibration reports with customers.				

Criteria	Description	Yes	No	NA	Comment
4.8	**Complaints**				
	The laboratory shall have a policy and procedure for the resolution of complaints received from customers or other parties. Records shall be maintained of all complaints and of the investigations and corrective actions taken by the laboratory (see also 4.11).				
4.9	**Control of Nonconforming Testing and/or Calibration Work**				
4.9.1	The laboratory shall have a policy and procedures that shall be implemented when any aspect of its testing and/or calibration work, or the results of this work, do not conform to its own procedures or the agreed requirements of the customer. The policy and procedures shall ensure that:				
a)	the responsibilities and authorities for the management of nonconforming work are designated and actions (including halting of work and withholding of test reports and calibration certificates, as necessary) are defined and taken when nonconforming work is identified				
b)	an evaluation of the significance of the nonconforming work is made				
c)	remedial actions are taken immediately, together with any decision about the acceptability of the nonconforming work				
d)	where necessary, the customer is notified and work is recalled				
e)	the responsibility for authorizing the resumption of work is defined				

Criteria	Description	Yes	No	NA	Comment
	Note: Identification of nonconforming work or problems with the quality system or with testing and/or calibration activities can occur at various places within the quality system and technical operations. Examples are customer complaints, quality control, instrument calibration, checking of consumable materials, staff observations or supervision, test report and calibration certificate checking, management reviews and internal or external audits.				
4.9.2	Where the evaluation indicates that the nonconforming work could recur or that there is doubt about the compliance of the laboratory's operations with its own policies and procedures, the corrective action procedures given in 4.11 shall be promptly followed.				
4.10.	**Improvement**				
	The laboratory shall continually improve the effectiveness of its management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.				
4.11	**Corrective Action**				
4.11.1	General				
	The laboratory shall establish a policy and procedure and shall designate appropriate authorities for implementing corrective action when nonconforming work or departures from the policies and procedures in the quality system or technical operations have been identified.				

Criteria	Description	Yes	No	NA	Comment
	Note: A problem with the quality system or with the technical operations of the laboratory may be identified through a variety of activities, such as control of nonconforming work, internal or external audits, management reviews, feedback from customers or staff observations.				
4.11.2	Cause Analysis				
	The procedure for corrective action shall start with an investigation to determine the root cause(s) of the problem.				
	Note: Cause analysis is the key and sometimes the most difficult part in the corrective action procedure. Often the root cause is not obvious and thus a careful analysis of all potential causes of the problem is required. Potential causes could include customer requirements, the samples, sample specifications, methods and procedures, staff skills and training, consumables, or equipment and its calibration.				
4.11.3	Selection and Implementation of Corrective Action				
	Where corrective action is needed, the laboratory shall identify potential corrective actions. It shall select and implement the action(s) most likely to eliminate the problem and to prevent recurrence.				
	Corrective actions shall be to a degree appropriate to the magnitude and the risk of the problem.				

Criteria	Description	Yes	No	NA	Comment
	The laboratory shall document and implement any required changes resulting from corrective action investigations.				
4.11.4	Monitoring of Corrective Actions				
	The laboratory shall monitor the results to ensure that the corrective actions taken have been effective.				
4.11.5	Additional Audits				
	Where the identification of nonconformance's or departures casts doubts on the laboratory's compliance with its own policies and the procedures, or on its compliance with this International Standard, the laboratory shall ensure that the appropriate areas of activity are audited in accordance with 4.14 as soon as possible.				
	Note: Such additional audits often follow the implementation of the corrective actions to confirm their effectiveness. An additional audit should be necessary only when a serious issue or risk to the business is identified.				
4.12	**Preventive Actions**				
4.12.1	Needed improvements and potential sources of nonconformities, either technical or concerning the management system, shall be identified. When improvement opportunities are identified or if preventive action is required, action plans shall be developed, implemented and monitored to reduce the likelihood of the occurrence of such nonconformities and to take advantage of the opportunities for improvement.				

Criteria	Description	Yes	No	NA	Comment
4.12.2	Procedures for preventive actions shall include the initiation of such actions and application of controls to ensure that they are effective.				
	Note 1: Preventive action is a pro-active process to identify opportunities for improvement rather than a reaction to the identification of problems or complaints. ***Note 2:*** Apart from the review of the operational procedures, the preventive action might involve analysis of data, including trend and risk analyses and proficiency-testing results.				
4.13	**Control of Records**				
4.13.1	General				
4.13.1.1	The Laboratory shall establish and maintain procedures for identification, collection, indexing, access, filing, storage, maintenance and disposal of quality and technical records. Quality records shall include reports from internal audits and management reviews as well as records of corrective and preventive actions.				
4.13.1.2	All records shall be legible and shall be stored and retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss. Retention times of records shall be established.				
	Note: Records may be in any media, such as hard copy or electronic media.				
4.13.1.3	All records shall be held secure and in confidence.				

Criteria	Description	Yes	No	NA	Comment
4.13.1.4	The laboratory shall have procedures to protect and back-up records stored electronically and to prevent unauthorized access to or amendment of these records.				
4.13.2	Technical Records				
4.13.2.1	The laboratory shall retain records of original observations, derived data and sufficient information to establish an audit trail, calibration records, staff records and a copy of each test report or calibration certificate issued, for a defined period. The records for each test or calibration shall contain sufficient information to facilitate, if possible, identification of factors affecting the uncertainty and to enable the test or calibration to be repeated under conditions as close as possible to the original. The records shall include the identity of personnel responsible for the sampling, performance of each test and/or calibration and checking of results.				
	Note 1: In certain fields it may be impossible or impracticable to retain records of all original observations. ***Note 2:*** Technical records are accumulations of data (see 5.4.7) and information, which result from carrying out tests and/or calibrations and which indicate whether specified quality or process parameters are achieved. They may include forms, contracts, work sheets, work books, check sheets, work notes, control graphs, external and internal test reports and calibration certificates, customers' notes, papers and feedback.				
4.13.2.2	Observations, data and calculations shall be recorded at the time they are made and shall be identifiable to the specific task.				

Criteria	Description	Yes	No	NA	Comment
4.13.2.3	When mistakes occur in records, each mistake shall be crossed out, not erased, made illegible or deleted, and the correct value entered alongside. All such alterations to records shall be signed or initialed by the person making the correction. In the case of records stored electronically, equivalent measures shall be taken to avoid loss or change or original data.				
4.14	**Internal Audits**				
4.14.1	The laboratory shall periodically, and in accordance with a predetermined schedule and procedure, conduct internal audits of its activities to verify that its operations continue to comply with the requirements of the quality system and this International Standard. The internal audit program shall address all elements of the quality system, including the testing and/or calibration activities. It is the responsibility of the quality manager to plan and organize audits as required by the schedule and requested by management. Such audits shall be carried out by trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited.				
	Note: The cycle for internal auditing shall normally be completed in one year.				
4.14.2	When audit findings cast doubt on the effectiveness of the operations or on the correctness or validity of the laboratory's test or calibration results, the laboratory shall take timely corrective action, and shall notify customers in writing if investigations show that the laboratory results may have been affected.				

Criteria	Description	Yes	No	NA	Comment
4.14.3	The area of activity audited, the audit findings and corrective actions that arise from them shall be recorded.				
4.14.4	Follow-up audit activities shall verify and record the implementation and effectiveness of the corrective action taken.				
4.15	**Management Reviews**				
4.15.1	In accordance with a predetermined schedule and procedure, the laboratory's executive management shall periodically conduct a review of the laboratory's quality system and testing and/or calibration activities to ensure their continuing suitability and effectiveness, and to introduce necessary changes or improvements. The review shall take account of:				
a)	the suitability of policies and procedures				
b)	reports from managerial and supervisory personnel				
c)	the outcome of recent internal audits				
d)	corrective and preventive actions				
e)	assessments by external bodies				
f)	the results of inter laboratory comparisons or proficiency tests				
g)	changes in the volume and type of the work				
h)	customer feedback				
i)	complaints				
J)	recommendations for improvement				

Criteria	Description	Yes	No	NA	Comment
k)	other relevant factors, such as quality control activities, resources and staff training				
	Note 1: A typical period for conducting a management review is once every 12 months. ***Note 2:*** Results should feed into the laboratory planning system and should include the goals, objectives and action plans for the coming year. ***Note 3:*** A management review includes consideration of related subjects at regular management meetings.				
4.15.2	Findings from management reviews and the actions that arise from them shall be recorded. The management shall ensure that those actions are carried out within an appropriate and agreed timescale.				
5.0	**TECHNICAL REQUIREMENTS**				
5.1	**General**				
5.1.1	Many factors determine the correctness and reliability of the tests and/or alibrations performed by a laboratory. These factors include contributions from: • human factors (5.2) • accommodation and environmental conditions (5.3) • test and calibration methods and method validation (5.4) • equipment (5.5) • measurement traceability (5.6) • sampling (5.7) • the handling of test and calibration items (5.8)				

Criteria	Description	Yes	No	NA	Comment
5.1.2	The extent to which the factors contribute to the total uncertainty of measurement differs considerably between (types of) tests and between (types of) calibrations. The laboratory shall take account of these factors in developing test and calibration methods and procedures, in the training and qualification of personnel, and in the selection and calibration of the equipment it uses.				
5.2	**Personnel**				
5.2.1	The laboratory management shall ensure the competence of all who operate specific equipment, perform tests and/or calibrations, evaluate results, and sign test reports and calibration certificates. When using staff who are undergoing training, appropriate supervision shall be provided. Personnel performing specific tasks shall be qualified on the basis of appropriate education, training, experience and/or demonstrated skills, as required.				
	Note 1: In some technical areas (e.g., non-destructive testing) it may be required that the personnel performing certain tasks hold personnel certification. The laboratory is responsible for fulfilling specified personnel certification requirements. The requirements for personnel certification might by regulatory, included in the standards for specific technical field, or required by the customer.				

Criteria	Description	Yes	No	NA	Comment
	Note 2: The personnel responsible for the opinions and interpretation included in test reports should, in addition to the appropriate qualifications, training, experience and satisfactory knowledge of the testing carried out, also have: • relevant knowledge of the technology used for the manufacturing of the items, materials, products, etc. tested, or the way they are used or intended to be used, and of the defects or degradations which may occur during or in service • knowledge of the general requirements expressed in the legislation and standards • an understanding of the significance of deviations found with regard to the normal use of the items, materials, products, etc. concerned				
5.2.2	The management of the laboratory shall formulate the goals with respect to the education, training and skills of the laboratory personnel. The laboratory shall have a policy and procedures for identifying training needs and providing training of personnel. The training program shall be relevant to the present and anticipated tasks of the laboratory.				

Criteria	Description	Yes	No	NA	Comment
5.2.3	The laboratory shall use personnel who are employed by, or under contract to, the laboratory. Where contracted and additional technical and key support personnel are used, the laboratory shall ensure that such personnel are supervised and competent and that they work in accordance with the laboratory's quality system.				
5.2.4	The laboratory shall maintain current job descriptions for managerial, technical and key support personnel involved in tests and/or calibrations.				
	Note: Job descriptions can be defined in may ways. As a minimum, the following should be defined: • the responsibilities with respect to performing tests and/or calibrations • the responsibilities with respect to the planning of tests and/or calibrations and evaluation of results • the responsibilities for reporting opinions and interpretations • the responsibilities with respect to method modification and development and validation of new methods • expertise and experience required • qualifications and training programs • managerial duties				

Criteria	Description	Yes	No	NA	Comment
5.2.5	The management shall authorize specific personnel to perform particular types of sampling, test and/or calibration, to issue test reports and calibration certificates, to give opinions and interpretations and to operate particular types of equipment. The laboratory shall maintain records of the relevant authorization(s), competence, educational and professional qualifications training, skills and experience of all technical personnel, including contracted personnel. This information shall be readily available and shall include the date on which authorization and/or competence is confirmed.				
5.3	**Accommodation and Environmental Conditions**				
5.3.1	Laboratory facilities for testing and/or calibration, including but not limited to energy sources, lighting and environmental conditions, shall be such as to facilitate correct performance of the tests and/or calibrations.				
	The laboratory shall ensure that the environmental conditions do not invalidate the results or adversely affect the required quality of any measurement. Particular care shall be taken when sampling and test and/or calibrations are undertaken at sites other than a permanent laboratory facility. The technical requirements for accommodation and environmental conditions that can affect the results of tests and calibrations shall be documented.				

Criteria	Description	Yes	No	NA	Comment
5.3.2	The laboratory shall monitor, control and record environmental conditions as required by the relevant specifications, methods and procedures or where thy influence the quality of the results. Due attention shall be paid, for example, to biological sterility, dust, electromagnetic disturbances, radiation, humidity, electrical supply, temperature, and sound and vibration levels, as appropriate to the technical activities concerned. Tests and calibrations shall be stopped when the environmental conditions jeopardize the results of the tests and/or calibrations.				
5.3.3	There shall be effective separation between neighboring areas in which there are incompatible activities. Measures shall be taken to prevent cross-contamination.				
5.3.4	Access to and use of areas affecting the quality of the tests and/or calibrations shall be controlled. The laboratory shall determine the extent of control based on its particular circumstances.				
5.3.5	Measures shall be taken to ensure good housekeeping in the laboratory. Special procedures shall be prepared where necessary.				

Criteria	Description	Yes	No	NA	Comment
5.4	**Test and Calibration Methods and Methods Validation**				
5.4.1	General				
	The laboratory shall use appropriate methods and procedures for all tests and/or calibrations within its scope. These include sampling, handling, transport, storage and preparation of items to be tested and/or calibrated, and, where appropriate, an estimation of the measurement uncertainty as well as statistical techniques for analysis of test and/or calibration data.				
	The laboratory shall have instructions on the use and operation of all relevant equipment, and on the handling and preparation of items for testing and/or calibration, or both, where the absence of such instructions could jeopardize the results of tests and/or calibrations. All instructions, standards, manuals and reference data relevant to the work of the laboratory shall be kept up to date and shall be made readily available to personnel (see 4.3). Deviation from test and calibration methods shall occur only if the deviation has been documented, technically justified, authorized, and accepted by the customer.				
	Note: International, regional or national standards or other recognized specifications that contain sufficient and concise information on how to perform the tests and/or calibrations do not need to be supplemented or rewritten as internal procedures if these standards are written in a way that they can be used as published by the operating staff in a laboratory. It may be necessary to provide additional documentation for optional steps in the method or additional details.				

Criteria	Description	Yes	No	NA	Comment
5.4.2	Selection of Methods				
	The laboratory shall use test and/or calibration methods, including methods for sampling, which meet the needs of the customer and which are appropriate for the tests and/or calibrations it undertakes. Methods published in international, regional, or national standards shall preferably be used. The laboratory shall ensure that it uses the latest valid edition of a standard unless it is not appropriate or possible to do so. When necessary, the standard shall be supplemented with additional details to ensure consistent application.				
	When the customer does not specify the method to be used, the laboratory shall select appropriate methods that have been published either in international, regional or national standards, or by reputable technical organizations, or in relevant scientific texts or journals, or as specified by the manufacturer of the equipment. Laboratory-developed methods or methods adopted by the laboratory may also be used if they are appropriate for the intended use and if they are validated. The customer shall be informed as to the method chosen. The laboratory shall confirm that it can properly operate standard methods before introducing the tests or calibrations. If the standard method changes, the confirmation shall be repeated.				
	The laboratory shall inform the customer when the method proposed by the customer is considered to be inappropriate or out of date.				

Criteria	Description	Yes	No	NA	Comment
5.4.3	Laboratory Developed Methods				
	The introduction of test and calibration methods developed by the laboratory for its own use shall be a planned activity and shall be assigned to qualified personnel equipped with adequate resources.				
	Plans shall be updated as development proceeds and effective communication amongst all personnel involved shall be ensured.				
5.4.4	Non-standard Methods				
	When it is necessary to use methods not covered by standard methods, these shall be subject to agreement with the customer and shall include a clear specification of the customer's requirements and the purpose of the test and/or calibration. The method developed shall have been validated appropriately before use.				
	Note: For new test and/or calibration methods, procedures should be developed prior to the tests and/or calibrations being performed and should contain at least the following information: • parameters or quantities and ranges to be determined • apparatus and equipment, including technical performance requirements • reference standards and reference materials required • environmental conditions required and any stabilization period needed				

Criteria	Description	Yes	No	NA	Comment

	• Description of the procedure, including:
	  • affixing of identification marks, handling, transporting, storing and preparation of items
	  • checks to be made before the work is started
	  • checks that the equipment is working properly and, where required, calibration and adjustment of the equipment before each use
	  • the method of recording the observations and results
	  • any safety measures to be observed
	• criteria and/or requirements for approval/rejection
	• data to be recorded and method of analysis and presentation
	• the uncertainty or the procedure for estimating uncertainty				

5.4.5	Validation of Methods				
5.4.5.1	Validation is the confirmation by examination and the provision of objective evidence that the particular requirements for a specific intended use are fulfilled.				

Criteria	Description	Yes	No	NA	Comment
5.4.5.2	The laboratory shall validate non-standard methods, laboratory-designed/developed methods, standard methods used outside their intended scope, and amplifications and modifications of standard methods to confirm that the methods are fit for the intended use. The validation shall be as extensive as is necessary to meet the needs of the given application or field of application. The laboratory shall record the results obtained, the procedure used for the validation, and a statement as to whether the method is fit for the intended use.				
	Note 1: Validation may include procedures for sampling, handling and transportation. ***Note 2:*** The techniques used for the determination of the performance of a method should be one of, or a combination of the following: • calibration using reference standards or reference materials • comparison of results achieved with other methods • interlaboratory comparisons • systematic assessment of the factors influencing the results • assessment of the uncertainty of the results based on scientific understanding of the theoretical principles of the method and practical experience ***Note 3:*** When some changes are made in the validated non-standard methods, the influence of such changes should be documented and, if appropriate, a new validation should be carried out.				

Criteria	Description	Yes	No	NA	Comment
5.4.5.3	The range and accuracy of the values obtainable from validated methods (e.g., the uncertainty of the results, detection limit, selectivity of the method, linearity, limit of repeatability and/or reproducibility, robustness against external influences and/or cross-sensitivity against interference from the matrix of the sample/test object), as assessed for the intended use, shall be relevant to the customers' needs.				
	Note 1: Validation includes specification of the requirements, determination of the characteristics of the methods, a check that the requirements can be fulfilled by using the method, and a statement on the validity. ***Note 2:*** As method-development proceeds, regular review should be carried out to verify that the needs of the customer are still being fulfilled. Any change in requirements requiring modifications to the development plan should be approved and authorized. ***Note 3:*** Validation is always a balance between costs, risks and technical possibilities. There are many cases in which the range and uncertainty of the values (e.g., accuracy, detection limit, selectivity, linearity, repeatability, reproducibility, robustness and cross-sensitivity) can only be given in a simplified way due to lack of information.				

Criteria	Description	Yes	No	NA	Comment
5.4.6	Estimation of Uncertainty of Measurements				
5.4.6.1	A calibration laboratory, or a testing laboratory performing its own calibrations, shall have and shall apply a procedure to estimate the uncertainty of measurement for all calibrations and types of calibrations.				
5.4.6.2	Testing laboratories shall have and shall apply procedures for estimating uncertainty of measurement. In certain cases the nature of the test method may preclude rigorous, metrologically and statistically valid calculation of uncertainty of measurement. In these cases the laboratory shall at least attempt to identify all the components of uncertainty and make a reasonable estimation, and shall ensure that the form of reporting of the result does not give a wrong impression of the uncertainty. Reasonable estimation shall be based on knowledge of the performance of the method and on the measurement scope and shall make use of, for example, previous experience and validation data.				

Criteria	Description	Yes	No	NA	Comment
	Note 1: The degree of rigor needed in an estimation of uncertainty of measurement depends on factors such as: • the requirements of the test method • the requirements of the customer • the existence of narrow limits on which decisions on conformance to a specification are based ***Note 2:*** In those cases where a well-recognized test method specifies limits to the values of the major sources of uncertainty of measurement and specifies the form of presentation of calculated results, the laboratory is considered to have satisfied this clause by following the test method and reporting instructions (see 5.10).				
5.4.6.3	When estimating the uncertainty of measurement, all uncertainty components which are of importance in the given situation shall be taken into account using appropriate methods of analysis.				
	Note 1: Sources contributing to the uncertainty include, but are not necessarily limited to, the reference standards and reference materials used, methods and equipment used, environmental conditions, properties and condition of the item being tested or calibrated, and the operator. ***Note 2:*** The predicted long-term behavior of the tested and/or calibrated item is not normally taken into account when estimating the measurement uncertainty. ***Note 3:*** For further information, see ISO 5725 and the Guide to the Expression of Uncertainty in Measurement.				

Criteria	Description	Yes	No	NA	Comment
5.4.7	Control of Data				
5.4.7.1	Calculations and data transfers shall be subject to appropriate checks in a systematic manner.				
5.4.7.2	When computers or automated equipment are used for the acquisition, processing, recording, reporting, storage or retrieval of test or calibration data, the laboratory shall ensure that:				
a)	computer software developed by the user is documented in sufficient detail and is suitably validated as being adequate for use				
b)	procedures are established and implemented for protecting data; such procedures shall include, but not be limited to, integrity and confidentiality of data entry or collection, data storage, data transmission and data processing				
c)	computers and automated equipment are maintained to ensure proper functioning and are provided with the environmental and operating conditions necessary to maintain the integrity of test and calibration data				
	Note: Commercial off-the-shelf software (e.g., word processing, database and statistical programs) in general use within their designed application range may be considered to be sufficiently validated. However, laboratory software configuration/modifications should be validated as in 5.4.7.2.a.				

Criteria	Description	Yes	No	NA	Comment
5.5	**Equipment**				
5.5.1	The laboratory shall be furnished with all items of sampling, measurement and test equipment required for the correct performance of the tests and/or calibrations (including sampling, preparation of test and/or calibration items, processing and analysis of test and/or calibration data). In those cases where the laboratory needs to use equipment outside its permanent control, it shall ensure that the requirements of this International Standard are met.				
5.5.2	Equipment and its software used for testing, calibration and sampling shall be capable of achieving the accuracy required and shall comply with specifications relevant to the tests and/or calibrations concerned. Calibration programs shall be established for key quantities or values of the instruments where these properties have a significant effect on the results. Before being placed into service, equipment (including that used for sampling) shall be calibrated or checked to establish that it meets the laboratory's specification requirements and complies with the relevant standard specifications. It shall be checked and/or calibrated before use (see 5.6).				
5.5.3	Equipment shall be operated by authorized personnel. Up-to-date instructions on the use and maintenance of equipment (including any relevant manuals provided by the manufacturer of the equipment) shall be readily available for use by the appropriate laboratory personnel.				

Criteria	Description	Yes	No	NA	Comment
5.5.4	Each item of equipment and its software used for testing and calibration and significant to the result shall, when practicable, be uniquely identified.				
5.5.5	Records shall be maintained for each item of equipment and its software significant to the tests and/or calibrations performed. The records shall include at least the following: • the identity of the item of equipment and its software • the manufacturer's name, type identification, and serial number or other unique identification • check that equipment complies with the specification (see 5.5.2) • the current location, where appropriate • the manufacturer's instructions, if available, or reference to their location • dates, results and copies of reports and certificates of all calibrations, adjustments, acceptance criteria, and the due date of next calibration • the maintenance plan, where appropriate, and maintenance carried out to date • any damage, malfunction, modification or repair to the equipment				

Criteria	Description	Yes	No	NA	Comment
5.5.6	The laboratory shall have procedures for safe handling, transport, storage, use and planned maintenance of measuring equipment to ensure proper functioning and in order to prevent contamination or deterioration.				
	Note: Additional procedures may be necessary when measuring equipment is used outside the permanent laboratory for tests, calibrations or sampling.				
5.5.7	Equipment that has been subjected to overloading or mishandling, gives suspect results, or has been shown to be defective or outside specified limits, shall be taken out of service. It shall be isolated to prevent its use or clearly labeled or marked as being out of service until it has been repaired and shown by calibration or test to perform correctly. The laboratory shall examine the effect of the defect or departure from specified limits on previous tests and/or calibrations and shall institute the "Control of nonconforming work" procedure (see 4.9).				
5.5.8	Whenever practicable, all equipment under the control of the laboratory and requiring calibration shall be labeled, coded or otherwise identified to indicate the status of calibration, including the date when last calibrated and the date or expiration criteria when recalibration is due.				

Criteria	Description	Yes	No	NA	Comment
5.5.9	When, for whatever reason, equipment goes outside the direct control of the laboratory, the laboratory shall ensure that the function and calibration status of the equipment are checked and shown to be satisfactory before the equipment is returned to service.				
5.5.10	When intermediate checks are needed to maintain confidence in the calibration status of the equipment, these checks shall be carried out according to a defined procedure.				
5.5.11	Where calibrations give rise to a set of correction factors, the laboratory shall have procedures to ensure that copies (e.g., in computer software) are correctly updated.				
5.5.12	Test and calibration equipment, including both hardware and software, shall be safeguarded from adjustments which would invalidate the test and/or calibration results.				
5.6	**Measurement Traceability**				
5.6.1	General				
	All equipment used for tests and/or calibrations, including equipment for subsidiary measurements (e.g., for environmental conditions) having a significant effect on the accuracy or validity of the result of the test, calibration or sampling shall be calibrated before being put into service. The laboratory shall have an established program and procedure for the calibration of its equipment.				

Criteria	Description	Yes	No	NA	Comment
	Note: Such a program should include a system for selecting, using, calibrating, checking, controlling and maintaining measurement standards, reference materials used as measurement standards, and measuring and test equipment used to perform tests and calibrations.				
5.6.2	Specific Measurements				
5.6.2.1	Calibration				
5.6.2.1.1.1	For calibration laboratories, the program for calibration of equipment shall be designated and operated so as to ensure that calibrations and measurements made by the laboratory are traceable to the International System of Units (SI).				
	A calibration laboratory establishes traceability of its own measurement standards and measuring instruments to the SI by means of an unbroken chain of calibrations or comparisons linking them to relevant primary standards of the SI units of measurement. The link to SI units may be achieved by reference to national measurement standards. National measurement standards may be primary standards, which are primary realizations of the SI units or agreed representations of SI units based on fundamental physical constants, or they may be secondary standards which are standards calibrated by another national metrology institute. When using external calibration services, traceability of measurement shall be assured by the use of calibration services from laboratories that can demonstrate competence, measurement capability and traceability. The calibration certificates issued by these laboratories shall contain the measurement results, including the measurement uncertainty and/or a statement of compliance with an identified metrological specification (see also 5.10.4.2).				

Criteria	Description	Yes	No	NA	Comment
	Note 1: Calibration laboratories fulfilling the requirements of this International Standard are considered to be competent. A calibration certificate bearing an accreditation body logo from a calibration laboratory accredited to this International Standard, for the calibration concerned, is sufficient evidence of traceability to the calibration data reported. ***Note 2:*** Traceability of SI units of measurement may be achieved by reference to an appropriate primary standard (see VIM:1993, 6.4) or by reference to a natural constant, the value of which in terms of the relevant SI unit is known and recommended by the General Conference of Weight and Measures (CGPM) and the International Committee for Weights and Measures (CIPM). ***Note 3:*** Calibration laboratories that maintain their own primary standard or representation of SI units based on fundamental physical constants can claim traceability to the SI system only after these standards have been compared, directly or indirectly, with other similar standards of a national metrology institute. ***Note 4:*** The term "identified metrological specification" means that it must be clear from the calibration certificate which specification the measurements have been compared with, by including the specification or by giving an unambiguous reference to the specification. ***Note 5:*** When the terms "international standard" or "national standard" are used in connection with traceability, it is assumed that these standards fulfil the properties of primary standards for the realization of SI units.				

Criteria	Description	Yes	No	NA	Comment
	Note 6: Traceability to national measurement standards does not necessarily require the use of the national metrology institute of the country in which the laboratory is located. ***Note 7:*** If a calibration laboratory wishes or needs to obtain traceability from a national metrology institute other than in its own country, this laboratory should select a national metrology institute that actively participated in the activities of BIPM either directly or through regional groups. ***Note 8:*** The unbroken chain of calibrations or comparisons may be achieved in several steps carried out by different laboratories that can demonstrate traceability.				
5.6.2.1.2	There are certain calibrations that currently cannot be strictly made in SI units. In these cases calibration shall provide confidence in measurements by establishing traceability to appropriate measurement standards such as:				
a)	the use of certified reference materials provided by a competent supplier to give a reliable physical or chemical characterization of a material				
b)	the use of specified methods and/or consensus standards that are clearly described and agreed by all parties concerned				

Criteria	Description	Yes	No	NA	Comment
	Participation in a suitable program of interlaboratory comparisons is required where possible.				
5.6.2.2	Testing				
5.6.2.2.1	For testing laboratories, the requirements given in 6.6.2.1 apply for measuring and test equipment with measuring functions used, unless it has been established that the associated contribution from the calibration contributes little to the total uncertainty of the test result. When this situation arises, the laboratory shall ensure that the equipment used can provide the uncertainty of measurement needed.				
	Note: The extent to which the requirements in 5.6.2.1 should be followed depends on the relative contribution of the calibration uncertainty to the total uncertainty. If calibration is the dominant factor, the requirements should be strictly followed.				
5.6.2.2.2	Where traceability of measurements to SI units is not possible and/or not relevant, the same requirements for traceability to, for example, certified reference materials, agreed methods and/or consensus standards are required as for calibration laboratories (see 5.6.2.1.2).				

Criteria	Description	Yes	No	NA	Comment
5.6.3	Reference Standards and Reference Materials				
5.6.3.1	Reference Standards				
	The laboratory shall have a program and procedure for the calibration of its reference standards. Reference standards shall be calibrated by a body that can provide traceability as described in 5.6.2.1. Such reference standards of measurement held by the laboratory shall be used for calibration only and for no other purpose, unless it can be shown that their performance as reference standards would not be invalidated. Reference standards shall be calibrated before and after any adjustment.				
5.6.3.2	Reference Materials				
	Reference materials shall, where possible, be traceable to SI units of measurement, or to certified reference materials. Internal reference materials shall be checked as far as is technically and economically practicable.				
5.6.3.3	Intermediate Checks				
	Checks needed to maintain confidence in the calibration status of reference, primary, transfer or working standards and reference materials shall be carried out according to defined procedures and schedules.				

Criteria	Description	Yes	No	NA	Comment
5.6.3.4	Transport and Storage				
	The laboratory shall have procedures for safe handling, transport, storage and use of reference standards and reference materials in order to prevent contamination or deterioration and in order to protect their integrity.				
	Note: Additional procedures may be necessary when reference standards and reference materials are used outside the permanent laboratory for tests, calibrations or sampling.				
5.7	**Sampling**				
5.7.1	The laboratory shall have a sampling plan and procedures for sampling when it carries out sampling of substances, materials or products for subsequent testing or calibration. The sampling plan as well as the sampling procedure shall be available at the location where sampling is undertaken. Sampling plans shall, whenever reasonable, be based on appropriate statistical methods. The sampling process shall address the factors to be controlled to ensure the validity of the test and calibration results.				
	Note 1: Sampling is a defined procedure whereby a part of a substance, material or product is taken to provide for testing or calibration of a representative sample of the whole. Sampling may also be required by the appropriate specification for which the substance, material or product is to be tested or calibrated. In certain cases (e.g., forensic analysis), the sample may not be representative but is determined by availability.				

Criteria	Description	Yes	No	NA	Comment
	Note 2: Sampling procedures should describe the selection, sampling plan, withdrawal and preparation of a sample or samples from a substance, material or product to yield the required information.				
5.7.2	Where the customer requires deviations, additions or exclusions from the documented sampling procedure, these shall be recorded in detail with the appropriate sampling data and shall be included in all documents containing test and/or calibration results, and shall be communicated to the appropriate personnel.				
5.7.3	The laboratory shall have procedures for recording relevant data and operations relating to sampling that forms part of the testing or calibration that is undertaken. These records shall include the sampling procedure used, the identification of the sampler, environmental conditions (if relevant) and diagrams or other equivalent means to identify the sampling location as necessary and, if appropriate, the statistics the sampling procedures are based upon.				
5.8	**Handling of Test and Calibration Items**				
5.8.1	The laboratory shall have procedures for the transportation, receipt, handling, protection, storage, retention and/or disposal of test and/or calibration items, including all provisions necessary to protect the integrity of the test or calibration item, and to protect the interests of the laboratory and the customer.				

Criteria	Description	Yes	No	NA	Comment
5.8.2	The laboratory shall have a system for identifying test and/or calibration items. The identification shall be retained throughout the life of the item in the laboratory. The system shall be designed and operated so as to ensure that items cannot be confused physically or when referred to in records or other documents. The system shall, if appropriate, accommodate a sub-division of groups of items and the transfer of items within and from the laboratory.				
5.8.3	Upon receipt of the test or calibration item, abnormalities or departures from normal or specified conditions, as described in the test or calibration method, shall be recorded. When there is doubt as to the suitability of an item for test or calibration, or when an item does not conform to the description provided, or the test or calibration required is not specified in sufficient detail, the laboratory shall consult the customer for further instructions before proceeding and shall record the discussion.				

Criteria	Description	Yes	No	NA	Comment
5.8.4	The laboratory shall have procedures and appropriate facilities for avoiding deterioration, loss or damage to the test or calibration item during storage, handling and preparation. Handling instructions provided with the item shall be followed. When items have to be stored or conditioned under specified environmental conditions, these conditions shall be maintained, monitored and recorded. Where a test or calibration item or a portion of an item is to be held secure, the laboratory shall have arrangements for storage and security that protect the condition and integrity of the secured items or a portion of an item is to be held secure, the laboratory shall have arrangements for storage and security that protect the condition and integrity of the secured items or portions concerned.				
	Note 1: Where test items are to be returned into service after testing, special care is required to ensure that they are not damaged or injured during the handling, testing or storing/waiting process. ***Note 2:*** A sampling procedure and information on storage and transport of samples, including information on sampling factors influencing the test or calibration result, should be provided to those responsible for taking and transporting the samples. ***Note 3:*** Reasons for keeping a test or calibration item secure can be the reasons of record, safety or value, or to enable complementary tests and/or calibrations to be performed later.				

Criteria	Description	Yes	No	NA	Comment
5.9	**Assuring the Quality of Test and Calibration Results**				
5.9.1	The laboratory shall have quality control procedures for monitoring the validity of tests and calibrations undertaken. The resulting data shall be recorded in such a way that trends are detectable and where practicable, statistical techniques shall be applied to the reviewing of the results. This monitoring shall be planned and reviewed and may include, but not be limited to the following:				
a)	regular use of certified reference materials and/or internal quality control using secondary reference materials				
b)	participation in interlaboratory comparison or proficiency-testing programs				
c)	replicate tests or calibrations using the same or different methods				
d)	retesting or recalibration of retained items				
e)	correlation of results for different characteristics of an item ***Note:*** The selected methods should be appropriate for the type and volume of work undertaken.				
5.9.2	Quality control data shall be analyzed and, where they are found to be outside pre-defined criteria, planned action shall be taken to correct the problem and to prevent incorrect results from being reported.				

Criteria	Description	Yes	No	NA	Comment
5.10	**Reporting the Results**				
5.10.1	General				
	The results of each test, calibration, or series of tests or calibrations carried out by the laboratory shall be reported accurately, clearly, unambiguously and objectively, and in accordance with any specific instructions in the test or calibration methods.				
	The results shall be reported, usually in a test report or a calibration certificate (see ***Note 1***), and shall include all the information requested by the customer and necessary for the interpretation of the test or calibration results and all information required by the method used. This information is normally that required by 5.10.2, and 5.10.3 or 5.10.4.				
	In the case of tests or calibrations performed for internal customers, or in the case of a written agreement with the customer, the results may be reported in a simplified way. Any information listed in 5.10.2 to 5.10.4 which is not reported to the customer shall be readily available in the laboratory which carried out the tests and/or calibrations.				
	Note 1: Test reports and calibration certificates are sometimes called test certificates and calibration reports, respectively. ***Note 2:*** The test reports or calibration certificates may be issued as hard copy or by electronic data transfer provided that the requirements of this International Standard are met.				

Criteria	Description	Yes	No	NA	Comment
5.10.2	Test Reports and Calibration Certificates				
	Each test report or calibration certificate shall include at least the following information, unless the laboratory has valid reasons for not doing do: 1. a title (e.g., "Test Report" or Calibration Certificate") 2. the name and address of the laboratory, and the location where the tests and/or calibrations were carried out, if different from the address of the laboratory 3. unique identification of the test report or calibration certificate (such as the serial number), and on each page the identification in order to ensure that the page is recognized as part of the test report or calibration certificate, and a clear identification of the end of the test report or calibration certificate 4. the name and address of the customer 5. identification of the method used 6. a description of, the condition of, and unambiguous identification of the item(s) tested or calibrated 7. the date of receipt of the test or calibration item(s) where this is critical to the validity and application of the results, and the date(s) of performance of the test or calibration				

Criteria	Description	Yes	No	NA	Comment
	8. reference to the sampling plan and procedures used by the laboratory or other bodies where these are relevant to the validity or application of the results 9. the test or calibration results with, where appropriate, the units of measurement 10. the name(s), function(s) and signature(s) or equivalent identification of person(s) authorizing the test report or calibration certificate 11. where relevant, a statement to the effect that the results relate only to the items tested or calibrated				
	Note 1: Hard copies of test reports and calibration certificates should also include the page number and total number of pages. ***Note 2:*** It is recommended that laboratories include a statement specifying that the test report or calibration certificate shall not be reproduced except in full, without written approval of the laboratory.				
5.10.3	Test Reports				
5.10.3.1	In addition to the requirements listed in 5.10.2, test reports shall, where necessary for the interpretation of the test results, include the following:				
a)	deviations from, additions to, or exclusions from the test method, and information on specific test conditions, such as environmental conditions				
b)	where relevant, a statement of compliance/non-compliance with requirements and/or specifications				

Criteria	Description	Yes	No	NA	Comment
c)	where applicable, a statement on the estimated uncertainty of measurement; information on uncertainty is needed in test reports when it is relevant to the validity or application of the test results, when a customer's instructions so requires, or when the uncertainty affects compliance to a specification limit				
d)	where appropriate and needed, opinions and interpretations (see 5.10.5)				
e)	additional information which may be required by specific methods, customers or groups of customers				
5.10.3.2	In addition to the requirements listed in 5.10.2 and 5.10.3.1, test reports containing the results of sampling shall include the following, where necessary for the interpretation of test results: • the date of sampling • unambiguous identification of the substance, material or product sampled (including the name of the manufacturer, the model or type of designation and serial numbers as appropriate) • the location of sampling, including any diagrams, sketches or photographs				

Criteria	Description	Yes	No	NA	Comment
	• a reference to the sampling plan and procedures used • details of any environmental conditions during sampling that may affect the interpretation of the test results • any standard or other specification for the sampling method or procedure, and deviations, additions to or exclusions from the specification concerned				
5.10.4	Calibration Certificates				
	In addition to the requirements listed in 5.10.2, calibration certificates shall include the following, where necessary for the interpretation of calibration results: • the conditions (e.g., environmental) under which the calibrations were made that have an influence on the measurement results • the uncertainty of measurement and/or a statement of compliance with an identified metrological specification or clauses thereof • evidence that the measurements are traceable (see ***Note 2*** in 5.6.2.1.1)				
5.10.4.2	The calibration certificate shall relate only to quantities and the results of functional tests. If a statement of compliance with a specification is made, this shall identify which clauses of the specification are met or net met.				

Criteria	Description	Yes	No	NA	Comment
	When a statement of compliance with a specification is made omitting the measurement results and associated uncertainties, the laboratory shall record those results and maintain them for possible future reference.				
	When statements of compliance are made, the uncertainty of measurement shall be taken into account				
5.10.4.3	When an instrument for calibration has been adjusted or repaired, the calibration results before and after adjustment or repair, if available, shall be reported.				
5.10.4.4	A calibration certificate (or calibration label) shall not contain any recommendation on the calibration interval except where this has been agreed with the customer. This requirement may be superseded by legal regulations.				
5.10.5	Opinions and Interpretations				
	When opinions and interpretations are included, the laboratory shall document the basis upon which the opinions and interpretations have been made. Opinions and interpretations shall be clearly marked as such in a test report.				

Criteria	Description	Yes	No	NA	Comment
	Note 1: Opinions and interpretations should not be confused with inspections and product certifications as intended in ISO/IEC 17020 and ISO/IEC Guide 65. ***Note 2:*** Opinions and interpretations included in a test report may comprise, but not be limited to the following: • an opinion on the statement of compliance/noncompliance of the results with requirements • fulfillment of contractual requirements • recommendations on how to use the results • guidance to be used for improvements ***Note 3:*** In many cases it might be appropriate to communicate the opinions and interpretations by direct dialogue with the customer. Such dialogue should be written down.				
5.10.6	Testing Calibration Results Obtained from Subcontractors				
	When the test report contains results of tests performed by subcontractors, these results shall be clearly identified. The subcontractor shall report the results in writing or electronically.				
	When a calibration has been subcontracted, the laboratory performing the work shall issue the calibration certificate to the contracting laboratory.				

Criteria	Description	Yes	No	NA	Comment
5.10.7	Electronic Transmission of Results				
	In the case of transmission of test or calibration results by telephone, telex, facsimile or other electronic or electromagnetic means, the requirements of this International Standard shall be met (see also 5.4.7).				
5.10.8	Format of Reports and Certificates				
	The format shall be designed to accommodate each type of test or calibration carried out and to minimize the possibility of misunderstanding or misuse.				
	Note 1: Attention should be given to the lay-out of the test report or calibration certificate, especially with regard to the presentation of the test or calibration data and ease of assimilation by the reader. ***Note 2:*** The headings should be standardized as far as possible.				
5.10.9	Amendments to Test Reports and Calibration Certificates				
	Material amendments to a test report or calibration certificate after issue shall be made only in the form of a further document, or data transfer, which includes the statement: "Supplement to Test Report (or Calibration Certificate), serial number… (or otherwise identified)", or an equivalent form of wording.				

Criteria	Description	Yes	No	NA	Comment
	Such amendments shall meet all the requirements of this International Standard.				
	When it is necessary to issue a complete new report or calibration certificate, this shall be uniquely identified and shall contain a reference to the original that it replaces.				

The signatures below recognize the above Quality Assurance Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director Date

Mary Doe, Quality Assurance Manager Date

End of Document

DNA Quality Audit Worksheet

http://www.fbi.gov/hq/lab/fsc/backissu/july2004/pdfs/seubert.pdf#search=%22DNA%20Quality%20Assurance%20Audit%20Criteria%20File%22

Criteria	Description	Yes	No	NA	Comment
	QUALITY ASSURANCE PROGRAM				
3.1	Does the DNA laboratory have an established and maintained documented quality system that is appropriate to the testing activities?				
3.1.1	Do clearly written and well understood procedures exist for the following:				
A	Goals and objectives				
B	Organization and management structure				
C	Personnel qualifications and training				
D	Facilities				
E	Evidence Control				
F	Validation				
G	Analytical procedures				
H	Calibration and maintenance				
I	Proficiency testing				
J	Corrective action				
K	Reports				

Criteria	Description	Yes	No	NA	Comment
L	Review				
M	Safety				
N	Audits				
	ORGANIZATION AND MANAGEMENT				
4.1.a	Has the managerial staff of the laboratory been provided the authority and resources needed to discharge their duties and meet the requirements of the standards in this document?				
4.1.b	Does the laboratory have a designated technical manager or leader who is accountable for the technical operations?				
4.1.c	Does the laboratory specify and document the responsibility, authority, and interrelation of all personnel who manage, perform or verify work affecting the validity of the DNA analysis? (CO 4.1.c)				
4.1.c (CO)	Does the laboratory have a CODIS manager or custodian who is accountable for CODIS operations?				
	PERSONNEL				
5.1	Do the laboratory personnel have the education, training and experience commensurate with the examination and testimony provided?				

Criteria	Description	Yes	No	NA	Comment
5.1.1	Does the laboratory have written job descriptions for all personnel to include responsibilities, duties and skills?				
5.1.2	Does the laboratory have a documented training program for qualifying all technical laboratory personnel?				
5.1.3	Does the laboratory have a documented program to ensure that technical qualifications are maintained through continuing education?				
5.1.3.1.a	Over the last year, has the technical manager or leader read current scientific literature?				
5.1.3.1.b	Over the last year, has the technical manager or leader attended at least one seminar, course, professional meeting or training session/ class which addresses subject matter related to DNA analysis?				
5.1.3.1.c (CO)	Over the last year, has the CODIS manager read current scientific literature?				
5.1.3.1.d (CO)	Over the last year, has the CODIS manager attended at least one seminar, course, professional meeting or training session/class which addresses subject matter related to DNA analysis?				
5.1.3.1.e	Over the last year, has each examiner/analyst read current scientific literature?				
5.1.3.1.f	Over the last year, has each examiner/analyst attended at least one seminar, course, professional meeting or training session/class which addressed subject matter related to DNA analysis?				

Criteria	Description	Yes	No	NA	Comment
5.1.4	Does the laboratory maintain records on the relevant qualifications, training, skills and experience of all technical personnel?				
5.2	Does the technical manager or leader satisfy the degree/educational, experience and duty requirements as listed in standards 5.2.1 through 5.2.3?				
5.2.1	Does the technical manager or leader of the laboratory meet the following degree/educational requirements or have a waiver as stated in standard 5.2.1.1?				
5.2.1.A	A graduate degree in a biology, chemistry or forensic science related area				
5.2.1.B	A minimum of 12 credit hours or its equivalent including a combination of graduate and undergraduate course work or classes covering the subject areas of:				
a	Biochemistry				
b	Genetics				
c	Molecular biology				
d	Statistics and/or population genetics				
5.2.1.1	Does the technical manager or leader possess a waiver from the ASCLD or other organization designated by the Director of the FBI?				

Criteria	Description	Yes	No	NA	Comment
5.2.2	Does the technical manager or leader of the laboratory have a minimum of three years forensic DNA laboratory experience?				
5.2.3	Does the technical manager or leader of the laboratory meet the duty requirements of this standard?				
5.2.3.1	Does the technical manager or leader manage the technical operations of the laboratory?				
5.2.3.2.a-1	Is the technical manager or leader responsible for evaluation all methods used by the laboratory?				
5.2.3.2.a-2	Is the technical manager or leader responsible for proposing new or modified analytical procedures to be used by the examiners?				
5.2.3.2.b-1	Is the technical manager or leader responsible for technical problem solving of analytical methods?				
5.2.3.2.b-2	Is the technical manager or leader responsible for the oversight of training, quality assurance, safety and proficiency testing in the laboratory?				
5.2.3.3	Is the technical manager or leader accessible to the laboratory to provide onsite, telephonic or electronic consultation as needed?				
5.3 (FO)	Does each examiner/analyst satisfy the degree/educational, experience and duty requirements as listed in standards 5.3.1 through 5.3.3?				
5.3.1	Does each examiner/analyst meet the following degree/educational requirements?				

Criteria	Description	Yes	No	NA	Comment
5.3.1.A	A BA/BS degree or its equivalent in a biology, chemistry, or forensic science related area?				
5.3.1.B	College course work or classes covering the subject areas of:				
a	Biochemistry				
b	Genetics				
c	Molecular Biology				
5.3.1.C	College coursework or training which covers the subject area of statistics and/or population genetics?				
5.3 (CO)	Does the CODIS manager or custodian satisfy the degree/ educational, experience and duty requirements as listed in the Convicted Offender standards 5.3.1 through 5.3.3?				
5.3.1	Does the CODIS manager or custodian possess a bachelor's degree in a natural science or computer science?				
5.3.2.a	Does the CODIS manager or custodian have a working knowledge of the following:				
a	Computers				
b	Computer networks				
c	Computer database management				
5.3.2.b	Does the CODIS manager or custodian have an understanding of DNA profile interpretation?				

Criteria	Description	Yes	No	NA	Comment
5.3.3	Does the CODIS manager or custodian meet the duty requirements of this position?				
5.3.3.a-1	Does the CODIS manager or custodian function as the system administrator of the laboratory's CODIS network?				
5.3.3.a-2	Is the CODIS manager or custodian responsible for the security of the DNA profile data stored in CODIS?				
5.3.3.b	Is the CODIS manager or custodian responsible for oversight of the CODIS computer training and quality assurance of data?				
5.5.3.c-1	Does the CODIS manager or custodian have the authority to terminate the laboratory's participation in CODIS in the event of a problem until the reliability of the computer data can be assured?				
5.3.3.c-2	Does the state CODIS manager or custodian have this authority over all CODIS sites under is/her jurisdiction?				
5.4	Does each technician meet the training and qualification requirements as stated in standards 5.4.1 and 5.4.2?				
5.4.1	Did each technician receive on the job training specific to their job function?				
5.4.2	Did each technician successfully complete a qualifying test before participating in forensic DNA typing responsibilities?				
5.5	Do all laboratory support personnel meet the requirements as stated in standard 5.5.1?				

Criteria	Description	Yes	No	NA	Comment
5.5.1	Do all laboratory support personnel possess the training, education and experience commensurate with their responsibilities as outlined in their job descriptions?				
	FACILITIES				
6.1	Is the laboratory designed to provide adequate security and minimize contamination?				
6.1.1	Is access to the laboratory controlled and limited?				
6.1.2	Are evidence examinations, DNA extractions and PCR setup conducted at separate times or in separate spaces?				
6.1.2 (CO)	Are evidence examinations, liquid sample examinations, DNA extractions and PCR setup conducted at separate times or in separate spaces?				
6.1.3	Is amplified DNA product generated, processed and maintained in a room(s) separate from the evidence examination, DNA extractions and PCR setup areas?				
6.1.3 (CO)	Is amplified DNA product generated, processed and maintained in a room(s) separate from the evidence examination, liquid sample examinations, DNA extractions and PCR setup areas?				
6.1.4 (CO)	If a robotic work station is used to carry out DNA extraction and amplification in a single room, can it be demonstrated that contamination is minimized and equivalent to that when performed manually in separate rooms?				

Criteria	Description	Yes	No	NA	Comment
6.1.4	Does the laboratory follow written procedures for monitoring, cleaning and decontaminating facilities and equipment?				
	EVIDENCE OR SAMPLE CONTROL				
7.1	Does the laboratory have and follow a documented evidence control system or sample inventory control system (Convicted Offender) for handling and preserving the integrity of physical evidence?				
7.1.1	Is each evidence sample (including Convicted Offender samples) labeled with a unique identifier in accordance with established agency policy?				
7.1.2	Does the laboratory maintain a chain of custody for all evidence?				
7.1.2 (CO)	Does the laboratory document and maintain the identity, collection, receipt, storage and disposition of samples?				
7.1.3	Does the laboratory follow documented procedures that minimize loss, contamination, and/or deleterious change of evidence?				
7.1.4	Does the laboratory have secure areas for evidence storage?				
7.1.4 (CO)	Does the laboratory have secure areas for sample storage including environmental controls consistent with the form or nature of the sample?				
7.2	Does the laboratory retain or return a portion of the evidence sample or extract where possible?				

Criteria	Description	Yes	No	NA	Comment
7.2.1 (FO)	Does the laboratory have a procedure requiring that evidence samples/ extract(s) be stored in a manner that minimizes degradation?				
	VALIDATION				
8.1	Does the laboratory use methods and procedures for forensic DNA analysis which have been validated prior to casework implementation?				
8.1.1	Have developmental validation studies been conducted and appropriately documented?				
8.1.2	Have novel forensic or database DNA methodologies utilized by the laboratory undergone developmental validation to ensure the accuracy, precision and reproducibility of the procedure?				
8.1.2.1	Is there documentation and is it available which defines and characterizes each locus?				
8.1.2.2 (FO)	Have species' specificity, sensitivity, stability and mixture studies been conducted?				
8.1.2.3 (FO)	Does the laboratory have access to a population data base which is documented and available for use in population statistics?				
8.1.2.3.1 (FO-a)	Where appropriate, has the database been tested for independence expectations?				

Criteria	Description	Yes	No	NA	Comment
8.1.2.3.1 (FO-b)	Does the data base information include allele and frequency distribution for the locus or loci obtained from relevant populations?				
8.1.3	Has the laboratory completed and documented internal validation studies?				
8.1.3.1.a	Has the procedure been tested using known and non-probative evidence samples?				
8.1.3.1.a-CO	Has the procedure been tested using known samples?				
8.1.3.1.b	Has the reproducibility and precision of the procedure been monitored and documented using human DNA control(s)?				
8.1.3.2 (FO)	Based on empirical data, have match criteria been established and documented?				
8.1.3.3	Has the analyst or examination team successfully completed a qualifying test utilizing the DNA analysis procedure prior to its incorporation into case work or database applications? (CO8.1.3.2)				
8.1.3.4	Have material modifications to analytical procedures been documented and subjected to validation testing?				
8.1.4 (FO)	If methods are not specified, does the laboratory, wherever possible, select methods that have been published by reputable technical organizations or in relevant scientific texts or journals, or which have been appropriately evaluated for a specific or unique application?				

Criteria	Description	Yes	No	NA	Comment
	ANALYTICAL PROCEDURES				
9.1	Does the laboratory have and follow written analytical procedures approved by laboratory management/technical manager or leader?				
9.1.1	Does the laboratory have a documented standard operating protocol for each analytical technique used?				
9.1.2	Do the analytical procedures describe reagents, sample preparation, extraction, equipment and controls which ware standard for DNA analysis and interpretation?				
9.1.3 (FO)	Does the laboratory have a procedure for the differential extraction of stains which contain semen?				
9.2	Does the laboratory use reagents that are suitable for the methods employed?				
9.2.1	Does the laboratory have written procedures for documenting commercial supplies and for the formulation of reagents?				
9.2.2	Are reagents labeled with the identity of the reagent, the date of preparation or expiration, and the identity of the individual preparing the reagent?				
9.2.3 (a)	Has the laboratory identified and evaluated the reagents critical to the analysis process prior to use in casework?				
9.2.3 (b)	Has the laboratory identified and evaluated the following critical reagents?				
a	Restriction enzyme				

Criteria	Description	Yes	No	NA	Comment
b	Commercial kits for performing genetic typing				
c	Agarose for analytical RFLP gels				
d	Membranes for Southern blotting				
e	K562 DNA or other human DNA controls				
f	Molecular weight markers used as RFLP sizing standards				
g	Primer sets				
h	Thermostable DNA polymerase				
9.3 (FO)	Does the laboratory have and follow a procedure for evaluating the quantity of DNA in samples?				
9.3.1	Does the laboratory use procedures for establishing the presence of high molecular weight DNA from RFLP casework samples?				
9.4	Does the laboratory monitor the analytical procedures using appropriate controls and standards? (CO 9.3)				
9.4.1	Does the laboratory use the following controls for RFLP casework analysis? (CO 9.3.1)				
9.4.1.1	Quantitation standards which estimate the amount of DNA recovered by extraction? (CO 9.3.1.1)				
9.4.1.2	K562 as a human DNA control? (CO 9.3.1.2)				
9.4.1.3	Molecular weight size markers, at defined intervals, for bracketing known and evidence samples? (CO 9.3.1.3)				

Criteria	Description	Yes	No	NA	Comment
9.4.1.4	Procedure to monitor the completeness of restriction enzyme digestion? (CO 9.3.1.4)				
9.4.2	Does the laboratory use the following controls for PCR casework or database analysis? (CO 9.3.2)				
9.4.2.1	Quantitation standards which estimate the amount of human nuclear DNA recovered by extraction? (CO 9.3.2.1)				
9.4.2.2	Positive and negative amplification controls? (CO 9.3.2.2)				
9.4.2.3 (FO)	Reagent blanks?				
9.4.2.4	Allelic ladders and/or internal size markers for variable number tandem repeat sequence PCR based systems? (CO 9.3.2.4)				
9.5	Does the laboratory check its DNA procedures annually or whenever substantial changes are made to the protocol(s) against an appropriate and available NIST standard reference material (SRM) or standard traceable to a NIST standard? (CO 9.4)				
9.6	Does the laboratory have and follow written general guidelines for the interpretation of data? (CO 9.5)				
9.6.1	Does the laboratory verify that all control results are within established tolerance ranges? (CO 9.5.1)				
9.6.2	Where appropriate, are visual matches supported by a numerical match criterion?				

Criteria	Description	Yes	No	NA	Comment
9.6.3	Has the 1996 National Research Council report and/or a court directed method been used for the statistical interpretation of a DNA profile for a given population and/or hypothesis or relatedness and are these calculations derived from an established population data base appropriate for the calculation?				
	EQUIPMENT CALIBRATION AND MAINTENANCE				
10.1	Does the laboratory use equipment which is suitable for the methods employed?				
10.2	Does the laboratory have a documented program for calibration of equipment and instruments?				
10.2.1	Where available and appropriate, are standards traceable to national or international standards used in the calibration of equipment?				
10.2.1.1	Where traceability to national standard of measurement is not applicable, does the laboratory provide satisfactory evidence of correlation of results?				
10.2.2	For each instrument requiring calibration, has the frequency of calibration been documented and has such documentation been retained in accordance with applicable Federal or state law?				
10.3	Does the laboratory have a documented program to ensure that instruments and equipment or properly maintained?				

Criteria	Description	Yes	No	NA	Comment
10.3.1	Have new instruments and equipment, or instruments and equipment that have undergone repair or maintenance, been calibrated before being used in casework analysis?				
10.3.2	Have written records or logs been maintained for maintenance service performed on instrument and equipment and has such documentation been retained in accordance with applicable Federal or state law?				
	REPORTS				
11.1	Does the laboratory have and follow written procedures for taking and maintaining case notes to support the conclusions drawn in laboratory requests?				
11.1 (CO)	Does the laboratory have and follow written procedures for generating and maintaining documentation for database samples?				
11.1.1 (FO)	Does the laboratory maintain in a case record, all documentation generated by examiners related to case analyses?				
11.1.1 (CO)	Does the laboratory have written procedures for the release of database sample information?				
a	Case identifier				
b	Description of evidence examined				
c	A description of methodology				

Criteria	Description	Yes	No	NA	Comment
d	Locus				
e	Results and/or conclusions				
f	An interpretative statement (either quantitative or qualitative)				
g	Date issued				
h	Disposition of evidence				
i	A signature and title or equivalent identification of the person(s) accepting responsibility for the content of the report				
11.1.3 (FO)	Does the laboratory have written procedures for the release of case report information?				
	REVIEW				
12.1 (FO)	Does the laboratory conduct administrative and technical reviews of all case files and reports to ensure conclusions and supporting data are reasonable and within the constraints of scientific knowledge?				
12.1 (CO)	Does the laboratory have and follow written procedures for reviewing database sample information, results and matches?				
12.1.1	Does the laboratory have a mechanism in place to address unresolved discrepant conclusions between analysts and reviewers?				

Criteria	Description	Yes	No	NA	Comment
12.2	Does the laboratory have and follow a written program that documents the annual monitoring of the testimony of each examiner?				
12.2 (CO)	Does the laboratory have and follow a written program that documents the annual monitoring of the testimony of laboratory personnel?				
	PROFICIENCY TESTING				
13.1	Do examiners and other personnel designated by the technical manager or leader who are actively engaged in DNA analysis undergo open external proficiency tests at regular intervals not to exceed 180 days?				
13.1.1	Does the laboratory maintain the following records for proficiency tests and is such documentation retained in accordance with applicable Federal or state law?				
a	The test set identifier				
b	Identity of the examiner				
c	Date of analysis and completion				
d	Copies of all data and notes supporting the conclusions				
e	The proficiency test results				
f	Any discrepancies noted				

Criteria	Description	Yes	No	NA	Comment
g	Corrective action taken				
13.1.2	Has the laboratory established at a minimum the following criteria for evaluation of proficiency tests?				
a	All reported inclusions are correct or incorrect.				
b	All reported exclusions are correct or incorrect.				
c	All reported genotypes and/or phenotypes are correct or incorrect according to consensus genotypes/phenotypes or within established empirically determined ranges.				
d	All results reported as inconclusive or uninterpretable are consistent with written laboratory guidelines. The basis for inconclusive interpretations in proficiency tests must be documented.				
e	All discrepancies/errors and subsequent corrective actions must be documented.				
f	All final reports are graded as satisfactory or unsatisfactory. A satisfactory grade is attained when there are no analytical errors for the DNA profile typing data. Administrative errors shall be documented and corrective actions taken to minimize the error in the future.				
g	All proficiency test participants shall be informed of the final test results.				

Criteria	Description	Yes	No	NA	Comment
	CORRECTIVE ACTION				
14.1	Does the laboratory have and follow written procedures for taking corrective action whenever proficiency testing discrepancies and/or case work errors are detected?				
14.1 (CO)	Does the laboratory have and follow written procedures for taking corrective action whenever proficiency testing discrepancies and/or analytical errors are detected?				
14.1.1	Does the laboratory maintain documentation retained in accordance with applicable Federal or state law?				
	AUDITS				
15.1	Are audits of the laboratory completed and documented annually?				
15.1.1	**Did the audit procedures address the following?**				
a	Quality assurance program				
b	Organization and management				
c	Personnel				
d	Facilities				

Criteria	Description	Yes	No	NA	Comment
e	Evidence control				
f	Validation				
g	Analytical procedures				
h	Calibration and maintenance				
i	Proficiency testing				
j	Corrective action				
k	Reports				
l	Review				
m	Safety				
n	Previous audits				
15.1.2	Has the laboratory retained all documentation pertaining to audits in accordance with relevant legal, agency, and state requirements?				
15.2	Did a second agency (external) participate in an annual audit of the laboratory at least once every two years?				

Criteria	Description	Yes	No	NA	Comment
	SAFETY				
16.1	Does the laboratory have and follow a documented environmental health and safety program?				
	SUBCONTRACTORS OF ANALYTICAL TESTING FOR WHICH VALIDATED PROCEDURES EXIST				
17.1	Does the laboratory require certification of compliance with these standards when a subcontractor performs forensic DNA analyses for the laboratory?				
17.1.1	Has the laboratory established and does the laboratory use appropriate review procedures to verify the integrity of the data received from the subcontractor?				

Criteria	Description	Yes	No	NA	Comment
17.1.1.A (CO)	Has the laboratory established and used review procedures which include (but are not limited to) each of the following?				
a	Random re-analysis of samples				
b	Visual inspection and evaluation of results/data				
c	Inclusion of QC samples				
d	On-site visits				

The signatures below recognize the above Quality Assurance Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director Date

Mary Doe, Quality Assurance Manager Date

End of Document

Equipment Inventory Form

Section Name				Date	
#	Instrument	Manufacturer	Model #	Serial #	Location
01					
02					
03					
04					
05					
06					
07					
08					
09					
10					
11					
12					
13					
14					

#	Instrument	Manufacturer	Model #	Serial #	Location
15					
16					
17					
18					
19					
20					
21					
22					
23					
24					
25					

Equipment Calibration Log

Section Name

Instrument		Manufacturer		Serial #
Date	**Reference Standard ID**	**Pass/Fail**	**Initials**	**Comments**

Instrument Maintenance Log

Section Name

Instrument	Manufacturer	Serial #

Date	Maintenance Performed	Comments

Chemical Inventory

Section Name

#	Chemical	Manufacturer	Lot #	Expiration Date	Original Amount	Location

Reference Standard Inventory

Section Name

#	Reference Standard/ Material	Manufacturer/ Source	Lot #	Expiration Date	Original Amount	Location

Reference Standard Validation Log

Section Name

#	Reference Standard/ Material	Manufacturer/ Source	Lot #	Expiration Date	Validated Y/N	Examiner

Name	Title

Training Record Log Form

Training Description	From	To	Hours
New Employee Orientation			
Administrative Policy Orientation			
Health and Safety Orientation			
Property and Evidence Orientation			
Quality Assurance Program Orientation			

Proficiency Test Database

Test Number	Discipline	Examination Type	Source	Examiner's Name	Date Assigned	Date Returned	Date Reviewed	Results

Proficiency Test Report

Name	Title
Examination	Date Assigned

Test Type (Check One)

☐ COMPETENCY TEST ☐ INTERNAL PROFICIENCY TEST ☐ EXTERNAL PROFICIENCY TEST

Sample Information

Proficiency Test #	
Sample Origin	☐ Commercial ☐ Internally Prepared ☐ Case Rework
Manufacturer	Vendor/Examiner/Case #
Sample Description	
Target Value	

Test Review

All reported results are correct.	☐ Yes ☐ No
Case notes are complete and support all reported results.	☐ Yes ☐ No
All results reported as inconclusive or uninterruptible are consistent with written laboratory guidelines, if applicable.	☐ Yes ☐ No
All discrepancies/errors and subsequent corrective actions must be documented.	☐ Yes ☐ No
DNA Specific Requirements	
All reported inclusions correct.	☐ Yes ☐ No
All reported exclusions correct.	☐ Yes ☐ No
All reported genotypes and/or phenotypes are correct according to the consensus genotypes/phenotypes or within established empirically determined ranges.	☐ Yes ☐ No
There are no analytical errors for DNA profile typing data.	☐ Yes ☐ No

Results

☐ **SATISFACTORY** ☐ **UNSATISFACTORY (*Comments Attached*)**

Proficiency Test Review

Examiner	**Date**
Technical Leader	**Date**
Quality Assurance Manager	**Date**

Testimony Review Form

Name	Title

Attorney Name	Case	
Testimony for:	☐ Prosecution	☐ Defense
Type of Proceeding:	☐ Deposition	☐ Trial
Type of Review:	☐ On-Site Observation	☐ Attorney Questionnaire
	☐ Transcript Review	☐ Attorney Interview

Area of Review	Below Stand.				Exceed Stand.	
Personal appearance	1	2	3	4	5	N/A
Voice						
Eye Contact						
Posture						
Courtroom procedure etiquette						
Vocabulary						
Confidence						
Responsiveness to questions						
Preparation and organization						
Use of visual demonstrations/evidence handling						
Cross examination demeanor						
Explanation of general scientific principles						
Explanation of procedures followed in the case						
Explanation of results in this case						
Technical accuracy						
Other:_____						

Comments:

Testimony Review

Examiner	Date
Supervisor	**Date**
Quality Assurance Manager	**Date**

Corrective Action Report Form

Date	CAR #

Risk/Issue Source

☐ Employee Suggestion ☐ Peer Group ☐ User Group
☐ Audit ☐ Proficiency Test ☐ Employee Performance

Risk or Issue: Describe risk or issue
Resolution: Describe steps taken to address the risk or resolve the issue.
Results: Describe effect of the steps taken to address the risk or resolve the issue and any follow up action required.
Describe Follow Up Action Required:

Issue Successfully Resolved

Employee	**Date**
Supervisor	**Date**
Quality Assurance Manager	**Date**

Corrective Action Report Log

CAR #	Corrective Action Description	Date Initiated	Date Resolved

Date	ITEM CREATION AND TRANSFER RECORD	Record Number

Items CREATED

NEW ITEM #	DESCRIPTION	CREATED BY	DATE CREATED

RECORD OF EVIDENCE CUSTODY

DATE	TIME	FROM	TO	PURPOSE

Examiner Analysis Authorization

ID #	Name	Authorized Analysis Type

Reagent Preparation Log

Section Name

Reagent Name

Chemicals Used

Chemical	Manufacture	Lot #

Preparation Procedure

1
2
3
4
5
6

QC Test Procedure

1
2

Date Prepared	Batch #	QC Test Pass/Fail	Initials	Comments (Expiration date if applicable)

PROGRAM OVERVIEW

Legal Authority

1 PURPOSE

This document establishes the **AGENCY NAME's** legal authority.

2 SCOPE

This policy applies to all factions of the **AGENCY NAME.**

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

The **AGENCY NAME** operates under the legal authority of INSERT STATUTE NAME AND LINK TO LEGAL CITATION OR LINK TO ARTICLES OF INCORPORATION.

- This policy complements Administrative Policy APP-102

5 PROCEDURE

There are no procedures that are directly applicable to the implementation of this policy.

6 APPROVAL

The signatures below recognize the above Quality Manual Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

PROGRAM OVERVIEW

Mission Statement

1 PURPOSE

This document defines **AGENCY NAME's** Quality Assurance Program Mission Statement.

2 SCOPE

This policy applies to all factions of the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

The mission of the AGENCY NAME Quality Assurance Program is to provide its users a sustainable level of quality scientific examination services based upon international standards of quality and dedication to the continual self improvement of its analytical and management systems.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

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PROGRAM OVERVIEW

Program Objectives

1 PURPOSE

This document defines **AGENCY NAME's** quality assurance program objectives.

2 SCOPE

This policy applies to all factions of the **AGENCY NAME.**

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

The objectives of the **AGENCY NAME** quality assurance program are:

- To maintain and improve the highest quality of service to the criminal justice system of the STATE/COUNTRY NAME.
- To heighten the awareness of all the management regarding the importance of quality assurance.
- To heighten the awareness of all the employees regarding the importance of quality assurance.
- To effectively channel the efforts all levels of the staff into a comprehensive, quality oriented program.
- To identify quality related problems in all operational areas and take corrective action and implement programs to prevent their recurrence.
- To enhance the analytical capabilities of the **AGENCY NAME.**

All employees agree to support the documented goals and objectives of the quality program by virtue of their employment.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

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QUALITY ASSURANCE PROGRAM OVERVIEW

Program Definition

1 PURPOSE

This document defines **AGENCY NAME's** quality assurance program.

2 SCOPE

This policy applies to all factions of the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

The **AGENCY NAME** Quality Assurance Program is defined as a planned system of activities whose purpose is to provide assurance that the production of high quality services is appropriate, dependable, and satisfactory.

The basic components of the AGENCY NAME Quality Assurance Program are:

- Documented technical procedures
- Validation of new technical procedures
- Employee training
- Proficiency testing
- Case documentation and review
- Quality control, instrument calibration and maintenance records
- Technical Leaders and Core Groups
- Audits and inspections
- Identification and correction of problems
- User agency feedback

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

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PROGRAM OVERVIEW

Quality Manager

1 PURPOSE

This document defines **AGENCY NAME's** quality manager requirements.

2 SCOPE

This policy applies to quality assurance section of the **AGENCY NAME.**

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

The Director will designate an individual as Quality Manager.

The Quality Assurance Manager shall have the authority and resources needed to carry out their duties and to identify the occurrence of departures from the quality system or from the procedures for performing tests and/or calibrations, and to initiate actions to prevent or minimize such departures.

The Quality Assurance Manager will be responsible for the implementation and operation of the Quality Assurance Program.

The Quality Assurance Manager will report directly to the Director on all issues regarding the Quality Assurance Program.

The Quality Assurance Manager may have duties outside the area of quality assurance.

The Director may contract the services of Quality Assurance Manager to a qualified individual or entity.

- The contracting of services will be subject to the policies and procedures of the AGENCY NAME.

4.1 JOB DESCRIPTION

The Quality Assurance Manager's duties including, but are not limited to:

- Maintenance and revision of the quality assurance manual
- Propose corrections and improvements to the quality system
- Evaluate quality assurance related recommendations and make adjustments to the quality assurance program as required
- Monitoring lab practices and verifying continuing compliance with policies and procedures
- Ensuring the validation of new protocols and methods

- Investigation of technical problems, proposal of remedial action and verification of their implementation
- Evaluation of instrumentation calibration and maintenance records
- Maintain the training records of AGENCY NAME personnel
- Recommends training opportunities to improve the quality of personnel
- Administration of proficiency tests and evaluation of results
- Periodic assessment of the adequacy of report review activities
- Scheduling, performance, and evaluation of internal/external audits
- Conduct, or cause to be conducted, an annual review of the quality system

4.2 AUXILIARY STAFF

The Director will designate a sufficient number of individuals to assist the Quality Assurance Manager in the performance of his duties.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

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PROGRAM OVERVIEW

Accreditation

1 PURPOSE

This document defines the **AGENCY NAME's** accreditation policy.

2 SCOPE

This policy applies to factions of the **AGENCY NAME.**

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

The **AGENCY NAME** recognizes the value of the validation of its quality systems through accreditation by a recognized laboratory accrediting body.

The **AGENCY NAME** will strive to achieve and maintain accreditation through one or more recognized laboratory accrediting bodies, to include but not be limited to:

- American Society of Crime Laboratory Directors/Laboratory Accreditation Board (ASCLD/LAB)
- International Standards Organization (ISO)
- National Forensic Science Technology Center (NFSTC)
- Other recognized laboratory accrediting body

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

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QUALITY ASSURANCE PROGRAM OVERVIEW

Commitment to Quality

1 PURPOSE

This document defines **AGENCY NAME's** commitment to quality.

2 SCOPE

This policy applies to all factions of the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

4.1 GENERAL

The **AGENCY NAME** recognizes that many factors determine the correctness and reliability of the tests and/or calibrations performed by a laboratory. These factors include contributions from:

- Human factors
- Accommodation and environmental conditions
- Test and calibration methods and method validation
- Equipment
- Measurement traceability
- Sampling
- The handling of test and calibration items

The **AGENCY NAME** is committed to improving the quality contribution and shall take account of these factors into account in developing test and calibration methods and procedures, in the training and qualification of personnel, and in the selection and calibration of the equipment it uses.

4.2 MANAGEMENT COMMITMENTS

The **AGENCY NAME** management is committed to comply with the international standard outlined in International Standards Organization standard for testing and calibration laboratories (17025) and to continually improve the effectiveness of their management system.

The laboratory management is commitment to the utilization of good professional practice and to the quality of its testing and calibration in servicing its customers.

The management systems utilized will support and augment the quality systems implemented by the **AGENCY NAME**.

4.3 EMPLOYEE COMMITMENTS

The **AGENCY NAME** employees are committed to support the management's efforts to comply with the international standards outlined in International Standards Organization standard for testing and calibration laboratories (17025) and to continually improve the effectiveness of their examinations and quality system.

Employees are committed to employ good professional and quality practices to the testing and calibration in servicing performed for its customers.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

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QUALITY ASSURANCE PROGRAM OVERVIEW

Change Management

1 PURPOSE

This document defines **AGENCY NAME's** quality assurance program change management policy.

2 SCOPE

This policy applies to all factions of the **AGENCY NAME.**

3 DEFINITIONS

The current revision of document QAM-P101 will be used as a guide to define terms.

4 POLICY

The senior management shall ensure that the integrity of the quality system is maintained when changes to the quality assurance team or quality system are planned and implemented.

The senior management shall periodically conduct a review of the laboratory's quality system and testing and/or calibration activities to ensure their continuing suitability and effectiveness, and to introduce necessary changes or improvements within the budgetary constraints. The review shall take account of:

- The suitability of policies and procedures
- Reports from managerial and supervisory personnel
- The outcome of recent internal audits
- Corrective and preventive actions
- Assessments by external bodies
- The results of inter laboratory comparisons or proficiency tests
- Changes in the volume and type of the work
- Customer feedback
- Complaints
- Recommendations for improvement
- Other relevant factors, such as quality control activities, resources and staff training

Findings from management reviews and the actions that arise from them shall be recorded. The management shall ensure that those actions are carried out within an appropriate and agreed timescale.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

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QUALITY ASSURANCE PROGRAM OVERVIEW

References

1 PURPOSE

This document defines **AGENCY NAME's** quality assurance program reference policy.

2 SCOPE

This policy applies to all factions of the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

All critical references described in this quality manual shall be maintained on file in the laboratory and are accessible to all laboratory staff and management.

4.1 CRITICAL REFERENCES

- Literature reference1 utilized by your laboratory to establish the quality system. (Hyper link to static document suggested.)
- Literature reference 2 utilized by your laboratory to establish the quality system. (Hyper link to static document suggested.)
- Literature reference … utilized by your laboratory to establish the quality system. (Hyper link to static document suggested.)

4.2 ADDITIONAL REFERENCES

- Non-critical literature reference utilized by your laboratory to establish the quality system. (Hyper link to static document not required.)
- Non-critical literature reference utilized by your laboratory to establish the quality system. (Hyper link to static document not required.)

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

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QUALITY ASSURANCE PROGRAM OVERVIEW

Customer Service

1 PURPOSE

This document defines **AGENCY NAME's** customer service policy.

2 SCOPE

This policy applies to all factions of the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

4.1 CUSTOMER CLARIFICATION

The AGENCY NAME shall afford the requesting customers cooperation to clarify the customer's request for examination.

Customers will be provided the opportunity to witness laboratory activity providing the laboratory is able to maintain confidentiality to other customers during such cases.

The AGENCY NAME seeks customer feedback on their services and general performance.

- The management team shall conduct user group meetings to establish a line of communication with customers.
- An examination satisfaction questionnaire shall sent to establish a line of communication between the **AGENCY NAME** and it customers.
    - A Customer Satisfaction Questionnaire shall accompany every examination report issued by the **AGENCY NAME**.

4.2 CUSTOMER COMPLAINTS

The **AGENCY NAME** shall establish a complaint procedure describing the process for the receipt and recording of complaints received from any party. Records of all complaints received are maintained according to the procedure. Complaints identified as nonconformities are processed according to the Corrective Action procedure.

The Quality Assurance Manager shall establish and maintain a file that contains all records of the comments, both positive and negative.

The Quality Assurance Manager shall present the AGENCY NAME management team a summary of the customer comments and questionnaire responses in an effort to identify management system improvements.

4.3 CUSTOMER SURVEY

The **AGENCY NAME** will periodically survey its users concerning the level of quality of the services it provides.

- Customer Survey form will be utilized for this purpose.

The Quality Assurance Manager will annually provide the senior management the results of the customer for use in identifying risks, issues, non-conformity or other situations that effect quality or customer satisfaction.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

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AUDITS, INSPECTIONS AND REVIEWS

Quality System Audits

1 PURPOSE

This document defines **AGENCY NAME's** quality system audit policy.

2 SCOPE

This policy applies to factions of the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

The AGENCY NAME will conduct and document an annual audit of its quality systems for compliance with established policies, rules and regulations as well as applicable criteria outlined by an accreditation entity responsible for validating the quality of the **AGENCY NAME** operation.

Technical Leaders or other recognized leaders within an examination discipline can conduct on-site technical audits, with the approval of the Quality Assurance Manager.

- These audits may be needed to determine the adequacy of training, equipment, personnel and facility at the laboratory and make recommendations for improvement.

The Quality Assurance Manager will be responsible for audit coordination and scheduling.

Additional audits may be conducted at the direction of the Director or the Quality Assurance Manager to address specific quality assurance concerns.

4.1 SCOPE

The scope of the annual audit will encompass all aspects of the quality system as outlined in the Quality Assurance Manual.

Audit subject matter should encompass at least the following:

- Case file reviews for each unit
- Staff interviews with members from each unit
- Inventory/spot checks of chemical/materials use, storage and labeling
- Inventory/spot checks of evidence packaging, storage and labeling

DNA laboratories will be audited using standards established by the DNA Advisory Board.

4.2 AUDITORS

4.2.1 Internal Auditors

The Director with the approval of the Quality Assurance Manager, may authorize the use of a qualified technical leaders or senior managers to conduct annual audits of the quality systems.

4.2.2 External Auditors

The Director may authorize the use of a qualified external source to perform annual audits of the quality systems.

External sources can include:

- Accreditation organizations
- Professionals from other laboratories
- Consultants

External auditors will be subject to the same reporting requirements as internal auditors.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

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AUDITS, INSPECTIONS AND REVIEWS

Inspections

1 PURPOSE

This document defines **AGENCY NAME's** inspection policy.

2 SCOPE

This policy applies to factions of the **AGENCY NAME.**

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

The **AGENCY NAME** will conduct safety inspections in accordance with the Health and Safety Manual requirements.

Additional non-quality assurance related inspections will be conducted and documented as required by the Director or the Quality Assurance Manager.

The results of all inspections will be documented and filed in accordance with the document retention policies.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

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AUDITS, INSPECTIONS AND REVIEWS

Audit Documentation

1 PURPOSE

This document defines **AGENCY NAME's** quality audit documentation policy.

2 SCOPE

This policy applies to audits conducted by the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

Internal auditors will utilize one of more of the following checklists to document their findings:

- Modified ASCLD/LAB checklist
- Modified ISO 17025 checklist
- Modified FBI DNA Quality Assurance Audit Document
- Other checklist authorized by the Quality Assurance Manager

External auditors document their findings utilizing the check lists and forms prescribed by their auditing body.

Each audit team will submit report to the Quality Assurance Manager within 30 calendar days of the completion of the audit.

The Quality Assurance Manager will provide the Director a summary report outlining deviations from standard procedure and recommendations for corrective action.

The **AGENCY NAME** will annually submit audit report to the accreditation entity responsible for validating the quality of the **AGENCY NAME's** operation.

- The report will be submitted prior to the deadline established by the accreditation entity.
- The audit report will be submitted in the format required by the accreditation entity.

The Quality Assurance Manager will establish and maintain a file for every internal and external audit. Each file will contain:

- A summary report of the auditor's findings.
- Copies of all deficiency reports that are generated as a result of the audit.
- Copies of all risk assessment/issue resolution reports that are generated as a result of the audit.
- Copies of relevant checklists used during the auditing process.

All audit, inspection and review reports will be filed in accordance with the document retention policy.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

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AUDITS, INSPECTIONS AND REVIEWS

Audit Reviews

1 PURPOSE

This document defines **AGENCY NAME's** quality audit review policy.

2 SCOPE

This policy applies to audits conducted by the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

The **AGENCY NAME** management team will review the results of the annual audit and take the corrective actions require to address detected deviations from quality assurance policies. The review shall take account of:

- The suitability of policies and procedures
- Reports from managerial and supervisory personnel
- The outcome of recent internal audits
- Corrective and preventive actions
- Assessments by external bodies
- The results of inter laboratory comparisons or proficiency tests
- Changes in the volume and type of the work
- Customer feedback
- Complaints
- Recommendations for improvement
- Other relevant factors, such as quality control activities, resources and staff training

A summary report of the results of the annual audit will be disseminated to all employees at the conclusion of the management team's review and comment.

Summary report dissemination can be accomplished through:

- Providing each employee a copy of the summary report
- Circulating a copy of the summary report with a routing slip
- A laboratory wide meeting to discuss the audit results
- Unit meetings to discuss the audit report results
- Meetings with individual employees, as required

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

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AUDITS, INSPECTIONS AND REVIEWS

Technical Procedure Deviation Policy

1 PURPOSE

This document establishes the **AGENCY NAME's** technical procedure deviation policy.

2 SCOPE

This policy applies to all technical procedures of the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

Only approved technical procedures that are documented in the relevant technical procedure manual will utilized.

Deviations from approved technical procedures are subject to review and approval by the Quality Assurance Manager prior to implementation.

Technical procedures that deviate from the approved technical procedures will be validated prior to use on case work.

4.1 EXAMPLES OF DEVIATIONS

- Use of expired materials.
  - Replacement chemicals may not be available from a manufacturer due to back-order situations.
  - Casework can continue with the expired chemical if it is deemed of good quality past its labeled expiration through control testing of standards or samples.
- Equipment out of calibration.
  - A reference standard may not be available from a manufacturer due to back-order situations and as a result, instrumentation cannot be calibrated on time.
  - Additionally, outside vendors who re-certify equipment may have backlogs that necessitate using an instrument before it is re-certified.
  - Casework can continue with the instrument if it is deemed of good quality past its labeled expiration through control testing of standards or samples.
- Use of different reagents, materials, etc.
  - Due to unavailability of reagents, etc. it may be necessary to deviate from the documented procedures.
- Deviations are not needed when:
  - Different amounts of the same chemicals/materials in the same ratio are used to formulate reagents, solutions, etc.
  - Equivalent materials, instruments, etc. are used to in a procedure to replace the designated item.

4.2 DOCUMENTATION

Minor deviations can be documented on the applicable case file, at the discretion of the Quality Assurance Manager.

A Laboratory Deviation Report Form will be generated for all other deviations.

The analyst who performed the deviation, the senior examiner or technical leader and the QA manager will sign Laboratory Deviation Report Form.

The Quality Assurance Manager will create and maintain a file to store all original Laboratory Deviation Report Forms.

A signed copy of the Laboratory Deviation Report Form will be included in the applicable case file.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

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AUDITS, INSPECTIONS AND REVIEWS

Control of Non-Conforming Work

1 PURPOSE

This document establishes the **AGENCY NAME's** control of non-conforming work policy.

2 SCOPE

This policy applies to all technical procedures of the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

The AGENCY NAME shall establish a policy and procedures to address situations when any aspect of its testing and/or calibration work, or the results of analytical work, do not conform to its own procedures or the agreed requirements of the customer.

4.1 RESPONSIBILITIES

The AGENCY NAME will:

- Ensure that the authority and the responsibility for controlling non-conformances are delegated to the appropriate management authorities.
- These authorities are authorized to halt any analytical testing or procedures related to the nonconformance and to invalidate test results that are affected.
- The responsible personnel authorized to resume work after a nonconformance is identified in the laboratory's corrective action procedure.

4.1.1 Follow-Up

If the non-conforming work could recur, or there are other significant problems identified, the corrective action procedures are promptly followed.

5 PROCEDURE

5.1 IDENTIFICATION

Non-conformances will be identified at any point within the quality system and technical operations. Identification methods include, but are not limited to:

- Customer complaints
- Unacceptable quality control samples

- Instrument problems
- Samples
- Environmental problems that affect results
- Purchased materials for laboratory use
- Staff observations
- Management reviews and audits

5.2 DOCUMENTATION

Identified non-conformances will be documented on the laboratory's corrective action form and initiate the laboratory's corrective action process. This process involves the evaluation of the impact on quality and operations.

5.3 DATA HOLD

When a non-conformance is detected, laboratory data is held and not released until the problem is resolved and verified by laboratory management in accordance with the corrective action process. Resumption of work is performed after the corrective action has been taken and approved.

Non-releasable data is not approved by management until product disposition has been made and documented. Dispositions or actions taken on a non-conforming work product are:

- Rework – action taken on non-conforming product so that it will fulfill the specified requirements.
- Redone – action taken to re-collect sample or reanalyze (redo) sample to bring the product into conformance.
- Use as is – approving the use of non-conforming product without rework or redoing, a disclaimer is made that the product was accepted and the quality requirements that the product did not meet are specified; and
- Unable to use – action taken if unable to resolve the problem. The receiver is notified that the data cannot be reported.

5.4 TECHNICAL REVIEW

Reworked or redone examinations are reviewed to verify that they comply with specifications.

5.5 CUSTOMER NOTIFICATION

When necessary, the customer is notified of the non-conformance and specifications may be changed depending on the usage of the data, for example, informational purposes only.

A customer supplied product (sample) which is lost, damaged or otherwise unsuitable will be annotated in the case file and reported to the customer verbally or electronically.

6 APPROVAL

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End of Document

DOCUMENT CONTROL

Manuals

1 PURPOSE

This document defines the **AGENCY NAME's** manual policy.

2 SCOPE

This policy applies to factions of the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

The **AGENCY NAME** will prepare and maintain policy and procedure manuals to ensure the quality of the work product in every section.

The **AGENCY NAME** will provide each employee the most current revision of the policies, procedures, analytical methods and forms that affect the performance of their assigned tasks.

4.1 OPERATIONAL POLICIES AND PROCEDURE MANUALS (OPP)

The **AGENCY NAME** will prepare and maintain an Operational Policy and Procedure manual that outlines the operational functions of policy and procedure manuals.

The content of the OPP manual shall focus on the functional issues which do not directly relate to laboratory examinations.

OPP topics will include but not be limited to:

- Administrative Policies and Procedures Manual
- Health and Safety Manual
- Property and Evidence Manual
- Quality Assurance Manual
- Forms

4.1.1 Administrative Policies and Procedure Manuals (APP)

The **AGENCY NAME** will prepare and maintain an Administrative Policy and Procedure Manual that outlines the administrative functions.

APP topics will include but not be limited to:

- Lab Management and Organization
- Physical Plant
- Personnel
- Case Management
- Document Control
- Security

4.1.2 Sample Control Manual (SCM)

The **AGENCY NAME** will prepare and maintain a Sample Control Manual (SCM).

The content of the SCM shall focus on the technical issues the proper handling of samples submitted for examination.

SCM topics will include but not be limited to:

- Administrative Issues
- Facilities
- Staffing Scheduling and Responsibilities
- Packaging and Handling
- Storage
- Evidence Control Procedures
- Disposition and Purging
- Forms

4.1.3 Health and Safety Manual (HAS)

The **AGENCY NAME** will prepare and maintain a Health and Safety Manual (HAS).

The content of the HAS shall focus on issues concerning health and safety.

HAS manual topics will include but not be limited to:

- Safety Responsibility and Authority
- Safety Practices and Procedures
- Occupant Emergency Plan
- Personal Protective Equipment
- Blood borne Pathogen Exposure and Control
- Chemical Hygiene Plan
- Hazardous Waste Disposal
- Spill Control and Containment
- Laboratory Fume Hoods
- Ergonomics and Office Safety

4.1.4 Quality Assurance Manual (QAM)

The **AGENCY NAME** will prepare and maintain a Quality Assurance Manual (QAM).

The contents of the QAM shall focus on issues concerning the quality of the examinations.

QAM topics will include but not be limited to:

- Quality Assurance Program Overview
- Audits, Evaluations and Reviews
- Document Control
- Equipment and Chemicals
- Personnel
- Evidence
- Laboratory Information Management System (LIMS)
- Issue Management

4.1.5 Forms

The **AGENCY NAME** will prepare and maintain the forms necessary to conduct official business.

4.2 TECHNICAL METHODS MANUALS (TMM)

The **AGENCY NAME** will prepare and maintain a series of Technical Methods Manuals (TMM) for each analytical section.

The contents of the TMM shall focus on the technical issues which directly related to laboratory examinations.

TMM topics will include but not be limited to:

- Training
- Analytical procedures
- Quality assurance procedures specific to that analytical area
- Documentation requirements
  - Case Notes
  - Case Reports
- Chemical inventories
- Equipment inventories
- Reference standard inventories
- Reference material inventories
- Forms specific to that analytical area

4.2.1 Training Manuals (TM)

The **AGENCY NAME** will prepare and maintain a training manual (TM) for each analytical section.

The content of the TM shall focus on the technical issues which directly related to laboratory examinations.

TM topics will include but not be limited to:

- Background
- Training program mechanics
- Individual training modules to include:
  - Objectives
  - Required Reading
  - Suggested Reading
  - Study and Discussion Exercises
  - Practical Exercises
  - Written Quiz
- Written final exam
- Practical final
- Moot court
- Supervised casework
- Unsupervised casework

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

The signatures below recognize the above Quality Manual Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

DOCUMENT CONTROL

Operational Document Development

1 PURPOSE

This document establishes the **AGENCY NAME's** controlled operational document development procedure.

2 SCOPE

This policy applies to all controlled operational documents of the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

The **AGENCY NAME** will develop a new or modify an existing controlled operational document when:

- The Director, senior management or Quality Assurance Manager identifies the need for a new or change of an existing controlled operational documents, or
- An employee suggests the need for a new or change of an existing controlled operational documents, or
- Changes in legal statutes or applicable case law require a new or change of an existing controlled operational documents, or
- Changes of the administrative regulations within the **AGENCY NAME** parent agency require a new or change of an existing controlled operational documents

5 PROCEDURE

5.1 DEVELOPMENT PROCEDURE

The Quality Assurance Manager, or his designate, will research and draft new or changes to existing controlled operational documents to address the needs identified through one of the above mechanisms.

All controlled operational documents changes or drafts will be submitted to the Director for review and comment after review by the Quality Assurance Manager

5.2 REVIEW PROCEDURE

The review process for all controlled operational documents changes or new drafts is as follows:

- The Quality Assurance Manager will review and submit with comment any operational controlled document change or draft to the Director.
- The Director will distribute the suggested operational controlled document change or draft to the senior management staff for review and comment.
- Comments and suggestions are incorporated into the proposed controlled operational document change or draft.
- The Director and the senior staff will review and comment on the amended operational controlled document change or draft.
- Comments and suggestions are incorporated into the amended controlled operational document change or draft.
- Final revision of the operational controlled document change or draft is submitted to the Director for approval.

5.3 APPROVAL PROCEDURE

- The Quality Assurance Manager prepares a final copy of the operational controlled document for the Director's signature.
- The Quality Assurance Manager signs and dates the final draft of the operational controlled document and forwards it to the Director for approval.
- The Director signs and dates the operational controlled document.
- The date of the Director signature is the effective date of the operational controlled document.

6 APPROVAL

The signatures below recognize the above Administrative Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

END OF DOCUMENT

DOCUMENT CONTROL

Operational Document Dissemination

1 PURPOSE

This document establishes the **AGENCY NAME's** controlled operational document dissemination procedure.

2 SCOPE

This policy applies to all controlled operational documents of the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

4.1 OPERATIONAL MANUAL

The Quality Assurance Manager or his designee will provide each employee an Operational Policy and Procedure Manual (OPP) containing all the most current revision of each controlled operational document.

Each copy of the OPP is considered a controlled document, designated for internal use only and will be given a unique manual number.

4.2 ACCEPTANCE, FAMILIARIZATION AND IMPLEMENTATION

By accepting an Operational Methods Manual, and its subsequent revisions, the employee agrees to familiarize them self with the contents and implement the policies and procedures to the best of their ability.

4.3 REVISIONS

The Quality Assurance Manager or his designee will disseminate copies of the new or revised controlled operational documents that have been approved by the Director.

- The disseminated documents may be in paper or electronic format.

Employees will replace all old revisions of the disseminated documents with the most recent revision upon receipt of the current revision from the Quality Assurance Manager.

The Quality Assurance Manager may issue an interim amendment to operational documents pending the re-issue of the officially formatted document.

- Interim amendments shall be clearly marked, initialed and dated.
- A revised officially formatted document shall be formally issued as soon as practicable.

4.4 EXTERNAL DISSEMINSATION

The Director must approve dissemination of controlled versions of operational or technical manuals outside the AGENCY NAME.

5 PROCEDURE

5.1 OPERATIONAL MANUAL

- The Quality Assurance Manager or his designee will provide the employee with a numbered Operational Policy and Procedure Manual containing all the most current revision of each controlled operational document.
- The Quality Assurance Manager will enter the employee's name on the appropriate line of the Operational Manual Distribution Log.
- The Employee will sign and date the Operational Manual Distribution Log, acknowledging receipt of the OPP.
- The Employee will sign and date the Operational Manual Distribution Log, acknowledging return of the issued OPP.

5.2 REVISIONS

5.2.1 Paper Copies

- The Quality Assurance Manager or his designee will prepare paper copies of the new or revised controlled operational documents that have been approved and signed by the Director.
- A paper copy of the new or revised controlled operational document will be placed into office mail box of each employee.
- The employee will remove the out dated revision of the controlled operational document and replace it as soon as reasonably possible.
- The employee will compare the outdated revision with the new revision, noting the changes.
- The employee will place the revised copy in the place of the outdated copy.
- The employee will discard the outdated copy.

5.2.2 Electronic Copies

- The Quality Assurance Manager or his designee will make an electronic copy to the operational controlled document that has been approved and signed by the Director.
  - The copy will be stored in a .PDF format that can be printed, or viewed, but not altered in any way.
- The Quality Assurance Manager will disseminate the new or revised controlled operational document to all employees via electronic mail.
- The employee will open and print the file.
- The employee will remove the out dated revision of the controlled operational document and replace it as soon as reasonably possible.
- The employee will compare the outdated revision with the new revision, noting the changes.
- The employee will place the revised copy in the place of the outdated copy.
- The employee will discard the outdated copy.

6 APPROVAL

The signatures below recognize the above Quality Assurance Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

DOCUMENT CONTROL

Operational Document Retirement

1 PURPOSE

This document establishes the **AGENCY NAME's** controlled operational document retirement policy.

2 SCOPE

This policy applies to all controlled operational documents of the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

Invalid or obsolete controlled operational documents will be promptly retired and removed from all points of issue or use to assure unintended use.

Invalid or obsolete administrative policies will be retained for either legal or knowledge preservation purposes are suitably marked.

- The Quality Assurance Manager will establish a file of retired or obsolete controlled operational documents.

Retired administrative policies will maintain their original unique document identification number.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

The signatures below recognize the above Quality Assurance Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

DOCUMENT CONTROL

Technical Document Development

1 PURPOSE

This document establishes the **AGENCY NAME's** controlled technical document development procedure.

2 SCOPE

This policy applies to all controlled technical documents of the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

The **AGENCY NAME** will develop a new or modify an existing controlled technical document when:

- The Director, senior management or Quality Assurance Manager identifies the need for a new or change of an existing controlled operational documents; or
- An employee suggests the need for a new or change of an existing controlled operational documents; or
- The introduction of new technology or instrumentation is incorporated into the analytical methods; or
- Scientific literature suggests alternative analytical methods; or
- Changes in legal statutes or applicable case law require a new or change of an existing controlled technical document; or
- Changes of the administrative regulations within the AGENCY NAME parent agency require a new or change of an existing controlled technical document.

5 PROCEDURE

5.1 DEVELOPMENT PROCEDURE

The Quality Assurance Manager, or his designate, will research and draft new or changes to existing controlled technical documents to address the needs identified through one of the above mechanisms.

All controlled technical document changes or drafts will be submitted to the Director for final approval after validation, review and comment by the Quality Assurance Manager and the relevant Peer Group.

5.2 VALIDATION PROCEDURE

All new technical procedures or equipment will be validated internally prior to application for inclusion in the respective manual and or applied to casework.

The validation process includes:

- **Literature research:** Review of publications, academic materials, safety procedures and protocols, etc. involving the technique or procedure being validated.
- **Standard samples:** The samples should be selected to represent the type of specimens to be routinely analyzed by the technique or procedure.
- **Consistency:** The methods tested and results must show the same outcome on each test.
- **Reproducibility:** The test must be reproducible by another individual using the original test documentation.
- **Specificity:** Does the test give results specific to the substrate tested for (i.e., false positives or not).
- **Sensitivity Studies:** Is the sensitivity so great many false positives occur. Is the sensitivity so low that many false negatives occur.
- **Environmental Studies:** When applicable, evaluate the method using known samples exposed to a variety of environmental conditions.

The Quality Assurance Manager will maintain a validation file for all new technical procedures that includes:

- Documentation sufficient to ensure that any qualified individual could evaluate what was done and replicates the validation process.
- Documentation in the form of either laboratory notes, reports, laboratory books or log books, which should include references, personal communications, etc.
- Documentation of external validation must identify the name, the research question, procedures, results and conclusion(s).

5.3 REVIEW PROCEDURE

The review process for all controlled technical documents changes or new drafts is as follows:

- The Quality Assurance Manager will review the draft controlled technical document change or draft and submit it, along with the validation information, to the Technical Leader of the appropriate Peer Group.
- The Director will distribute the suggested controlled technical document change or draft and associated validation information to Peer Group members for review and comment.
- Comments and suggestions are incorporated into the proposed controlled technical document change or draft.
- The Technical Leader and the Peer Group members will review and comment on the amended controlled technical document change or draft.

- Comments and suggestions are incorporated into the amended controlled technical document change or draft.
- Final revision of the controlled technical document change or draft is submitted to the Director for approval, through the Quality Assurance Manager.

5.4 APPROVAL PROCEDURE

- The Quality Assurance Manager prepares a final copy of the controlled technical document for the Director's signature.
- The Quality Assurance Manager signs and dates the final draft of the controlled technical document and forwards it to the Director of the AGENCY NAME for approval.
- The Director signs and dates the controlled technical document.
- The date of the Director signature is the effective date of the controlled technical document.

6 APPROVAL

The signatures below recognize the above Quality Assurance Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

DOCUMENT CONTROL

Technical Document Dissemination

1 PURPOSE

This document establishes the **AGENCY NAME's** controlled technical document dissemination procedure.

2 SCOPE

This policy applies to all controlled technical documents of the **AGENCY NAME.**

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

4.1 TECHNICAL MANUAL

The Quality Assurance Manager or his designee will provide each employee a Technical Methods Manual (TMM) for each examination discipline the employee is responsible for.

Each copy of the TMM is considered a controlled document, designated for internal use only and will be given a unique manual number.

4.2 ACCEPTANCE, FAMILIARIZATION AND IMPLEMENTATION

By accepting a Technical Methods Manual, and its subsequent revisions, the employee agrees to familiarize them self with the contents and implement the policies and procedures to the best of their ability.

4.3 REVISIONS

The Quality Assurance Manager or his designee will disseminate copies of the new or revised controlled technical documents that have been approved by the Director.

- The disseminated documents may be in paper or electronic format.

Employees will replace all old revisions of the disseminated documents with the most recent revision upon receipt of the current revision from the Quality Assurance Manager.

The Quality Assurance Manager may issue an interim amendment to technical documents pending the re-issue of the officially formatted document.

- Interim amendments shall be clearly marked, initialed and dated.
- A revised officially formatted document shall be formally issued as soon as practicable.

4.4 EXTERNAL DISSEMINSATION

The Director must approve dissemination of controlled versions of operational or technical manuals outside the AGENCY NAME.

5 PROCEDURE

5.1 TECHNICAL MANUAL

- The Quality Assurance Manager or his designee will provide the employee with a numbered Technical Methods Manual for each examination discipline the employee is responsible for.
- The Quality Assurance Manager will enter the employee's name on the appropriate line of the Technical Manual Distribution Log.
- The Employee will sign and date the Technical Manual Distribution Log, acknowledging receipt of the TMM.
- The Employee will sign and date the Technical Manual Distribution Log, acknowledging return of the issued TMM.

5.2 REVISIONS

5.2.1 Paper Copies

- The Quality Assurance Manager or his designee will prepare paper copies of the new or revised controlled technical documents that have been approved and signed by the Director.
- A paper copy of the new or revised controlled operational document will be placed into office mail box of each employee who requires the revision.
- The employee will remove the out dated revision of the controlled operational document and replace it as soon as reasonably possible.
- The employee will compare the outdated revision with the new revision, noting the changes.
- The employee will place the revised copy in the place of the outdated copy.
- The employee will discard the outdated copy.

5.2.2 Electronic Copies

- The Quality Assurance Manager or his designee will make an electronic copy to the controlled technical document that has been approved and signed by the Director of the AGENCY NAME.
  - The copy will be stored in a .PDF format that can be printed, or viewed, but not altered in any way.
- The Quality Assurance Manager will disseminate the new or revised controlled technical document to the employees who require the revision via electronic mail.
- The employee will open and print the file.
- The employee will remove the out dated revision of the controlled operational document and replace it as soon as reasonably possible.
- The employee will compare the outdated revision with the new revision, noting the changes.
- The employee will place the revised copy in the place of the outdated copy.
- The employee will discard the outdated copy.

6 APPROVAL

The signatures below recognize the above Quality Assurance Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

DOCUMENT CONTROL

Technical Document Retirement

1 PURPOSE

This document establishes the **AGENCY NAME's** controlled technical document retirement policy.

2 SCOPE

This policy applies to all controlled technical documents of the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

Invalid or obsolete controlled technical documents will be promptly retired and removed from all points of issue or use to assure unintended use.

Invalid or obsolete administrative policies will be retained for either legal or knowledge preservation purposes are suitably marked.

- The Quality Assurance Manager will establish a file of retired or obsolete controlled technical documents.

Retired controlled technical documents will maintain their original unique document identification number.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

The signatures below recognize the above Quality Assurance Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

DOCUMENT CONTROL

Controlled Document Review

1 PURPOSE

This document establishes the **AGENCY NAME's** controlled document review policy.

2 SCOPE

This policy applies to all controlled documents of the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

All controlled documents will be periodically reviewed for content and relevance.

Documents that require changes will be modified using the procedures outlined in the operational or technical document development policy.

Modified documents will be disseminated using the procedures outlined in the operational or technical document dissemination policy.

Obsolete documents will be retired using the procedures outlined in the operational or technical document retirement policy.

The Quality Assurance Manager will establish and maintain an inventory of all controlled documents. The inventory information shall include:

- File name
- Revision number
- Descriptive title
- Status
- Approval date
- Review due date

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

The signatures below recognize the above Quality Assurance Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

DOCUMENT CONTROL

Examination Documentation

1 PURPOSE

This document establishes the **AGENCY NAME's** examination documentation policy.

2 SCOPE

This policy applies to all documents generated during the examination process of the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

Examination documentation will be sufficient to ensure that a qualified individual could evaluate the examination performed and the resulting data, replicate it if required and reasonably achieve the conclusion expressed in the examination report.

The **AGENCY NAME** will maintain a case file under a unique Laboratory Record Number for each examination performed.

The examination file will contain any document generated in connection with examination of the item(s) submitted for examination.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

The signatures below recognize the above Quality Assurance Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

DOCUMENT CONTROL

Examination Notes

1 PURPOSE

This document establishes the **AGENCY NAME's** examination notes policy.

2 SCOPE

This policy applies to all documents generated during the examination process of the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

The **AGENCY NAME** will preserve all documents related to the submission, storage, examination and disposal of items submitted for examination or storage.

Examination notes shall provide sufficient information and documentation to support the conclusion rendered in the case report and allows another competent examiner to come to the same conclusion upon review.

Examination notes will document the use of appropriate controls and standards specified in the technical procedures to ensure the validity of examination results.

4.1 FORMAT

Examination note format is left to the discretion of the examiner.

Handwritten notes will be legible.

Handwritten notes or observations must be in ink, not pencil.

- Pencil (including color) may be appropriate for diagrams or making tracings.

Abbreviations are acceptable if they are readily comprehensible to a reviewer and a key is available.

Any items in the examination note packet less than 8 1/2" x 11" shall be sealed to an 8 1/2" x 11" paper to preclude loss.

- Each item will be affixed and sealed in such a manner as to allow for immediate detection of a missing item.

4.2 CONTENT

Examination notes will contain:

- Copy of the sample submission form.
- Copy of all relevant chain of custody information.
- Itemized description of the packaging received.
- Itemized description of the evidence received.
- Detailed description of the items examined.
- Where appropriate, diagrams and/or photographs should be used in addition to narratives to record observations.
- All charts, graphs, photos, photomicrographs, worksheets and instrumental data.
    - Photocopies may be suitable in some instances where the original information is not in a form that is conducive to storage in the case file.
- Copy of the examination documentation generated by another person, use to formulate the examiner's conclusion.
    - The results of subcontracted examinations shall be reported in writing or electronically and be included in the examination notes.

Each page of the examination documentation packet will contain:

- The record number.
- The examiners' signature or initials.
    - The examiner's signature or initials must be handwritten.
- The date generated.
- The page number, and total number of pages.
- Machine generated dates, Record Number, and pagination are acceptable.

Instrumental operating parameters should be noted when instrumental analysis is conducted.

- Batch logs may be used for this purpose.
- Batch logs may be more appropriately kept in a central location, but these logs need to be identified in the appropriate discipline's procedure manual.

4.3 COMPUTER USE

Each analytical section will establish procedures to address situations when computers or automated equipment are used for the acquisition, processing, recording, reporting, storage or retrieval of test data. The procedure will follow the process in the analytical section's data protection procedure.

- If computer software is developed by the user, its development is documented in detail and algorithms are validated.

- The laboratory's data protection procedure addresses the protection of the data to include, but not limited to data integrity, data confidentiality during entry, collection, storage, transmission and processing.
- Computers and automated equipment are maintained to ensure proper functioning and are provided with the environmental and operating conditions to maintain the integrity of test and data.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

The signatures below recognize the above Quality Assurance Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

DOCUMENT CONTROL

Examination Note Corrections

1 PURPOSE

This document establishes the **AGENCY NAME's** examination note correction policy.

2 SCOPE

This policy applies to all documents generated during the examination process of the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

Examination note information will not be obliterated or erased.

All corrections to case notes must be made by an initialed single strikeout, initialed by the corrector and dated if the correction was made different than the date on the page.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

The signatures below recognize the above Quality Assurance Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

DOCUMENT CONTROL

Examination Note Corrections

1 PURPOSE

This document establishes the **AGENCY NAME's** examination note dissemination policy.

2 SCOPE

This policy applies to all documents generated during the examination process of the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

Examination notes will accompany the case report through the review process.
Examination notes will not be disseminated with case report in the normal course of business.

- Examination notes will be considered work product whose content has been incorporated into the report.

Examination notes will be provided in response to a subpoena Duces Tatum from a court of record or in response to a Freedom of Information Request that has been submitted to the Agencies Public Information Officer.

- The requesting party will be assessed a reproduction charge of $x.00 per page.
- The fees for reproducing case notes will be deposited into the General Fund.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

The signatures below recognize the above Quality Assurance Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

DOCUMENT CONTROL

Examination Reports

1 PURPOSE

This document establishes the **AGENCY NAME's** examination report policy.

2 SCOPE

This policy applies to all reports generated during the examination process of the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

A minimum of one examination report will be generated for each sample submission.

Each analyst who conducts a complete or partial examination will generate a report summarizing their examination and the any subsequent conclusion.

When the test report contains results of tests performed by subcontractors, these results shall be clearly identified.

4.1 FORMAT

Each case report will be produced using the Official Examination Report Form.

4.2 CONTENT

The reporting analyst is the person responsible that the examination report is an accurate representation of the examination results.

The examination report will contain a summary of all relevant information from the case notes.

- The significance of associations will be communicated clearly and qualified properly.

Examination reports will contain the following information:

- Examining laboratory identity
- Date issues
- Laboratory file number
- Submitting agency file number
- Name of the individual requesting the examination(s)
- Examiner's name

- A list and description of the exhibit(s) submitted for examination
- Description of the examination(s) performed
- Results of the examination
- Chain of custody information

Reports of situations in which no examinations were conducted will contain the following information:

- Examining laboratory identity.
- Date issued.
- Laboratory file number.
- Submitting Agency File Number.
- Name of the individual requesting the examination(s).
- Examiner's name.
- A list and description of the exhibit(s) received.
- No examination statement for each exhibit not analyzed.
- Chain of custody information.
    - Chain of custody information is not required if the items did not leave the custody of the Property and Evidence Section.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

The signatures below recognize the above Quality Assurance Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

DOCUMENT CONTROL

Examination Report Review

1 PURPOSE

This document establishes the **AGENCY NAME's** examination report review policy.

2 SCOPE

This policy applies to all reports generated during the examination process of the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

All reports will receive a technical review and an administrative review prior to dissemination.

4.1 TECHNICAL REVIEW

A technical review will be conducted by an individual who has expertise in the discipline being examined and is authorized by the Director or the Quality Assurance Manager to perform technical review.

- The Quality Assurance Manager will maintain a list of the individuals who are qualified to perform technical reviews and their respective analytical disciplines.

The technical reviewer confirms that the examination notes provide sufficient information and documentation to support the conclusion rendered in the examination report and allows another competent examiner to come to the same conclusion upon review.

Calculations and data transfers shall be subject to appropriate checks in a systematic manner.

Details of technical reviews are as follows:

- **DNA:** reviews of analytical/examination results, including genotyping sheets and statistical analysis sheets, instrumental printouts, notes and drawings that aid in forming conclusions.
- **Serology:** reviews of examination results, including notes, photographs and drawings that aid in forming conclusions and assuring that second reads of all confirmatory tests and all amylase tests have been performed.
- **Drug:** reviews of analytical/examination results, including instrumental printouts, notes and drawings that aid in forming conclusions.

- **Identification:** Reviews of examination results, including photographs, notes and drawings that aid in forming conclusions and assuring that verifications of identifications have been performed.
- **Firearms:** Reviews of examination results, including photographs, notes and drawings that aid in forming conclusions and assuring that verifications of identifications have been performed.
- **Trace:** Reviews of analytical/examination results, including instrumental printouts, notes and drawings that aid in forming conclusions.
- **Digital Evidence:** Reviews of examination results, including photographs, notes and drawings that aid in forming conclusions.

The technical reviewer will place his initials under the examiner's name if he concurs with the examination results.

4.2 ADMINISTRATIVE REVIEW

An administrative review will be conducted by the examiner's supervisor, or his designee, after the technical review and before report dissemination.

- Administrative reviews may be performed by anyone who demonstrated familiarity with laboratory documentation and reporting policies.

The administrative and technical review may be performed concurrently if the supervisor is approved to conduct the technical review.

An administrative review will be conducted to ensure that the documentation was properly and completely filled out, there are no spelling or grammatical errors in the report, that the report is complete with the proper wording and the report is addressed to the proper agency and individual.

The administrative reviewer will place his initials under the examiner's name if the report meets report complies with the **AGENCY NAME** reporting requirements.

4.3 DISCREPANCIES

Technical and administrative corrections to case file or report will be conducted prior to report dissemination.

Discrepancies between the reviewer and analyst's assessments will discuss and resolved if possible.

- A qualified examiner or technical leader can be consulted if necessary.

If the issue cannot be resolved the issue will be referred to the Quality Assurance Manager.

The Quality Assurance Manager will make final decision in situations concerning philosophical differences between the analyst and the reviewer.

Corrective action reports will be filed and procedures implemented in situations concerning analytical procedures.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

The signatures below recognize the above Quality Assurance Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

DOCUMENT CONTROL

Examination Report Corrections

1 PURPOSE

This document establishes the **AGENCY NAME's** examination report correction policy.

2 SCOPE

This policy applies to all reports generated during the examination process of the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

Every effort will be made to ensure that reports are error free prior to distribution outside the laboratory.

A corrected report will be generated, reviewed and disseminated as soon an error has been brought to the attention of the **AGENCY NAME**.

The corrected report will have the same format as the original report, with the following additions:

- The word "AMMENDMENT" will be placed in bold type under the laboratory case file number.
- A single line strike out will be place through the portion of the report be deleted.
- The corrected portion of the report will be inserted using bold face type.

The corrected report will receive an administrative review prior to dissemination.

The amended report will be disseminated in accordance with the documents dissemination policy.

The original report will be maintained as a part of the examination file.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

The signatures below recognize the above Quality Assurance Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

DOCUMENT CONTROL

Examination Report Dissemination

1 PURPOSE

This document establishes the **AGENCY NAME's** examination report dissemination policy.

2 SCOPE

This policy applies to all reports generated during the examination process of the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

Examination reports will be disseminated in accordance with the **AGENCY NAME's** documents dissemination policy.

A copy of the original report will be maintained as a part of the case file.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

The signatures below recognize the above Quality Assurance Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

DOCUMENT CONTROL

Examination Report Storage

1 PURPOSE

This document establishes the **AGENCY NAME's** examination report storage policy.

2 SCOPE

This policy applies to all reports generated during the examination process of the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

Examination reports will be stored in accordance with the AGENCY NAME's document storage policy.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

The signatures below recognize the above Quality Assurance Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

DOCUMENT CONTROL

Technical Procedure Acceptance

1 PURPOSE

This document establishes the **AGENCY NAME's** technical procedure acceptance policy.

2 SCOPE

This policy applies to all technical procedures used by the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

The technical procedures used will be generally accepted in the field or supported by data gathered and recorded in a scientific manner.

5 PROCEDURE

The Technical Document Development Policy of the Quality Assurance Manual will be used as a guideline for the development and validation of technical procedures.

6 APPROVAL

The signatures below recognize the above Quality Assurance Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

CHEMICALS AND EQUIPEMNT

Weights and Measures

1 PURPOSE

This document establishes the **AGENCY NAME's** weights and measures policy.

2 SCOPE

This policy applies to all measurements performed by the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

The metric system is the standard unit of measurement of the **AGENCY NAME**.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

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Mary Doe, Quality Assurance Manager	Date

End of Document

CHEMICALS AND EQUIPMENT

Measuring Device Calibration

1 PURPOSE

This document establishes the **AGENCY NAME's** measuring device calibration policy.

2 SCOPE

This policy applies to all weighing and measuring devices used for the analysis of items submitted to the **AGENCY NAME** of examination.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

All devices used for weighing or measuring must be calibrated periodically for accuracy and the results recorded in a log.

- Calibrations shall be performed using certified reference materials and/or internal quality control using secondary reference materials.

Each analytical section will be developed and documented individual calibration procedures in the quality assurance section of their respective technical manuals.

This policy applies to, but is not limited to:

- balances
- pipettes
- calipers
- micrometers
- bullet measuring devices
- trigger pull devices

This policy does not apply to fixed volume/weight/etc. items purchased to conform to set standards (i.e. graduated cylinders, beakers, volumetric flasks, and fixed volume pipettes with bulb delivery systems).

Whenever practicable, all equipment requiring calibration shall be labeled, coded or otherwise identified to indicate the status of calibration, including the date when last calibrated and the date or expiration criteria when recalibration is due.

Each analytical section shall establish procedures to ensure that copies of correction factors are correctly updated, where calibrations give rise to a set of correction factors.

Each analytical section shall establish procedures to safeguard measuring devices from adjustments which would invalidate the test and/or calibration results.

Each analytical section shall establish traceability of its own measurement standards and measuring instruments to the SI by means of an unbroken chain of calibrations or comparisons linking them to relevant primary standards of the SI units of measurement. The link to SI units may be achieved by reference to national measurement standards. National measurement standards may be primary standards, which are primary realizations of the SI units or agreed representations of SI units based on fundamental physical constants, or they may be secondary standards which are standards calibrated by another national metrology institute.

When using external calibration services, traceability of measurement shall be assured by the use of calibration services from laboratories that can demonstrate competence, measurement capability and traceability. The calibration certificates issued by these laboratories shall contain the measurement results, including the measurement uncertainty and/or a statement of compliance with an identified metrological specification.

In situations in which calibrations cannot be strictly made in SI units the calibration shall provide confidence in measurements by establishing traceability to appropriate measurement standards such as:

- The use of certified reference materials provided by a competent supplier to give a reliable physical or chemical characterization of a material.
- The use of specified methods and/or consensus standards that are clearly described and agreed by all parties concerned.
- Participation in a suitable program of interlaboratory comparisons is required where possible.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

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CHEMICALS AND EQUIPMENT

Instrument Calibration

1 PURPOSE

This document establishes the **AGENCY NAME's** instrument calibration policy.

2 SCOPE

This policy applies to all instruments used for the analysis of samples submitted to the **AGENCY NAME** for examination.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

The AGENCY NAME will only utilize instruments and related software that is capable of achieving the accuracy required and shall comply with specifications relevant to the tests and/or calibrations concerned.

All instruments used for the examination samples must be calibrated for accuracy prior to being placed into service. The results shall be recorded in a log.

- Calibrations shall be performed using certified reference materials and/or internal quality control using secondary reference materials.
- All instruments used for the examination samples must be calibrated periodically for accuracy and the results recorded in a log.
- Calibrations shall be performed using certified reference materials and/or internal quality control using secondary reference materials.

All instruments used to perform examinations will be routine calibrated based upon the manufacturer's recommendations.

- More frequent calibrations are encouraged.

Each analytical section will develop and document individual calibration procedures in the quality assurance section of their respective technical manuals.

Instruments that have been shown to be defective or outside specified limits, shall be taken out of service until it can be shown that it is performing correctly.

- Out of service instruments shall be isolated or clearly labeled or marked as being out of service to prevent its use.

The analytical section shall examine the effect of the defect or departure from specified limits on previous tests and/or calibrations and shall institute the "Control of nonconforming work" procedure.

Each analytical section shall establish procedures to ensure that copies of correction factors are correctly updated, where calibrations give rise to a set of correction factors.

Each analytical section shall establish procedures to safeguard instruments from adjustments which would invalidate the test and/or calibration results.

Each analytical section shall establish traceability of its own measurement standards and measuring instruments to the SI by means of an unbroken chain of calibrations or comparisons linking them to relevant primary standards of the SI units of measurement. The link to SI units may be achieved by reference to national measurement standards. National measurement standards may be primary standards, which are primary realizations of the SI units or agreed representations of SI units based on fundamental physical constants, or they may be secondary standards which are standards calibrated by another national metrology institute.

When using external calibration services, traceability of measurement shall be assured by the use of calibration services from laboratories that can demonstrate competence, measurement capability and traceability. The calibration certificates issued by these laboratories shall contain the measurement results, including the measurement uncertainty and/or a statement of compliance with an identified metrological specification.

In situations in which calibrations cannot be strictly made in SI units the calibration shall provide confidence in measurements by establishing traceability to appropriate measurement standards such as:

- The use of certified reference materials provided by a competent supplier to give a reliable physical or chemical characterization of a material.
- The use of specified methods and/or consensus standards that are clearly described and agreed by all parties concerned.
- Participation in a suitable program of interlaboratory comparisons is required where possible.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

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CHEMICALS AND EQUIPMENT

Instrument Calibration Logs

1 PURPOSE

This document establishes the **AGENCY NAME's** instrument calibration log policy.

2 SCOPE

This policy applies to all instruments used for the analysis of samples submitted to the **AGENCY NAME** for examination.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

A calibration log will be maintained for each instrument utilized to perform examinations. The calibration log will be located within close proximity of its respective instrument.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

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CHEMICALS AND EQUIPMENT

Equipment Inventories

1 PURPOSE

This document establishes the **AGENCY NAME's** equipment inventory policy.

2 SCOPE

This policy applies to all equipment used for the analysis of samples submitted to the **AGENCY NAME** for examination.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

The AGENCY NAME shall be furnished with all items of sampling, measurement and test equipment required for the correct performance of examinations performed on samples submitted for examination.

The Quality Assurance Manager will establish and maintain a master inventory of the equipment utilized to perform examinations.

- Each item of equipment and its software used for testing and calibration and significant to the result shall, when practicable, be uniquely identified.

Each analytical section will establish and maintain an inventory of the equipment utilized to perform examinations.

- Each item of equipment and its software used for testing and calibration and significant to the result shall, when practicable, be uniquely identified.

The Quality Assurance Manager will annually update the master inventory of equipment utilized to perform examinations.

The Equipment Inventory Form will contain the following information:

- Instrument type
- Manufacturer
- Model
- Serial Number
- Date acquired
- Location

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

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End of Document

CHEMICALS AND EQUIPMENT

Equipment Maintenance Logs

1 PURPOSE

This document establishes the **AGENCY NAME's** equipment maintenance log policy.

2 SCOPE

This policy applies to all equipment used for the analysis of samples submitted to the **AGENCY NAME** for examination.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

All equipment used to perform examinations will be maintained based upon the manufacturer's recommendations.

All preventative and restorative maintenance procedures will be documented.

A maintenance log will be maintained for each instrument utilized to perform forensic examinations.

The maintenance log will be located within close proximity of its respective piece of equipment.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

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CHEMICALS AND EQUIPMENT

External Equipment Use

1 PURPOSE

This document establishes the **AGENCY NAME's** external equipment use policy.

2 SCOPE

This policy applies to all equipment used for the analysis of samples submitted to the **AGENCY NAME** for examination.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

The **AGENCY NAME** will only utilize validated technical procedures in which it possesses the instruments and equipment to adequately perform the procedure.

Personnel will only utilize equipment that is calibrated and maintained by the **AGENCY NAME**.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

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John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

CHEMICALS AND EQUIPMENT

Chemical Inventories

1 PURPOSE

This document establishes the **AGENCY NAME's** chemical inventory policy.

2 SCOPE

This policy applies to all chemicals used for the analysis of samples submitted to the **AGENCY NAME** for examination.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

The Quality Assurance Manager will maintain a master inventory of the chemicals utilized to perform examinations.

Each analytical section will maintain an inventory of the chemicals utilized to perform examinations.

The Quality Assurance Manager will maintain a master inventory of the chemicals utilized to perform examinations.

The Quality Assurance Manager will annually update the master inventory of chemicals utilized to perform examinations.

The chemical inventory form will contain the following information:

- Chemical name
- Manufacturer
- Lot Number
- Expiration Date
- Original Amount
- Location

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

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CHEMICALS AND EQUIPMENT

Expired Chemical Usage

1 PURPOSE

This document establishes the **AGENCY NAME's** expired chemical usage policy.

2 SCOPE

This policy applies to all chemicals used for the analysis of samples submitted to the **AGENCY NAME** for examination.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

Chemicals that have reached their expiration dated will not be used for the examination of samples submitted to the AGENCY NAME for examination.

All chemicals that have reached their expiration date will be removed from circulation and disposed of in accordance with the appropriate Health and Safety procedure.

The Quality Assurance Manager will annually evaluate the master inventory of chemicals to identify chemical who have reached their expiration date.

Each analytical section will annually evaluate their chemical inventory to identify chemicals who have reached their expiration date.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

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John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

CHEMICALS AND EQUIPMENT

External Chemical Use

1 PURPOSE

This document establishes the **AGENCY NAME's** external chemical use policy.

2 SCOPE

This policy applies to all chemicals used for the analysis of items submitted to the **AGENCY NAME** for examination.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

AGENCY NAME personnel will not utilize chemical to perform examinations that were not procured by the **AGENCY NAME** from a validated vendor.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

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John Smith, Laboratory Director	Date
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CHEMICALS AND EQUIPMENT

Chemical Procurement

1 PURPOSE

This document establishes the **AGENCY NAME's** chemical procurement policy.

2 SCOPE

This policy applies to all chemicals used for the analysis of items submitted to the **AGENCY NAME** for examination.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

The **AGENCY NAME** will only procure the amount of chemicals required to meet its immediate analytical needs.

- Employees will evaluate their respective laboratory operations to ensure that the appropriate quantities of chemicals are ordered.

The technical leader, or his designee, will review all chemical orders prior to submission to the vendor to ensure the chemical meets the specifications outlined in the test method.

The **AGENCY NAME** will only utilize vendors that provide chemicals from a traceable source.

- The Quality Assurance Manager shall maintain a list of approved vendors.

The Quality Assurance Manager will periodically review vendor performance by evaluating one or more of the following criteria:

- Availability of items from a traceable source
- Delivery performance
- Cost

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

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John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

CHEMICALS AND EQUIPMENT

Chemical Receipt

1 PURPOSE

This document establishes the **AGENCY NAME's** chemical receipt policy.

2 SCOPE

This policy applies to all chemicals used for the analysis of samples submitted to the **AGENCY NAME** for examination.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

Employees who purchase or receive shipments of chemicals shall do so in such a manner as to ensure their integrity.

Employees who purchase or receive shipments of chemicals must be trained in the safe handling of hazardous substances.

5 PROCEDURE

5.1 AGENCY RECEIPT

Employees who perform chemical receiving and supply function will:

- Compare the type and quantity of chemicals received to the procurement order.
  - Chemicals that are incorrectly ordered should be returned to the manufacturer.
- Will not accept chemical container(s) or compressed gas cylinder(s) without an identifying label.
- File a copy of the chemical's MSDS in the master MSDS file, if one does not already exist.
- Will enter the following information into the master chemical inventory form.
  - Chemical Name.
  - Manufacturer.
  - Lot Number.
  - Original Amount.
  - Expiration Date.
  - Storage Location.
- Forward the chemicals and the associated MSDSs to the ordering unit or employees.
  - If a chemical is received without an MSDS, the unit ordering the chemical should attempt to obtain a copy of the MSDS.
    - MSDSs may be obtained upon request from the manufacturer.

5.2 UNIT RECEIPT

Units receiving chemicals shall:

- File a copy of the chemical's MSDS in the Unit's MSDS file, if one does not already exist, and ensure that they are readily accessible to employees.
- Will enter the following information into the Unit's chemical inventory:
  - Chemical Name.
  - Manufacturer.
  - Lot Number.
  - Original Amount.
  - Expiration Date.
  - Storage Location.

6 APPROVAL

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John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

CHEMICALS AND EQUIPMENT

Reference Standards and Materials Inventory

1 PURPOSE

This document establishes the **AGENCY NAME's** reference standards and materials inventory policy.

2 SCOPE

This policy applies to all reference standards and materials used by the **AGENCY NAME.**

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

The Quality Assurance Manager will maintain a master list of all reference standards and all reference materials.

Each analytical section will maintain a list of all reference standards and all reference materials used in their section.

Each analytical section shall establish procedures for safe handling, transport, storage and use of reference standards and reference materials in order to prevent contamination or deterioration and in order to protect their integrity.

The Quality Assurance Manager will annually update the master list reference standards and reference materials.

The reference material and reference standard list will contain the following information.

- Reference Material/Standard Name
- Manufacturer
- Lot #
- Serial # (Standards)
- Expiration Date (Materials)
- Original Amount (If applicable)
- Location

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

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John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

CHEMICALS AND EQUIPMENT

Reference Standards and Materials Validation

1 PURPOSE

This document establishes the **AGENCY NAME's** reference standards and materials validation policy.

2 SCOPE

This policy applies to all reference standards and materials used by the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

Each analytical section shall obtain the reference standards and materials necessary to ensure the accuracy and precision of the examinations they perform.

All reference standards and materials shall be validated prior to being placed into service.

- Failure to meet the acceptance criteria will result in the reference material being taken out of service.

Primary reference materials will be verified by the appropriate instrumentation/method prior to use and subsequently every other year.

- Verification can include comparing to literature or instrument library spectra, chromatograms or other reliable sources, or, in the case of tablets obtained from a pharmacist, identification based on manufacturer markings along with any other analytical data from traceable sources that can be obtained.
- Laboratory created materials obtained from known sources do not need verification, but will be replaced with new samples as the materials lose their QC indicating values.
- Reference materials which are run on an instrument where the data is stored in that instrument's library will not need to be re-run unless the parameters of the instrument are changed such that it will affect the results for comparisons being made.

Secondary reference materials which are used for daily quality control work will be taken out of use and replaced if it loses its quality control indicating value.

The Quality Assurance Manager will maintain a master list of the validation of all reference standards and all reference materials.

Each analytical section will maintain a list of the validation of all reference standards and all reference materials used in their section.

The Quality Assurance Manager will annually update the master list of the validation of all reference standards and reference materials.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

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Mary Doe, Quality Assurance Manager	Date

End of Document

CHEMICALS AND EQUIPMENT

Reagent Preparation Logs

1 PURPOSE

This document establishes the **AGENCY NAME's** reagent preparation log policy.

2 SCOPE

This policy applies to all chemical reagents used for the analysis of samples submitted to the **AGENCY NAME** for examination.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

Reagent preparation logs will be maintained for all reagents prepared and used to perform examinations.

The reagent preparation log will contain the following information:

- Reagent Name
- Chemicals used
  - Information to include the manufacturer and lot number
- Method of preparation
- Quality control test performed
- The date prepared
- The initials of the individual who prepared the reagent
- Batch number of the reagent

Each analytical section will maintain a master file of all reagent preparation logs.

Aliquots of bulk reagents will be labeled with:

- The reagent name
- Batch number
- Date transferred from the bulk solution

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

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End of Document

CHEMICALS AND EQUIPMENT

Equipment Procurement

1 PURPOSE

This document establishes the **AGENCY NAME's** equipment procurement policy.

2 SCOPE

This policy applies to all equipment used for the analysis of samples submitted to the **AGENCY NAME** for examination.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

The **AGENCY NAME** will only procure equipment that has been validated for the type of examination that will be the focus its use.

The **AGENCY NAME** will only utilize vetted vendors to procure equipment used for examining samples.

The Quality Assurance Manager will periodically review vendor performance by evaluating one or more of the following criteria:

- Availability of items from a traceable source
- Reliability and performance of equipment
- Delivery performance
- Cost

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

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Mary Doe, Quality Assurance Manager	Date

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CHEMICALS AND EQUIPMENT

Equipment Receipt

1 PURPOSE

This document establishes the **AGENCY NAME's** equipment receipt policy.

2 SCOPE

This policy applies to all equipment used for the analysis of samples submitted to the **AGENCY NAME** for examination.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

Upon receipt, all equipment will be installed using manufacturer's specifications.

All equipment procured by the **AGENCY NAME** will be validated prior to being utilized for testing samples submitted for examination.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

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CHEMICALS AND EQUIPMENT

Reference Standard and Material Procurement

1 PURPOSE

This document establishes the **AGENCY NAME's** reference standard and material procurement policy.

2 SCOPE

This policy applies to all reference standards and materials used for the analysis of items submitted to the **AGENCY NAME** for examination.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

The **AGENCY NAME** will only procure the amount of reference standards and materials required to meet its immediate analytical needs.

- Employees will evaluate their respective laboratory operations to ensure that the appropriate quantities are ordered.

The technical leader, or his designee, will review all reference standard and material orders prior to submission to the vendor to ensure they meet the specifications outlined in the test method.

The **AGENCY NAME** will only utilize vendors that provide reference standards and materials from a traceable source.

- The Quality Assurance Manager shall maintain a list of approved vendors.

The Quality Assurance Manager will periodically review vendor performance by evaluating one or more of the following criteria:

- Availability of items from a traceable source
- Delivery performance
- Cost

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

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CHEMICALS AND EQUIPMENT

Reference Standard and Material Receipt

1 PURPOSE

This document establishes the **AGENCY NAME's** reference standard and material receipt policy.

2 SCOPE

This policy applies to all reference standards and materials used for the analysis of samples submitted to the **AGENCY NAME** for examination.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

Employees who purchase or receive shipments of reference standards and materials shall do so in such a manner as to ensure their integrity.

Employees who purchase or receive shipments of reference standards and materials must be trained in the safe handling of hazardous substances.

5 PROCEDURE

5.1 AGENCY RECEIPT

Employees who perform reference standards and materials receiving and supply function will:

- Compare the type and quantity of reference standards and materials received to the procurement order.
  - Reference standards and materials that are incorrectly ordered should be returned to the manufacturer.
- Will not accept container(s) or compressed gas cylinder(s) without an identifying label.
- File a copy of the reference standards and material's MSDS in the master MSDS file, if one does not already exist.
- Will enter the following information into the master reference standards and materials inventory form.
  - Reference standards and material name.
  - Manufacturer.
  - Lot Number.
  - Original amount.

- Expiration Date.
- Storage location.

- Forward the reference standard or material and the associated MSDSs to the ordering unit or employees.
  - If a reference standard or material is received without an MSDS, the unit ordering the chemical should attempt to obtain a copy of the MSDS.
  - MSDSs may be obtained upon request from the manufacturer.

5.2 UNIT RECEIPT

Units receiving chemicals shall:

- File a copy of the MSDS in the Unit's MSDS file, if one does not already exist, and ensure that they are readily accessible to employees.
- Will enter the following information into the Unit's reference standards and materials inventory:
  - Reference standard or material name.
  - Manufacturer.
  - Lot Number.
  - Original amount.
  - Expiration Date.
  - Storage location.

6 APPROVAL

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John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

CHEMICALS AND EQUIPMENT

Equipment Use

1 PURPOSE

This document establishes the **AGENCY NAME's** equipment use policy.

2 SCOPE

This policy applies to all equipment used for the analysis of samples submitted to the **AGENCY NAME** for examination.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

Only authorized personnel will operate equipment used to examine samples submitted to the AGENCY NAME for examination.

All equipment used for the examination samples must be calibrated periodically for accuracy and the results recorded in a log.

- Calibrations shall be performed using certified reference materials and/or internal quality control using secondary reference materials.

Each analytical section shall maintain up-to-date instructions on the use and maintenance of equipment used to the examination of samples submitted to the AGENCY NAME for examination.

- The manual will be located in close proximity to the piece of equipment for use by the appropriate laboratory personnel.
- The manual shall including any relevant manuals provided by the manufacturer.

Each analytical section shall establish procedures for safe handling, transport, storage, use and planned maintenance of measuring equipment to ensure proper functioning and in order to prevent contamination or deterioration.

- These procedures shall be incorporated into the analytical sections technical methods manual.

Equipment that has been subjected to overloading or mishandling, gives suspect results, has been shown to be defective or outside specified limits, shall be taken out of service until it can be shown that it is performing correctly.

- Out of service equipment shall be isolated or clearly labeled or marked as being out of service to prevent its use.

The analytical section shall examine the effect of the defect or departure from specified limits on previous tests and/or calibrations and shall institute the "Control of nonconforming work" procedure.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

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Mary Doe, Quality Assurance Manager	Date

End of Document

PERSONNEL

Minimum Qualifications

1 PURPOSE

This document establishes the **AGENCY NAME's** employee minimum qualifications policy.

2 SCOPE

This policy applies to all personnel employed by the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

Employees will posses the minimum qualifications outlined in the Administrative Policy and Procedures Manual for their respective job title.

Analytical sections may establish additional minimum requirements for examiners assigned to their section.

- Qualifications beyond those established in the Administrative Policy and Procedures Manual will be documented in the section's Technical Methods Manual.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

The signatures below recognize the above Quality Assurance Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

PERSONNEL

Training

1 PURPOSE

This document establishes the **AGENCY NAME's** employee training policy.

2 SCOPE

This policy applies to all personnel employed by the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

All employees will be provided training which will allow them to competently perform their assigned duties.

4.1 NEW EMPLOYEE

All new employees will receive basic training and orientation concerning the policies and procedures associated with operation of the **AGENCY NAME**.

New employee training will include, but not be limited to:

- Administrative policy and procedure orientation
- Property and evidence section orientation
- Health and safety orientation
- Quality assurance program orientation

4.2 TECHNICAL TRAINING

All employees will be provided basic technical training in their respective job to allow them to competently perform their assigned duties.

The content and duration of the technical training an employee receives is outlined in the Technical Methods Manual of the section the employee is assigned.

4.3 IN-SERVICE TRAINING

All employees will be provided in-service training opportunities that will allow them to enhance their technical skills.

The content and duration of the in-service training an employee receives may be outlined in the Technical Methods Manual of the section the employee is assigned.

In-service training may be provided through one or more of the following venues:

- In-house training program
- Professional Association
- College/University
- Vendor
- Law Enforcement Agency

All employees will be provided an annual review of the Health and Safety Manual.

4.4 REMEDIAL TRAINING

Remedial training will be provided to employees whose performance has been identified to be below standard.

Below standard performance can be identified through one or more of the following methods:

- Below standard performance in written and practical training exercises
- Administrative or technical review of reports and case files
- Proficiency test deficiency report
- Corrective Action Report
- Testimony monitoring
- Supervisory evaluation
- Peer review

Every effort will be made to remediate an employee's substandard performance to an acceptable level.

An employee with substandard performance may be transferred to a position that is better suited to their knowledge skills and abilities, after three (3) months of documented unsuccessful remediation training.

4.5 DOCUMENTATION

The Quality Assurance Manager will create and maintain a training file for each employee.

All employees will complete a Training Record Critique form and submit it to the Quality Assurance Manager at the completion of all training sessions.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

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PERSONNEL

Proficiency Test Evaluation

1 PURPOSE

This document establishes the **AGENCY NAME's** proficiency test evaluation policy.

2 SCOPE

This policy applies to all proficiency tests administered by the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

The Quality Assurance Manager, or his designee, will compare the laboratory results of the analyst to the target value supplied by the test provider.

Satisfactory results meet the following minimum criteria:

- All reported results are correct.
- All results reported as inconclusive or uninterruptible are consistent with written laboratory guidelines.
- All discrepancies, errors and subsequent corrective actions must be properly documented and carried out.

Unsatisfactory results occur when any of the above criteria are not met and necessitate the submission of an incident/corrective action report.

A Proficiency Test Discrepancy form will be completed in conjunction with the Proficiency Test Report form if remedial action is indicated as a result of review of the analyst's report and notes. If a discrepancy report is generated:

- The Quality Assurance Manager will have a conference with the analyst, technical leader and the analyst's supervisor to discuss the actions required to address the discrepancy.
- The analyst will not automatically assume the responsibility for the discrepancy.

If the discrepancy is a methodology issue, the method will be adjusted as required before case work is resumed.

If the discrepancy is an instrumental issue, the instrument will be serviced or adjusted as required before case work is resumed.

If the discrepancy is an analyst issue, remedial training and a follow up proficiency test will be required before the analyst will be allowed to resume case work.

Discrepancy Classes:

- **Class I:** The nature and cause of the discrepancy raises immediate concern regarding the quality of work.
- **Class II:** The discrepancy is due to a problem which may affect the quality of the work, but is not persistent or serious enough to cause immediate concern for the over-all quality of the work product.
- **Class III:** The discrepancy is determined to have only minimal effect or significance, be unlikely to reoccur, is not systematic, and does not significantly affect the fundamental reliability of the work product.

The Quality Assurance Manager will prepare a Corrective Action Report to address any issues that arise from the discrepancy report conference.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

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PERSONNEL

Proficiency Test Documentation

1 PURPOSE

This document establishes the **AGENCY NAME's** proficiency test documentation policy.

2 SCOPE

This policy applies to all proficiency tests administered by the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

4.1 PROFICIENCY TEST DATABASE

The Quality Assurance Manager will create and maintain a database of all proficiency tests administered.

The database information will include, but not be limited to:

- Test Number
- Discipline
- Examination Type
- Source
- Examiner's Name
- Date Assigned
- Date Returned
- Date Reviewed
- Results

The proficiency test database will be maintained for the life of the AGENCY NAME.

4.2 EMPLOYEE PROFICIENCY TEST FILES

The Quality Assurance Manager will establish and maintain a proficiency test file for every employee with examination responsibilities.

Employee proficiency test files will include:

- The Proficiency Test Report form for every proficiency test taken

- Any Proficiency Test Discrepancy forms
- Copies of any Corrective Action Reports associated with a proficiency discrepancy

Employee proficiency test files will be maintained for a period of 5 years after the employee terminates employment.

4.3 PROFICIENCY TEST CASE FILES

The Quality Assurance Manager will establish and maintain proficiency test case file repository.

All proficiency test reports and case files will be stored in the proficiency test case file repository.

Proficiency test case files will be filed by sequentially by proficiency test number.

4.4 DISSEMINATION

A person's proficiency test report for the specific examination type and dates will be the only document provided in response to a request for proficiency test record.

- Proficiency test reports for unrelated examination types will be considered irrelevant and will not provide.
- Proficiency test case files will be available if subsequent subpoenas request they be disclosed.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

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PERSONNEL

Testimony Review

1 PURPOSE

This document establishes the **AGENCY NAME's** testimony review policy.

2 SCOPE

This policy applies to all personnel with testimony responsibilities employed by the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

All employees with testimony responsibilities will be reviewed annually.

- If the employee does not testify within a calendar year this will be documented, and a review will be conducted at the next opportunity.

5 PROCEDURE

The employee's supervisor, or designee, is responsible for conducting the annual testimony review.

- If the appropriate personnel are not available to review testimony in person, transcripts may be reviewed or the attorneys involved may either be interviewed or a questionnaire can be sent to them.

Testimony reviews can be performed during:

- Court testimony,
- Depositions; or
- Pre-trial/admissibility hearings

A Testimony Review Form (QAM-F018) will be used to document the employee's testimony review.

5.1 RATING

Meets Expectation: The employee has met the requirements outlined below satisfactorily.
Above Expectations: The employee has exceeded the requirements outlined below.

- The reviewer shall explain in the "comments/suggestions for improvement" section what additional, unexpected factors the criminalist contributed to their testimony.

Below Expectations: The employee has not met the requirements outlined below satisfactorily

- The reviewer shall explain in the "comments/suggestions for improvement" section what action the criminalist shall be required to take to improve their testimony and how this action relates to the requirements as listed below.
- Following this, a moot court will be held for the analyst, if necessary. A second review will be conducted as soon as possible.

5.2 RATING CRITERIA

- Personal Appearance.
  - Dressed in a professional manner.
  - Avoid wearing distracting jewelry, pins or other large paraphernalia.
- Voice.
  - Volume should be loud enough for jury, etc. to hear but not so loud as to be disturbing.
  - Tone should be neutral and friendly without being condescending or defensive.
  - Explanations should be fluid, unhurried and not be halted.
- Eye Contact.
  - Make eye contact with the jury (or in the case of non-jury trials the attorneys and judge), making sure to face them and direct all answers to them.
- Posture.
  - When on the stand posture should be erect with no slouching.
  - Sit comfortably at the stand, but avoid unnecessary movement such as swinging of feet or spinning of chairs.
- Courtroom Procedure Etiquette.
  - Answers should be polite and non-confrontational.
  - Ask permission from the presiding judge prior to reviewing any documentation or materials that were brought to the stand.
  - Swearing in should be done while stationary, not walking to the stand and by answering "I will" or "I do" versus "yes".
- Vocabulary.
  - When explaining examinations and procedures, use layman's terms.
  - Use proper word enunciation.

    - Avoid using slang, jargon or clichés.
- Confidence/Control.
    - Respond to all questions confidently.
    - Maintain composure under pressure from the defense.
- Responsiveness to Questions.
    - Answer only the question that is asked.
    - Avoid feeling the need to continue explaining when the attorney remains silent.
- Preparation and Organization.
    - Answers to qualifying questions should be delivered smoothly.
    - Case files and notes should be reviewed prior to testimony so that they are organized in a manner that is easy to refer to and they only need to be referred to for details.
- Use of Visual Demonstrations/Evidence Handling.
    - When applicable, try to use visual aids during jury trials to clarify examination procedures or show results.
    - All proper chain of custody and evidence handling procedures should be followed whenever possible.
- Cross Examination Demeanor.
    - Show no bias towards defense or prosecution by reacting to questions from either side in an equally courteous and professional manner, thereby providing fair and impartial testimony.
- Explanation of General Scientific Principles.
    - Be able to deliver explanations of the scientific background regarding their examinations smoothly.
- Explanation of Procedures Followed in the Case.
    - Be familiar with all procedures in place that were used for examinations including protocols, evidence handling and QA procedures.
    - There should be a smooth delivery of descriptions of all procedures used.
- Explanation of Results in the Case.
    - Be familiar with the examinations performed prior to testimony by reviewing all examination notes and documentation so that referring to notes excessively during testimony is not necessary.
    - Be familiar with victim(s) and suspect(s) names and how they are properly pronounced.
- Technical Accuracy.
    - Answers must reflect actual practice, policy and procedure.
    - If an answer to a question is not known, this should be simply stated instead of guessing or supplying answers that may not be appropriate.
    - The reviewer goes over the results with the analyst that testified to provide feedback on the testimony.
    - Both the reviewer and analyst will then sign the review to indicate that they have gone over it together.
    - If the analyst being reviewed disagrees with comments made, they can make note of this on the review, prior to signing it.

6 APPROVAL

The signatures below recognize the above Quality Assurance Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

PERSONNEL

Testimony Review Documentation

1 PURPOSE

This document establishes the AGENCY NAME's testimony review documentation policy.

2 SCOPE

This policy applies to all personnel with testimony responsibilities employed by the AGENCY NAME.

3 DEFINITIONS

The current revision of document APP-P001 will be used as a guide to define terms.

4 POLICY

The Quality Assurance Manager will establish and maintain a record of the review of the performance of employees with testimony responsibilities.

A Testimony Review Form will be utilized to document an employee's testimony performance.

5 PROCEDURE

The supervisor, or his designee, will discuss the Testimony Review Form results with the employee, shortly after the conclusion of the testimony review.

The employee and the supervisor, or his designee, will sign the bottom of the Testimony Review Form at the conclusion of the discussion and forward the document to the Quality Assurance Manager.

The Quality Assurance Manager will establish and maintain a database to ensure all employees with testimony responsibilities receive their annual review.

Upon receipt of a signed Testimony Review Form the Quality Assurance Manager will:

- Update the Testimony Review Database.
- Sign the Testimony Review Form.
- Place the Testimony Review Form in the Employee's personnel file.

6 APPROVAL

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End of Document

PERSONNEL

Professional Association Affiliation

1 PURPOSE

This document establishes the **AGENCY NAME's** professional association affiliation policy.

2 SCOPE

This policy applies to all personnel employed by the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

The **AGENCY NAME** encourages employees to become active members in job related professional associations.

The **AGENCY NAME** will pay an employee's annual dues for one or more job related professional associations, when funding is available.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

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End of Document

PERSONNEL

Professional Meeting Attendance

1 PURPOSE

This document establishes the **AGENCY NAME's** professional meeting attendance policy.

2 SCOPE

This policy applies to all personnel employed by the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

The **AGENCY NAME** encourages employees to attend the meetings of related professional associations.

The **AGENCY NAME** will pay an employee's meeting fees, travel expenses, or both to job related professional association meetings, when funding is available.

- Funding preference will be given to employees who:
  - Officers of the professional association
  - Presenting scientific or professional research
  - Coordinating a training workshop
  - Attending a workshop or seminar that is unavailable elsewhere

The **AGENCY NAME** may authorize employees to attend professional meetings as part of their work duties, if the employee will pay their own meeting related expenses.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

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PERSONNEL

Professional Training

1 PURPOSE

This document establishes the **AGENCY NAME's** professional training policy.

2 SCOPE

This policy applies to all personnel employed by the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

The **AGENCY NAME** encourages employees to attend job related professional training sessions.

The **AGENCY NAME** will pay an employee's fees, travel expenses, or both to job related professional training sessions, when funding is available.

The **AGENCY NAME** may authorize employees to attend job related professional training sessions as part of their work duties, if the employee will pay their own related expenses.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

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End of Document

PERSONNEL

Continuing Education

1 PURPOSE

This document establishes the **AGENCY NAME's** continuing education policy.

2 SCOPE

This policy applies to all personnel employed by the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

The **AGENCY NAME** encourages employees to attend job related continuing education classes.

The **AGENCY NAME** WIll pay an employee's fees, travel expenses, or both to job related continuing education classes, when funding is available.

The **AGENCY NAME** may authorize employees to attend job related continuing education classes as part of their work duties, if the employee will pay their own related expenses.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

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End of Document

PERSONNEL

Professional Certifications

1 PURPOSE

This document establishes the **AGENCY NAME's** professional certification policy.

2 SCOPE

This policy applies to all personnel employed by the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

The **AGENCY NAME** encourages employees to obtain job related professional certifications.

The **AGENCY NAME** will pay an employee's fees, travel expenses, or both to obtain job related professional certifications, when funding is available.

The **AGENCY NAME** may authorize employees to attend job related professional certifications as part of their work duties, if the employee will pay their own related expenses.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

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End of Document

PERSONNEL

Technical Leaders

1 PURPOSE

This document establishes the **AGENCY NAME's** technical leader policy.

2 SCOPE

This policy applies to all factions of the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

The Director will appoint Technical Leaders to provide technical oversight and leadership in each forensic discipline.

Technical Leaders will report directly to the Quality Assurance Manager.

Technical leaders will provide the Quality Assurance Manager technical guidance in monitoring the quality of analysis within their disciplines and make recommendations for quality improvement.

Technical leaders shall have the authority and resources needed to carry out their duties and to identify the occurrence of departures from the quality system or from the procedures for performing tests and/or calibrations, and to initiate actions to prevent or minimize such departures.

Each Technical Leader will act as the chairman of the Peer Group of analysts of the analytical discipline he represents.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

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End of Document

PERSONNEL

Peer Groups

1 PURPOSE

This document establishes the **AGENCY NAME's** peer group policy.

2 SCOPE

This policy applies to all factions of the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

A Peer Group will be established for each analytical discipline.

Each peer group will be comprised of analyst with examination responsibilities in the respective discipline.

Technical Leaders will serve as the chair the group.

Managers will not have a seat on an active peer group.

Each Peer Group will convene at least once a year.

- The Technical Leader or Quality Assurance Manager may convene peer group meetings as required.

4.1 DISCIPLINES

Peer groups may be established for the following forensic disciplines:

- Crime Scene/Primary Examiner
- Drug Analysis / Clandestine Labs
- DNA
- Firearms/Tool marks
- Forensic Biology
- Latent Prints
- Questioned Documents
- Toxicology/Breath Alcohol Testing
- Trace Evidence
- Digital Imaging
- LIMS

- Safety
- Evidence Technician (ET)
- Forensic Laboratory Support Specialist (FLSS)
- Other as identified by the Quality Assurance Manager

4.2 DUTIES

The Peer Group's duties include:

- Ensure uniform methodology and procedures in all laboratories within the discipline.
- Ensure standard training protocols for new employees, and re-training of existing employees as needed, within the discipline.
- Ensure that procedures and training manuals for the discipline accurately reflect established standards and comply with accreditation requirements.
- Assure quality control within the discipline.
- Ensure proficiency testing for the discipline is administered within established guidelines.
- Responsible for the evaluation and implementation of new methodologies and equipment.
- Enhance continuous improvement in the discipline through promoting member participation in training opportunities, professional organizations, research and publication and by recognition of achievements.
- Develop and update effective tactical plans to address program direction, staffing, training, equipment, and quality assurance needs within the discipline.
- Ensure methodologies are in compliance with health and safety requirements.
- Resolve technical issues concerning the discipline as needed.
- Ensure effective communication with all members of the discipline, and with management.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

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Mary Doe, Quality Assurance Manager	Date

END OF DOCUMENT

PERSONNEL

Conflict of Interest

1 PURPOSE

This document establishes the **AGENCY NAME's** conflict of interest policy.

2 SCOPE

This policy applies to all employees of the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

Employees with not engage in activities that will produce any undue internal and external commercial, financial and other pressures and influences that may adversely affect the quality of their work.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

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PERSONNEL

Proficiency Test Program

1 PURPOSE

This document establishes the **AGENCY NAME's** proficiency test program policy.

2 SCOPE

This policy applies to all employees with examination responsibilities.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

The Quality Assurance Manager will establish and administer a proficiency testing program to ensure the aptitude of examiners to perform the examination they are assigned.

All examiners will demonstrate an understanding of the theoretical and practical knowledge of the instruments, methods and procedures used prior to being assigned unsupervised examination duties.

All new employees must successfully complete one or more competency tests in each area they have examination they are responsible for, prior to being assigned unsupervised examination duties.

All employees with examination responsibilities will annually be given one or more proficiency tests in each area of examination they are responsible for.

Proficiency tests will be procured from test providers that are approved by the relevant accrediting body.

- An external provider may be utilized if an examination area does not have a test provider approved by the accrediting body.

Re-examination or blind techniques may be incorporated into the proficiency testing program.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

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PERSONNEL

Contract labor

1 PURPOSE

This document establishes the **AGENCY NAME's** contract labor policy.

2 SCOPE

This policy applies to all employees with examination responsibilities.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

The Director may authorize the use of contract labor to perform testing and calibration activities to augment staffing levels.

Contract labor conducting examination and calibration activities will:

- Be subject to the same education and minimum qualification requirements that a permanent employee performing the same function.
- Comply with the conditions of proficiency testing program prior to being assigned unsupervised examination duties.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

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PERSONNEL

Quality Roles of Personnel

1 PURPOSE

This document establishes the **AGENCY NAME's** contract labor policy.

2 SCOPE

This policy applies to all employees with examination responsibilities.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

General roles and responsibilities for AGENCY NAME personnel are summarized as follows:

4.1 QUALITY MANAGER

- Ensures that the management system is established, implemented, and maintained in conformance with the requirements of ISO/IEC 17025.
- Advocates and coordinates quality improvements to the management system.

4.2 TECHNICAL MANAGERS

- Oversee the quality of technical functions.
- Ensure compliance with the requirements of ISO/IEC 17025.
- Ensure management system procedures, applicable standards, specifications, and regulations are followed.
- Ensure that qualified, skilled, and trained personnel and other resources are available.
- Ensure that products and services satisfy customer requirements.

4.3 EXAMINERS

- Ensure the quality of their work.
- Operate in conformance with the requirements of the management system.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

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SAMPLE CONTROL

Sample Submission

1 PURPOSE

This document establishes the **AGENCY NAME's** sample submission policy.

2 SCOPE

This policy applies to all samples submitted the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

All samples submitted for examination will follow the guidelines established in Administrative Policies and Procedures, and Sample Control Manual.

4.1 EVIDENCE LOG-IN

All samples will be logged into the Sample Control Section prior to the performance of any examination.

All samples will be logged into the Sample Control Section using the guidelines outlined in Administrative Policies and Procedures and Property and Evidence Manual.

4.2 CASE NUMBERING

Each case submitted for examination will be assigned a unique case record number (RN).

Case record numbers will be assigned using the guidelines established in Administrative Policies and Procedures.

4.3 SAMPLE PACKAGING

The Sample Control Section will not accept evidence that is improperly packaged.

- This policy applies to the initial intake of samples and the return of samples after laboratory examination.

Property and Evidence Section personnel may assist individuals properly package evidence prior to submission using guideline established in Property and Evidence Manual.

4.4 MARKING AND SEALING

All samples submitted for examination will be in properly sealed and marked containers.

- This policy applies to the initial intake of samples and the return of samples after laboratory examination.

Package marking and sealing guidelines are established in Property and Evidence Manual.

4.5 SPECIAL HANDLING PROCEDURES

Samples that require special handling will be handled using the guidelines established in Administrative Policies and Procedures and Property and Evidence Manual.

5 PROCEDURE

There are currently no quality assurance manual procedures that directly affect the implementation of this policy.

6 APPROVAL

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End of Document

SAMPLE CONTROL

Sample Transfers

1 PURPOSE

This document establishes the **AGENCY NAME's** sample transfer policy.

2 SCOPE

This policy applies to all sample transfers of the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

All sample transfers will be documented using the policies and procedures outlined in the Sample Control Manual.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

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End of Document

SAMPLE CONTROL

Loss, Cross Transfer, and Contamination

1 PURPOSE

This document establishes the **AGENCY NAME's** loss, cross transfer and contamination policy.

2 SCOPE

This policy applies to all samples submitted the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

There shall be effective separation between neighboring areas in which there are incompatible activities to prevent cross-contamination.

Employees will make every effort to avoid the loss, cross transfer or contamination of samples submitted for examination.

Employees will immediately notify their supervisor in the event of loss, cross transfer or contamination of evidence.

The supervisor will initiate a Corrective Action Report to document the circumstances surrounding the loss, cross transfer or contamination of samples and its ultimate resolution.

- The original Corrective Action Report will be placed into the case file.
- A copy of the Corrective Action Report will be filed with the Quality Assurance Manager.

5 PROCEDURE

- A Corrective Action Report will be generated.
  - The Corrective Action Report will:
    - Describe the issue or risk.
    - Describe the ideal resolution.
    - Present it to a supervisor or manager.
- The supervisor or manager will review and sign the form and forwards it to the Quality Assurance Manager's office.
  - The Quality Assurance Manager is responsible for ensuring all Corrective Action Reports are resolved in a timely manner.
  - The Quality Assurance Manager's office will establish and maintain a file for each Corrective Action Report initiated.

- The Quality Assurance Manager's office will assign a unique file number to each Corrective Action Report.
- The Quality Assurance Manager's office will create and maintain a Corrective Action Report Log to monitor the resolution status each Corrective Action Report.

- The Quality Assurance Manager will assign and individual or group to investigate the merits of the corrective and propose a resolution.
- The investigator or investigative group will issue a report containing the following sections:
  - Background.
  - Applicable quality assurance policies and procedures.
  - Interviews and Investigative.
  - Proposed Resolution.
- The Quality Assurance Manager will state a resolution to the corrective action based upon:
  - The investigation report.
  - Personal interview with the parties involved.
  - The parties involved accept the Quality Assurance Manager decision.

6 APPROVAL

The signatures below recognize the above Quality Assurance Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

SAMPLE CONTROL

Item/Sub-Item Creation

1 PURPOSE

This document establishes the **AGENCY NAME's** creation of items or sub-items policy.

2 SCOPE

This policy applies to all samples submitted the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

The creation of items or sub-items will be documented in the examiner's examination notes.

5 PROCEDURE

Each new item or sub-item will be assigned a unique identification number.

- The number should correspond with the item number of the original item, but must be modified in such a way as to be unique to the new item.

The Item Creation and Transfer Record will be used to document the creation of items and sub-items that are not consumed in analysis.

The new items and sub-items will be packaged and labeled properly in accordance with Sample Control Manual guidelines.

6 APPROVAL

The signatures below recognize the above Quality Assurance Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

SAMPLE CONTROL

Intra Laboratory Transfer Documentation

1 PURPOSE

This document establishes the **AGENCY NAME's** policy concerning intra laboratory sample transfer.

2 SCOPE

This policy applies to all samples submitted the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

The intra laboratory transfer of samples between examiners for examination purposes will be documented with the use of an Item Creation/Transfer Record.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

The signatures below recognize the above Quality Assurance Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

SAMPLE CONTROL

Sample Return

1 PURPOSE

This document establishes the **AGENCY NAME's** sample return policy.

2 SCOPE

This policy applies to all samples submitted the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

All samples will be sealed and repackaged into their original containers prior to return to the Sample Control Section.

All samples will be returned to the Sample Control Section at the conclusion of the examination process.

The Sample Control Section will return exhibits to the submitting agency or individual at the conclusion of the examination process.

- The AGENCY NAME does not provide long term storage for samples submitted to its laboratory for examination.
- The Director may authorize a deviation to this policy.

5 PROCEDURE

Administrative Policies and Procedures Manual and the Property and Evidence Manual provide procedures that directly affect the implementation of this policy.

6 APPROVAL

The signatures below recognize the above Quality Assurance Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

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SAMPLE CONTROL

Sample Release

1 PURPOSE

This document establishes the **AGENCY NAME's** sample release policy.

2 SCOPE

This policy applies to all samples submitted the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

Samples will only be released to the agency or individual who originally submitted the samples for examination upon presentation of documentation authorizing the return of the requested samples.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

The signatures below recognize the above Quality Assurance Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

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SAMPLE CONTROL

Individual Characteristic Database Samples

1 PURPOSE

This document establishes the **AGENCY NAME's** Individual characteristic database sample policy.

2 SCOPE

This policy applies to all sample used to establish **AGENCY NAME** individual characteristic databases.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

Individual characteristic database samples will be treated as evidentiary samples, reference material or examination documentation, depending on the circumstances surrounding their use.

- Individual characteristic database samples will be treated as evidentiary samples during their acquisition and initial examination.
- Individual characteristic database samples will be treated as reference material during their subsequent storage and use as comparison material.
- Data from the examination of individual characteristic database samples will be utilized as examination documentation in the same manner other reference materials are used.

Each individual characteristic database sample will be assigned a uniquely identified number.

- Multiple samples from the same source will each be assigned a unique identifier.

Individual characteristic database samples will be protected from loss, cross transfer, contamination and deleterious change.

Access to characteristic database samples will be restricted to those persons authorized by the Director and outlined by the associated technical methods manual.

A technical methods manual will be prepared for each individual characteristic database.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

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SAMPLE CONTROL

Sample Control Manual

1 PURPOSE

This document establishes the **AGENCY NAME's** sample control manual policy.

2 SCOPE

This policy applies to all samples submitted to the **AGENCY NAME** for examination.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

The AGENCY NAME shall establish and maintain a sample control manual to ensure the integrity of the samples submitted for examination.
The sample control manual shall have:

- Procedures for the transportation, receipt, handling, protection, storage, retention and/or disposal of test and/or calibration items, including all provisions necessary to protect the integrity of the test or calibration item, and to protect the interests of the laboratory and the customer.
- A system for identifying test and/or calibration items.
  - The identification shall be retained throughout the life of the item in the laboratory.
  - The system shall be designed and operated so as to ensure that items cannot be confused physically or when referred to in records or other documents.
  - The system shall, if appropriate, accommodate a sub-division of groups of items and the transfer of items within and from the laboratory.
- Procedures to record abnormalities or departures from normal or specified conditions, as described in the test or calibration method upon receipt of samples submitted for examination.
  - When there is doubt as to the suitability of an item for examination, or when an item does not conform to the description provided, or the examination required is not specified in sufficient detail, the laboratory shall consult the customer for further instructions before proceeding and shall record the discussion.
- Procedures and appropriate facilities for avoiding deterioration, loss or damage to the test or calibration item during storage, handling and preparation.
  - Handling instructions provided with the item shall be followed.
  - When items have to be stored or conditioned under specified environmental conditions, these conditions shall be maintained, monitored and recorded.

- Where a sample or a portion of a sample is to be held secure, the laboratory shall have arrangements for storage and security that protect the condition and integrity of the secured items or a portion of a sample is to be held secure, the laboratory shall have arrangements for storage and security that protect the condition and integrity of the secured sample or portions concerned.

Each analytical section shall include a sample control section in their respective technical methods manual.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

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LABORATORY INFORMATION MANAGEMENT

Laboratory Information Management System

1 PURPOSE

This document establishes the **AGENCY NAME's** laboratory information management system policy.

2 SCOPE

This policy applies to all information utilized by the **AGENCY NAME** management.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

The **AGENCY NAME** will establish and maintain a laboratory information management system (LIMS) to provide meaningful information that will assist the laboratory in accomplishing the laboratory objectives.

The LIMS will consist of one or more computerized databases which will allow the laboratory to monitor that case flow and productivity.

The **AGENCY NAME** will establish and maintain a LIMS Policy and Procedure Manual to ensure the accuracy of the information placed into the LIMS.

The Director will designate an individual to act as the LIMS Administrator to ensure the accuracy of the information place into and retrieved from the LIMS.

The LIMS Administrator will provide monthly reports to the Director as required.

5 PROCEDURE

The Laboratory Information Management System Policy and Procedure Manual will be used as a guideline for the implementation of this policy.

6 APPROVAL

The signatures below recognize the above Quality Assurance Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

ISSUE MANAGEMENT

Risk Identification

1 PURPOSE

This document establishes the **AGENCY NAME's** risk identification policy.

2 SCOPE

This policy applies to all factions of the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

The AGENCY NAME will make every effort to identify all risks that could pose a threat to the quality of the examinations preformed by its personnel.

The Quality Assurance Manager will initiate a corrective action report within ten (10) days of notification of a risk that may affect the quality of the examinations performed by the **AGENCY NAME**.

4.1 AGENCY PERFORMANCE

Risks associated with the overall quality system may be identified through one or more of the following means:

- Employee Suggestions
- Peer Groups
- User Groups
- Audits

4.1.1 Employee Suggestions

Employees are encouraged to submit suggestions on quality risks to the senior management senior management for review.

- All employee suggestions will be presented to the senior management in writing.
- Employee suggestions may be signed or unsigned.

The senior management will address all employee suggestions in a timely manner.

- Employee suggestions will be discussed at the scheduled senior management meeting following the submission of the employee suggestions, when practical.
- The senior management will provide feedback to the employee submitting quality risk suggestions concerning his suggestion.

Employees who submit quality risk suggestions will never be subjected to punitive action as a result of their submission.

4.1.2 Peer Groups

Peer Groups are encouraged to submit suggestions on quality risks to the senior management senior management for review.

- Peer Group suggestions will be presented to the senior management in writing.
- Peer Group suggestions will be signed by the Peer Group Chairman.

The senior management will address all Peer Group suggestions in a timely manner.

- Peer Group suggestions will be discussed at the next scheduled senior management meeting following the submission of the Peer Group suggestions, when practical.
- The senior management will provide feedback to the Peer Group submitting quality risk suggestions concerning his suggestion.

Peer Group members who submit quality risk suggestions will never be subjected to punitive action as a result of their submission.

4.1.3 User Groups

The **AGENCY NAME** will conduct regularly scheduled meetings with the users in an effort to identify potential quality risks.

The **AGENCY NAME** will periodically survey its users concerning the level of quality of the services it provides.

- Customer Survey form will be utilized for this purpose.

The senior management will address all User Group suggestions in a timely manner.

- User Group suggestions will be discussed at the scheduled senior management meeting following the submission of the employee suggestions, when practical.
- Customer survey information will be compiled on a quarterly basis and the results discussed by the senior management.
- The senior management will provide feedback to the User Group concerning quality risk suggestions and survey results.

4.1.4 Audits

The AGENCY NAME will conduct annual audits of its quality systems to identify potential quality risks.

The senior management will review all audit files and address any quality risks identified during an audit in a timely manner.

Annual quality systems audits will be conduct in conjunction with annual audits required by accrediting organizations.

4.2 EMPLOYEE PERFORMANCE

Risks associated with employee performance may be identified through one or more of the following means:

- Proficiency Testing
- Case Review
- Testimony Monitoring

4.2.1 Proficiency Tests

Employees with case work responsibilities will be given an annual proficiency test in every discipline or sub discipline which regular casework is performed to identify potential quality risks.

4.2.2 Case Review

All reports will receive a technical review and an administrative review to identify quality risks prior to dissemination.

4.2.3 Testimony Monitoring

All employees with testimony responsibilities will be reviewed annually to identify quality risks.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

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John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

ISSUE MANAGEMENT

Issue Identification

1 PURPOSE

This document establishes the **AGENCY NAME's** issue identification policy.

2 SCOPE

This policy applies to all factions of the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

The AGENCY NAME will make every effort to identify all issues that could pose a threat to the quality of the examinations preformed by its personnel.

The Quality Assurance Manager will initiate a corrective action report within three (3) days of notification of an issue that may affect the quality of the examinations performed by the AGENCY NAME.

4.1 AGENCY PERFORMANCE

Issues associated with the overall quality system may be identifies through one or more of the following means:

- Employee Suggestions
- Peer Groups
- User Groups
- Audits

4.1.1 Employee Suggestions

Employees are encouraged to submit suggestions on quality issues to the senior management senior management for review.

- All employee suggestions will be presented to the senior management in writing.
- Employee suggestions may be signed or unsigned.

The senior management will address all employee suggestions in a timely manner.

- Employee suggestions will be discussed at the scheduled senior management meeting following the submission of the employee suggestions, when practical.

- The senior management will provide feedback to the employee submitting quality issue suggestions concerning his suggestion.

Employees who submit quality issue suggestions will never be subjected to punitive action as a result of their submission.

4.1.2 Peer Groups

Peer Groups are encouraged to submit suggestions on quality issues to the senior management senior management for review.

- Peer Group suggestions will be presented to the senior management in writing.
- Peer Group suggestions will be signed by the Peer Group Chairman.

The senior management will address all Peer Group suggestions in a timely manner.

- Peer Group suggestions will be discussed at the next scheduled senior management meeting following the submission of the Peer Group suggestions, when practical.
- The senior management will provide feedback to the Peer Group submitting quality issue suggestions concerning his suggestion.

Peer Group members who submit quality issue suggestions will never be subjected to punitive action as a result of their submission.

4.1.3 User Groups

The AGENCY NAME will conduct regularly scheduled meetings with the users in an effort to identify potential quality issues.

The AGENCY NAME will periodically survey its users concerning the level of quality of the services it provides.

- Customer Survey form will be utilized for this purpose.

The senior management will address all User Group suggestions in a timely manner.

- User Group suggestions will be discussed at the scheduled senior management meeting following the submission of the employee suggestions, when practical.
- Customer survey information will be compiled on a quarterly basis and the results discussed by the senior management.
- The senior management will provide feedback to the User Group concerning quality issue suggestions and survey results.

4.1.4 Audits

The AGENCY NAME will conduct annual audits of its quality systems to identify potential quality issues.

The senior management will review all audit files and address any quality issues identified during an audit in a timely manner.

Annual quality systems audits will be conduct in conjunction with annual audits required by accrediting organizations.

4.2 EMPLOYEE PERFORMANCE

Issues associated with employee performance may be identified through one or more of the following means:

- Proficiency Testing
- Case Review
- Testimony Monitoring

4.2.1 Proficiency Tests

Employees with case work responsibilities will be given an annual proficiency test in every discipline or sub discipline which regular casework is performed to identify potential quality issues.

4.2.2 Case Review

All reports will receive a technical review and an administrative review to identify quality issues prior to dissemination.

4.2.3 Testimony Monitoring

All employees with testimony responsibilities will be reviewed annually to identify quality issues.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

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John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

ISSUE MANAGEMENT

Corrective Action Reports

1 PURPOSE

This document establishes the **AGENCY NAME's** corrective action reports policy.

2 SCOPE

This policy applies to all factions of the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

The **AGENCY NAME** will utilize corrective action reports to document their effort to identify and resolve risks, issues and non-conformance that have been brought to the attention of senior management.

The **AGENCY NAME** will utilize the information deemed from the corrective action reports to:

- Identify the cause of the risk, issue or non-conformance
- Select and implement the appropriate corrective action measure
- Monitor the effect of the corrective action measure
- Require additional audits or follow up actions as required

5 PROCEDURE

The Quality Assurance Manager will generate a Corrective Action Report Form to document the risk or issue and the preventative action taken to address the risk or corrective action taken to address the issue.

- A corrective action report will be initiated within three (3) days of notification of a potential issue.
- A corrective action report will be initiated within ten (10) days of notification of a potential risk.

The Quality Assurance Manager will assign a unique file number to each corrective action report initiated using the following format:

- CAR-XX-YYY
  - CAR: Corrective Action Report
  - XX: The last two digits of the calendar year the report was initiated
  - YYY: Sequential report number beginning with 001 on 1 January of every calendar year

The Quality Assurance Manager will establish and maintain a file for each corrective action report initiated.

- All Corrective Action Reports will be filed by CAR number.

The Quality Assurance Manager is responsible for ensuring all Corrective Action Reports are completed and their respective risks and issues are resolves in a timely manner.

- The Quality Assurance Manager will create and maintain a log of Corrective Action Reports to monitor the resolution status each corrective action.

The Quality Assurance Manager will provide the senior manager an update on all outstanding corrective actions at the senior staff meeting.

6 APPROVAL

The signatures below recognize the above Quality Assurance Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

ISSUE MANAGEMENT

Corrective Actions

1 PURPOSE

This document establishes the **AGENCY NAME's** corrective action policy.

2 SCOPE

This policy applies to all factions of the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

The **AGENCY NAME** will initiate corrective actions to resolve risks, issues and address non-conformance situations that have been brought to the attention of senior management in a timely manner.

The **AGENCY NAME** will document all situations in which require corrective actions.

The **AGENCY NAME** will utilize the information deemed from the corrective action reports to:

- Identify the cause of the risk, issue, or non-conformance.
- Select and implement the appropriate corrective action measure.
- Monitor the effect of the corrective action measure.
- Require additional audits or follow up actions as required.

5 PROCEDURE

The Quality Assurance Manager will initiate corrective action to address the situations that effect quality as follows:

- A corrective action will be initiated immediately upon notification of non-conformity situation.
- A corrective action will be initiated within three (3) days of notification of a potential issue.
- A corrective action will be initiated within ten (10) days of notification of a potential risk.

The Quality Assurance Manager will take the following steps to during the corrective action process:

- Assign a unique file number to each corrective action.
- Initiate a Corrective Action Report Form and file.
- Document the situation that requires corrective action.
- Identify a person or persons to investigate and identify the root cause of the situation that requires corrective action.
- Establish and implement the steps required to successfully resolve the situation that requires corrective action.
- Monitor and document the effect of the corrective action measures.
- Perform additional audits or follow up actions as required.

The Quality Assurance Manager will provide the senior management an update on all outstanding corrective actions at the senior staff meeting.

6 APPROVAL

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John Smith, Laboratory Director	Date
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End of Document

EXAMINATION METHODS

Examination Method Selection

1 PURPOSE

This document establishes the **AGENCY NAME's** examination method selection policy.

2 SCOPE

This policy applies to all examination methods utilized by the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

The **AGENCY NAME** shall use examination, to include sampling, test methods which meet the needs of the customer and which are appropriate for the tests and/or calibrations it undertakes.

Examiners will only utilized validated examination methods that have been incorporated into the technical method manual of the analytical section responsible for the examination.

Examiners may utilize validated examination methods that are not part of the analytical section's technical methods manual if:

- The examination method is specifically requested by the customer; and
- The method has been validated in-house; and
- All of the chemicals, equipment and consumable items are available; and
- The examiner has the knowledge, skill and abilities to conduct the requested examination.

The examiner shall inform the customer when a requested method is inappropriate or out of date and suggest an alternative method that is within the examination capabilities of the **AGENCY NAME**.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

The signatures below recognize the above Quality Assurance Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

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End of Document

EXAMINATION METHODS

Examination Requests

1 PURPOSE

This document establishes the **AGENCY NAME's** examination request policy.

2 SCOPE

This policy applies to all examination requests received by the **AGENCY NAME.**

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

4.1 ORIGINAL REQUEST

The AGENCY NAME will only accept requests for examination for perform services that are within the scope of capabilities.

- A portion of the examination may be subcontracted to another laboratory upon mutual agreement.
- The agreement will be documented.

An AGENCY NAME request for examination form will accompany every will accompany every request for tender.

- The request for examination form will contain space for the customer to identify the testing to be performed and the methods to be utilized.

All requests for examination will be reviewed to ensure the AGENCY NAME can perform the services requested prior to the accepting samples for examination.

- Differences between the request for examination and the capabilities of the AGENCY NAME shall be resolved before any work commences.
- Each request for examination shall be acceptable both to the AGENCY NAME and the customer.

4.2 REQUEST MODIFICATION

All requests to modify the original request for examination will be reviewed to ensure the AGENCY NAME can perform the services requested prior to the accepting samples for examination.

- Differences between the modification requested and the capabilities of the AGENCY NAME shall be resolved before any work commences.

The AGENCY NAME will record and maintain any change in the request for examination after the original request for examination has been accepted.

- Records shall include pertinent discussions with a customer relating to the customer's requirements or the results of the work.
- Records shall be maintained of discussions concerning modifications to the original request for examination that were not implemented and the reason for such action.

Deviations from the services on the request for examination for are not authorized without the Customer's consent.

The Customer will be notified about the need to deviate from the examinations to be performed or the methods that will be utilized prior to the performance of any examination.

The modification record shall include:

- The name of the customer's representative.
- The name of the AGENCY NAME representative.
- Time and date of the request.
- Details of the customer's request.
- AGENCY NAME's ability to address the request.
- Any adjustment in price resulting in the modification to the request for examination.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

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End of Document

EXAMINATION METHODS

Contract Examination Services

1 PURPOSE

This document establishes the **AGENCY NAME's** contract examination services policy.

2 SCOPE

This policy applies to all examination performed by the **AGENCY NAME.**

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

4.1 GENERAL

The AGENCY NAME will only report results of examinations performed by its personnel utilizing its resources.

The AGENCY NAME will refer the customer to a facility that can address the customer's needs if the AGENCY NAME cannot adequately address the requirements of the request for examination.

4.2 EXCEPTIONS

4.2.1 Contract Laboratories

The Director may authorize the use of contract laboratories to perform examinations to temporarily address unforeseen circumstances.

The customer will be notified and consent to the use of contract laboratory prior to commencing any examinations.

- The notification and consent will be documented.

Contract laboratories will be have a documented quality assurance program that meets the accreditation or certification standards help by the AGENCY NAME.

- The Quality Assurance Manager review the contract laboratory's quality assurance manual to ensure it complies.
- The Quality Assurance Manager shall maintain a register of all contract laboratories used for tests and/or calibrations services.
- Contract laboratories shall provide the Quality Assurance Manager a copy of all accreditation and certification credentials to demonstrate it compliance to quality standards.

Contract laboratories will on utilize validated internationally accepted methods that meet the customer's examination requirements.

The subcontractor shall report the results in writing or electronically and be included in the examination case file.

When the test report contains results of tests performed by subcontractors, these results shall be clearly identified.

4.2.2 Contract Labor

The Director may authorize the use of contract labor to perform testing and calibration activities.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

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EXAMINATION METHODS

Environmental Factors

1 PURPOSE

This document establishes the **AGENCY NAME's** environmental factor policy.

2 SCOPE

This policy applies to all examination performed by the **AGENCY NAME.**

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

The **AGENCY NAME** shall monitor, control and record environmental conditions as required by the relevant specifications, methods and procedures or where thy influence the quality of the results. Due attention shall be paid in test areas in effected by:

- Biological sterility
- Dust
- Electromagnetic disturbances
- Radiation, humidity
- Electrical supply
- Temperature
- Sound and vibration levels

Tests and calibrations shall be stopped when the environmental conditions jeopardize the results of the tests and/or calibrations.

The temperatures of sample storage areas which operate above or below ambient temperature will be continually monitored and the temperatures recorded.

- Samples will be relocated to an appropriate storage location if the temperature of the storage area +/- **YY** degrees from the designated setting for more and **XX** hours.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

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EXAMINATION METHODS

Examination Method Validation

1 PURPOSE

This document establishes the **AGENCY NAME's** examination method validation policy.

2 SCOPE

This policy applies to all examination methods utilized by the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

The **AGENCY NAME** shall only use examination methods that have been validated by the respective analytical section and are included in the section's technical methods manual.

Analytical sections may develop and introduction test and calibration methods developed for its own use if:

- The development of the method is assigned to qualified personnel equipped with adequate resources.
- The method is validated prior to use in testing or calibration of samples submitted to the AGENCY NAME for examination.

The validation process shall address attributes and data quality objectives that include but are not limited to:

- Accuracy
- Precision
- Specificity
- Detection limit
- Limit of quantitation
- Linearity
- Range
- Ruggedness or robustness

The validation process includes:

- **Literature research:** Review of publications, academic materials, safety procedures and protocols, etc. involving the technique or procedure being validated.
- **Standard samples:** The samples should be selected to represent the type of specimens to be routinely analyzed by the technique or procedure.
- **Consistency:** The methods tested and results must show the same outcome on each test.
- **Reproducibility:** The test must be reproducible by another individual using the original test documentation.
- **Specificity:** Does the test give results specific to the substrate tested for (i.e. false positives or not).
- **Sensitivity Studies:** Is the sensitivity so great many false positives occur. Is the sensitivity so low that many false negatives occur.
- **Environmental Studies:** When applicable, evaluate the method using known samples exposed to a variety of environmental conditions.

The Quality Assurance Manager will maintain a validation file for all new technical procedures.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

The signatures below recognize the above Quality Assurance Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

EXAMINATION METHODS

Examination Method Uncertainty

1 PURPOSE

This document establishes the **AGENCY NAME's** examination method uncertainly policy.

2 SCOPE

This policy applies to all examination methods utilized by the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

The **AGENCY NAME** does not perform calibration activities. At such time that calibration activities are performed, the AGENCY NAME will address the requirements of ISO/IEC 17025, 5.4.6.1.

The technical methods of each analytical section will contain a procedure to estimate the uncertainty of measurement for testing activities.

The application of details in cases where the nature of the test method may preclude rigorous, metrologically and statistically valid, calculation of uncertainty of measurement is addressed in the procedure.

An attempt is made to identify all the components of uncertainty and make a reasonable estimation of the measurement uncertainty. This estimation is based on knowledge, experience, and validation data of the performance of the method and on the measurement scope. If needed as a part of the laboratory data, the uncertainty estimation is reported.

When estimating the uncertainty of measurement, all important uncertainty components are recorded in the uncertainty records for each determination and test technology.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

The signatures below recognize the above Quality Assurance Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

EXAMINATION METHODS

Sampling

1 PURPOSE

This document establishes the **AGENCY NAME's** sampling policy.

2 SCOPE

This policy applies to all examinations performed by the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

Each analytical section shall establish a sampling plan and procedures for sampling for the examinations it performs on samples submitted to the AGENCY NAME for analysis.

- Sampling plans shall, whenever reasonable, be based on appropriate statistical methods.
- The sampling process shall address the factors to be controlled to ensure the validity of the test and calibration results.
- The sampling plan shall be recorded in detail with the appropriate sampling data and shall be included in all documents containing test and/or calibration results, and shall be communicated to the appropriate personnel when the customer requires deviations, additions or exclusions from the documented sampling procedure.
- The sampling plan shall have procedures for recording relevant data and operations relating to sampling that forms part of the testing or calibration that is undertaken. These records shall include the sampling procedure used, the identification of the sampler, environmental conditions (if relevant) and diagrams or other equivalent means to identify the sampling location as necessary and, if appropriate, the statistics the sampling procedures are based upon.

The sampling plan will be documented in the analytical sections technical methods manual.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

The signatures below recognize the above Quality Assurance Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

Appendix E

Quality Assurance Manual

(Revision XX)

This document represents the quality assurance policies of the **AGENCY NAME**. All additions, deletions and modifications to this document are done in accordance with the policy preparation policy. This document is the property of the **AGENCY NAME** and can not be reproduced without authorization.

Official revisions are incorporated annually. Interim modifications will be documented and implemented in accordance to the document modification policy. A copy of the interim modification will be distributed and inserted into the appropriate portion of each printed section of this manual.

The signatures below recognize the total volume as the official quality assurance policy of the **AGENCY NAME** effective **DATE**.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

CONTENTS

1 Introduction

The **AGENCY NAME** Quality Assurance Manual (hereafter referred to as QAM) has been prepared to meet the requirements for laboratory accreditation of the International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) 17025 (2005). It has been formatted using clause numbers from ISO/IEC 17025 to provide ease in review.

2 Controlled Distribution of the Quality Manual

The **INSERT NAME OF RESPONSIBLE PARTY** is responsible for maintaining the official master copy of the **AGENCY NAME** operational manuals, including the QAM. General distribution of this manual is accomplished using a combination of paper and electronic formats. Annual review is coordinated by the **INSERT NAME OF RESPONSIBLE PARTY**.

3 Quality Policy Statement

AGENCY NAME is committed to laboratory accreditation according to the requirements of ISO/IEC 17025 and **LIST OTHER APPLICABLE ACCREDITIATION BODIES**. This commitment is evidenced by the approval signatures for this manual.

The quality policy statement is stated in Subsection 4.2.2.

4 Management Requirements

4.1 Organization

4.1.1 Legal Authority

The AGENCY NAME operated under the legal authority as defined by LIST THE RELIVANT STATAUTE(S), LAW(S), ADMINISTRATIVE REGULATION(S) OR COMPANY CHARTER THAT DEFINES THE AGENCY NAME LEGAL AUTHORITY.

The UMBRELLA ORGANIZATION is responsible for establishing the organization's commitment to the management system, implementing it, and delegating responsibility for its accomplishment.

The Director of the AGENCY NAME is responsible for issuing policy and procedures for the laboratory(s) and monitoring their implementation.

Laboratory management, including supervisory analysts and quality managers, is responsible for ensuring that analytical activities meet the requirements of the agency, its customers, and regulations in LIST APPLICABLE STATUTES OR ADMINISTRATIVE REGULATIONS. In addition, each person involved in the generation of data is part of the management system.

4.1.2 Operational Guidelines

The intent of **AGENCY NAME** is to operate testing laboratories according to the following requirements:

- **AGENCY NAME** policies and procedures
- Federal and State laws and regulations
- Customer contracts
- ISO/IEC 17025
- American Association of Laboratory Accreditation (A2LA)
- **LIST OTHER RELIVANT REGULATION BODIES**

4.1.3 Management System Scope

The management systems of the **AGENCY NAME** shall be responsible for the operation of the following permanent facilities:

- INSERT Address Headquarters facility
- INSERT address of regional facility 1
- INSERT address of regional facility 2
- INSERT address of regional facility …

4.1.4 Functional Organization

The **AGENCY NAME** laboratories are a part of the **UMBRELLA ORGANIZATION NAME**. The organizational charts and key personnel are found in the following documents:

- DOCUMENT #: General Organization Structure.
- DOCUMENT #: Management Organization Structure.
- DOCUMENT #: Examination Section 1 Organization Structure.
- DOCUMENT #: Examination Section 2 Organization Structure.
- DOCUMENT #: Examination Section … Organization Structure.

4.1.5 Laboratory Components

- The **AGENCY NAME** has managerial staff with the authority to discharge their duties as reflected in the prepared job descriptions by the laboratory.

  This authority includes the implementation, maintenance, and improvement of the management system.
  Management authorities are defined in **AGENCY NAME** position descriptions.
  The resources needed to discharge these duties are identified in Section 5.2 to Section 5.6.
  The identification of departures from the management system and testing requirements is documented according to the laboratory's corrective action procedure.

- Employees will not engage in activities that place any undue internal and external commercial, financial and other pressures and influences that may adversely affect the quality of their work.

Employees will disclose any financial matter that might adversely affect the integrity of their work.
Employees will obtain approval of outside employment activity.

- Reports of information and data are transmitted and filed in accordance with official policies, directives, and notices of the **AGENCY NAME**.

  Reports and data are not released until reviewed and verified.
  The majority of reports are sent to internal customers only, except as required by law or regulation.
  Information is released only to the customer or designated representative.
  AGENCY NAME facilities are controlled-access buildings to further ensure protection of data.

- To avoid conflicts of interest, pressures, and influences, employees are familiar with and observe the **AGENCY NAME** Code of Conduct.

  These principles of ethics can be found at DOCUMENT #.
  Two core concepts are embodied in these principles:

  (a) Employees shall not use public office for private gain.
  (b) Employees shall act impartially and not give preferential treatment to any private organization or individual.

  An employee who performs laboratory testing performs and documents a demonstration of competence as prescribed in Subsection 5.2.

- The **AGENCY NAME** is part of the **UMBRELLA ORGANIZATION**. The organization and the relationship among the staff is reflected in the organizational chart maintained by the Quality Assurance Manager.
- Job responsibilities for employees are documented in the management system procedures and operating instructions.

  Position descriptions are maintained by the AGENCY NAME.

- The employees performing testing have access to consensus standards, instrument manufacturers' manuals, and laboratory procedures for reference.
- Demonstration of competence for technical personnel is documented and used as evidence of desired familiarity with laboratory methods.
- The Supervisor is responsible for the technical operations of the laboratory.
- The laboratory Quality Assurance Manager is responsible for the laboratory's management system and its implementation.

  The Quality Assurance Manager has direct access to the Laboratory Director, who is responsible for decisions concerning policy and resources.

- Qualified laboratory personnel are assigned to serve in the absence of key managerial personnel, such as Laboratory Director, Quality Manager, and Supervisor.

e.g., The Supervisor or Deputy Director may serve in the absence of the Laboratory Director; either the Laboratory Director, Deputy Director or Supervisor may serve in the absence of the QMS Manager; and senior technical personnel may serve in the absence of Supervisors.

- Laboratory personnel are aware of their function and contribution in the management system and of its objectives.
- Effective communication from management occurs through the use of but not limited to memos, newsletters, electronic presentations, emails, or verbally to laboratory personnel regarding the effectiveness of the management system.

4.1.6 Related Procedures

Insert references to procedures that are specific to this section.

4.2 Management System

4.2.1 Management System Outline

The laboratory management system is outlined in the following documents:

- Quality manual
- Written procedures
- Work Instructions
- References; and
- Forms and records.

This management system is established to address the requirements in ISO/IEC 17025. Each entity establishes and maintains a master list of procedures per the procedure for document control. The quality policy and quality objectives for the **AGENCY NAME** are included in Subsection 4.2.2. The documents listed above are accessible to all personnel and are included in the **AGENCY NAME's** training program.

4.2.2 Management System Policy

4.2.2.1 Mission INSERT THE MISSION STATEMENT

4.2.2.2 Commitments to Quality The laboratory management and personnel are committed to performing quality activities to assure integrity, accuracy, precision, reliability and timeliness of the data.

4.2.2.3 Standard of Service The **AGENCY NAME's** standard of service for the testing program is defined by the ISO/IEC 17025 requirements and the following:

- Established and maintained documented procedures for laboratory operation based upon consensus methods for testing. Methods are specified or cited in the compliance program and compendiums, or by the customer. In some cases, testing and procedures as established by the instrument manufacturer are used.
- Sample handling and management procedures to maintain integrity of both the samples and the documentation to support the analytical data.

- Maintenance of records in such manner that facilitates retrieving them later. Records are maintained in the analyst worksheet packet filed by sample number. Records may be archived on- or off-site depending on the home district of the collector. Archival retention periods are stated in the laboratory's document control and management procedure.
- Employment of qualified and trained personnel to perform the tasks to support the laboratory objectives. Performance demonstrations by technical personnel conducting laboratory methods are conducted and documented.
- Routine maintenance of quality control data to support testing results by demonstrating that measurement processes are maintained in statistical control. Accuracy and precision control charts are used to monitor performance.
- Maintenance of an instrument calibration program that provides measurement traceability to International System of Units (SI) units. This is accomplished with the use of national, international, or industry accepted standards of measurement.

AGENCY NAME personnel follow the policies included in this document, the processes described in their operating procedures, and the processes described in specific laboratory methods.

Changes to management system documents are made according to the document control procedure and involve periodic revisions of this document as part of the annual management review of the management system.

An internal audit process is used to evaluate the effectiveness of the management system established for laboratory operations. It is the policy of **AGENCY NAME** to participate in interlaboratory proficiency programs as these are announced and as requested by the accrediting body.

The sections in this document describe elements and reference procedures that outline the management system established to accomplish the mission of the laboratory.

Test reports and the communication of information generated by the laboratory are conducted under the direction of the Director.

The operational procedures for the laboratory are listed in its master list**,** as described in the laboratory's document control procedure**.**

4.2.2.3.1 Management System Objectives The following management system objectives are taken into account as part of the reviews performed by management.

The primary objective is to assure the accuracy and precision of laboratory results so that they will be reliable, interpretable, repeatable, and defensible. Data quality objectives are described in the terms of:

- accuracy
- precision
- detection and quantitation limits
- timeliness; and
- comparability

The second objective is to establish and maintain national and international recognition through compatibility with the requirements of relevant standards.

Third, strive to meet or exceed the customer's needs and expectations for precision, accuracy, sensitivity, and specificity.

Fourth, maintain the **AGENCY NAME's** reputation for quality by fostering continuous process improvement and problem prevention.

4.2.2.3.2 Management System Awareness and Implementation The management system documents and test methods are included as training elements in the laboratory's training program addressed in the laboratory training procedure.

The implementation of the quality policies is evidenced by the manner in which work activities are conducted. Implementation of the management system procedures is evidenced by the generation of required records. The audit and management review activities are the mechanisms that are used to monitor the implementation effort of the laboratory management system.

4.2.2.3.3 Commitment to ISO/IEC 17025. The policies for operation of the laboratory management system are established to address the requirements of ISO/IEC 17025. The **AGENCY NAME** is committed to laboratory accreditation according to the requirements of ISO/IEC 17025. This commitment is evident by the approval signatures by Director and the Quality Assurance Manager for this quality manual.

4.2.2.4 Evidence of Management's Commitment Evidence of management's commitment to the management system and its continual improvement in effectiveness is demonstrated by but not limited to participation of managers in the management reviews, performance of internal audits, proficiency testing, and the analysis of quality control samples.

4.2.2.5 Effective Communication Effective communication from management occurs through the use of but not limited to memos, newsletters, electronic presentations, emails, or verbally to laboratory personnel regarding the importance of meeting customer, statutory, and regulatory requirements.

4.2.2.6 Procedures and Outline of the Management System Management system procedures supporting quality policies are cited in the Related Procedures at the end of each section of this Volume. The outline of the management system is included in Subsection 4.2.1. Where needed, each laboratory shall have procedures to implement the quality policies at the local level and include these procedures in its Master List. Laboratories shall include a reference to the corresponding requirements in this Volume.

4.2.2.7 Roles and Responsibilities General roles and responsibilities for ORA laboratory personnel are summarized as follows:

- Quality Manager.
  - Ensures that the management system is established, implemented, and maintained in conformance with the requirements of ISO/IEC 17025.
  - Advocates and coordinates quality improvements to the management system.
- Responsible Managers (technical management).
  - Oversee technical functions.
  - Ensure compliance with the requirements of ISO/IEC 17025.
  - Ensure management system procedures, applicable standards, specifications, and regulations are followed.
  - Ensure that qualified, skilled, and trained personnel and other resources are available.
  - Ensure that products and services satisfy customer requirements.
- Analysts.
  - Ensure the quality of their work.
  - Operate in conformance with the requirements of the management system.

4.2.2.8 Management System Integrity The management system process and procedures as defined in this manual maintain the integrity of the management system when changes such as a change in the structure of the organization or management, or a change is a policy or procedure are made.

4.2.3 Related Procedures

Insert references to procedures that are specific to this section.

4.3 Document Control

4.3.1 General

The document control and management procedure in each laboratory describes the process for controlling quality documents that form part of its management system. The quality documents include those required for the generation of laboratory data. These documents include those published by the laboratory and those published externally. Documents of external origin include regulations, standards, test methods, instructions and manuals.

4.3.2 Document Approval and Issue

4.3.2.1 Approval and Issue Documents issued to personnel in the laboratory as part of the management system are reviewed and approved for use prior to issue in accordance with the laboratory's document control and management procedure. The laboratory's master list identifies the current revision status and distribution of documents in the management system. Through the use of the master list, quality documents are posted to personnel to preclude the use of invalid or obsolete documents.

4.3.2.2 Procedure Content The laboratory's master list and document control and record management procedure provide for the following:

- Authorized management system documents and external documents are at locations where operations essential to the effective functioning of the laboratory are performed.
- Documents are reviewed according to a schedule and revised to ensure continuing suitability and conformance with the management system and ISO/IEC 17025 requirements.
- Invalid or obsolete documents are promptly removed from all points of issue or use, or marked as *Uncontrolled* to assure against unintended use.
- Obsolete documents retained for either legal or knowledge preservation purposes are marked as *Archived*.

4.3.2.3 Document Identification A document control header as described in the laboratory's document control and management procedure uniquely identifies management system documents generated by the laboratory. Such identification includes the date of revision, identification number and inclusive pagination. The issuing authority is indicated by the name of the approving official in the document history section of each document.

4.3.3 Document Changes

Changes to documents are reviewed and approved in accordance with the laboratory's document control and management procedure. Unless designated otherwise, this procedure is followed by the

same personnel or function as in the original review or approval. The use of reference documents and information is required upon which to base the review and approval.

4.3.3.1 The altered or new text is identified either in the document, on a cover page, or in attachments.

4.3.3.2 The laboratory's document control and management procedure addresses the handling of document amendments by hand pending reissue.

4.3.3.3 Computerized Systems The laboratory's document control and management procedure addresses the control of electronic management system documents.

4.3.4 Related Procedures

Insert references to procedures that are specific to this section.

4.4 Review of Requests, Tenders, and Contracts

4.4.1 Review

The **INSERT NAME OF APPROPRIATE SECTION** develops and issues the annual work plan for the **AGENCY NAME**. The work plan is based on several factors such as the budget, the number of analysts and amount of resources, the Director's performance goals, the compliance program accomplishment goals, the inventory of regulated industry maintained by the field units, and targeted products. Distribution of assignments is by Program Assignment Code (PAC) and full time equivalent (FTE) hours within the different program areas. The compliance programs specify or cite the methods for analyses. The AGENCY NAME management team reviews the annual work plan to ensure that each laboratory section has the capability and resources to provide the requested services. Any differences between the work plan and the **AGENCY NAME** capability are resolved.

Requests not covered by compliance programs or assignments are reviewed prior to receipt of samples by the **AGENCY NAME** management when possible.

The results of this process are discussed and documented as part of the **AGENCY NAME's** annual management review.

4.4.2 Records of Review

The **AGENCY NAME** will maintain records of work plan reviews, changes, and change requests. Records are also maintained of discussions regarding ad hoc assignments.

4.4.3 Subcontracting Laboratories

The policies regarding the use of subcontracting laboratories are found in Subsection 4.5, Subcontracting of Tests. The customer requesting collaborative testing by laboratories outside of the **AGENCY NAME** is responsible for the work done by such labs. The **AGENCY NAME** is not responsible for such work under these circumstances.

4.4.4 Contract Deviations

Requests for deviations from work assignments or compliance programs are processed by the **LIST THE APPROPRIATE SECTION**. **THE APPROPRIATE SECTION** interacts with the customer to determine whether the requested changes are acceptable. Records of contract changes are maintained.

4.4.5 Amendments to Contracts

If a contract needs to be amended after work has commenced, the same contract review process is repeated and any amendments are communicated to all affected personnel named in the contract.

4.4.6 Related Procedures

Insert references to procedures that are specific to this section.

4.5 Subcontracting of Tests

The **AGENCY NAME** does not subcontract routine analyses within its scope of accreditation.

Collaborative activities conducted with external laboratories, such as universities, are research in nature and do not involve the routine analysis of **AGENCY NAME** samples.

4.5.1 Subcontracting Laboratories

Based on workload fluctuations and resource needs, the **AGENCY NAME** may request samples assigned to other **AGENCY NAME** laboratories for analysis. Samples are administratively transferred after arrangements are made to ensure that the receiving laboratory has the capacity and capability to complete it in a timely manner.

Samples are shipped according to Department of Transportation (DOT), United States Post Office (USPS), and carrier regulations. The manual for the Field Accomplishments and Compliance Tracking System (FACTS) describes the procedure for documenting administratively transferred samples (ATS).

4.5.2 Notification of Customer

The customer will be notified if any portion of the examination process is to be performed by a subcontract laboratory. The notification and the customer's approval or rejection of use of a subcontracting laboratory will be documented in the case file.

4.5.3 Laboratory Responsibility

The subcontracting laboratory to which the sample(s) have been transferred assumes responsibility for the work performed on the sample.

4.5.4 Related Procedures

Insert references to procedures that are specific to this section.

4.6 Purchasing Services and Supplies

4.6.1 Procedure

The **AGENCY NAME** or designated purchasing agents will use the **UMBRELLA OGANIZATION NAME's** procedures for the procurement of materials, supplies and services that critically affect the quality of the tests or calibrations. These procedures describe the process for the selection, purchase, reception and storage of equipment, services and supplies, including reagents and laboratory consumable materials, used in the performance of the tests and calibrations. Each laboratory section has work instructions describing the processing of requisitions.

4.6.2 Inspection and Verification

The laboratory section's work instructions describe how purchased equipment, supplies, services, reagents, and consumable materials that critically affect the quality of tests or calibrations are inspected or verified prior to use or concurrently with use. Inspection or verification criteria are used to establish conformance with requests made by the customer, included in standard specifications, or defined in the methods.

4.6.3 Purchasing Documents

Purchasing documents for items affecting the quality of **AGENCY NAME** output describe the services or supplies ordered. These purchasing documents are reviewed and approved for technical content prior to submission.

4.6.4 Records and Registry

Records of supplier evaluations and a list of approved suppliers are maintained by purchasers of laboratories equipment, services, and supplies.

4.6.5 Related Procedures

Insert references to procedures that are specific to this section.

4.7 Service to the Customer

4.7.1 Customer Requests

The **AGENCY NAME** affords the requesting customer cooperation to clarify the customer's request within the framework of the contract review process described in Section 4.4. The **AGENCY NAME** maintains communications regarding deviations from contract work. Communications regarding compliance programs, workplan and assignments are conducted.

The opportunity for the customer to witness examination activity is given upon request, providing the **AGENCY NAME** is able to maintain confidentiality to other customers during such cases.

4.7.2 Customer Feedback

The **AGENCY NAME** seeks customer feedback on their services and general performance. Records of the comments, both positive and negative, are maintained and are taken into account for identifying management system improvements during the reviews performed by management.

4.7.3 Related Procedures

Insert references to procedures that are specific to this section.

4.8 Complaints

The **AGENCY NAME** has a complaint procedure describing the process for the receipt and recording of complaints received from any party. Records of all complaints received are maintained according to the procedure. Complaints identified as nonconformities are processed according to Section 4.10 Corrective Action.

4.9 Control of Non-conforming Work

4.9.1 Procedure

The **AGENCY NAME** has a control of non-conforming work procedure that is implemented when any aspect of their testing work, or the results of this work, does not conform to requirements of the management system, testing methods, or the requests of the customer. This procedure addresses the following elements:

- Responsibilities and authorities for the management of identified non-conforming work and taking actions such as the halting of work, the withholding of test reports
- Application of criteria to evaluate the significance of non-conforming work
- Remedial action taken, together with any decision about the acceptability of the non-conforming work
- Notification of the customer, and if necessary, recall of work
- Responsibility for authorizing the resumption of work

4.9.2 Follow-up

If the non-conforming work could recur, or there are other significant problems identified, the corrective action procedures in Section 4.10 Corrective Action are promptly followed.

4.9.3 Related Procedures

Insert references to procedures that are specific to this section.

4.10 Corrective Action

4.10.1 General

The **AGENCY NAME** has a corrective action procedure that designates the authorities for implementing corrective action when one of the following is identified:

- Non-conforming work
- Departures from the policies and procedures in the management system
- Departures from required technical operations

4.10.2 Cause Analysis

The procedure for corrective action includes investigating and determining the root cause of the non-conformance.

4.10.3 Selection and Implementation of Corrective Actions

Potential corrective actions are identified. The action most likely to eliminate the problem and to prevent recurrence is selected.

The corrective action chosen addresses the magnitude of the non-conformance and the risk attributed to the non-conformance.

Corrective actions are documented, and any changes resulted from the corrective action investigation are implemented.

4.10.4 Monitoring of Corrective Actions

The corrective action procedure addresses the monitoring for the effectiveness of corrective actions performed.

4.10.5 Additional Audits

Where the identification of non-conformances or departures casts doubts on the laboratory's conformance with management system policies and procedures or conformance with ISO/IEC 17025, the areas of activity affected by the non-conformance are audited as soon as possible in accordance with Section 4.13 Internal Audits.

4.10.6 Related Procedures

Insert references to procedures that are specific to this section.

4.11 Preventive Action

4.11.1 General

Sources for needed improvements and potential sources of non-conformance are identified according to the process described in the laboratory's preventive action procedure**,** and are part of the management review process. Preventive actions plans are developed, implemented, and monitored to address the identified opportunities for improvement.

4.11.2 Procedure

The procedure includes the initiation of action. The management review process monitors the effectiveness of such actions in providing improvement to the management system.

4.11.3 Related Procedures

Insert references to procedures that are specific to this section.

4.12 Control of Records

4.12.1 General

4.12.1.1 Procedure The **AGENCY NAME** has a control of records procedure for identifying, collecting, indexing, accessing, filing, storing, maintaining, and disposing of quality and technical records. Quality records include reports from internal audits, management reviews, corrective actions, and preventive actions.

4.12.1.2 Legibility, Storage, and Retention Records are to be legible. Laboratory reports are archived upon final review to the designated home district office for storage. Laboratory reports can be retrieved by requesting the report from the designated home district record management center. A record retention schedule is included in the laboratory's administrative procedure.

4.12.1.3 Security and Confidentially Access is controlled in **AGENCY NAME** facilities; only authorized personnel are allowed in the laboratory and record management center. Records are stored in secured areas. Records are confidential and redacted before release in accordance with Freedom of Information (FOI) process.

4.12.1.4 Electronic Records The **AGENCY NAME** has a procedure describing the protection and back-up of electronic records. The procedure also describes the safeguards in place to prevent unauthorized access to or amendment of electronic records.

4.12.2 Technical Records

4.12.2.1 Retained Records, Audit Trail, and Identification Laboratory reports, depending on the type of analysis, include the original observations, derived data, calculations, standard preparation, instrument printouts, and results. These reports are retained in accordance with the document retention policy.

Staff records, equipment calibration, and verification reports are retained in accordance with the document retention policy. The records contain sufficient information to establish an audit trail.

The records of each test contain sufficient information in order to repeat the test under conditions as close as possible to the original. This information includes factors that affect uncertainty and any environmental conditions that affect the test.

The laboratory report will identify:

- The personnel responsible for sampling
- The personnel responsible for performance of each test, and
- The personnel for checking the results

4.12.2.2 Recording and Identification Observations, data, and calculations are recorded at the time they are made and are identifiable to the activity performed. Method numbers and titles are used to provide traceability of records to activities.

4.12.2.3 Corrections When errors occur in records, each mistake is lined out, not erased, not made illegible, nor deleted. The correct value is entered, initialed, and dated. In the case of records stored electronically, equivalent measures are taken to avoid loss or change of original data.

4.12.2.4 Related Procedures Insert references to procedures that are specific to this section.

4.13 Internal Audits

4.13.1 General

Internal audits are conducted according to a schedule included in the laboratory's audit procedure. Internal audits are conducted of activities to verify that operations continue to conform to the requirements of the management system, ISO/IEC 17025 and other applicable accrediting bodies.

The internal audit program addresses all elements of the management system, including testing activities. The Quality Assurnce Manager is responsible for the coordination of internal audits as listed by the schedule and requested by management.

Trained and qualified personnel are responsible for conducting internal audits. Audits are performed by personnel other than those who performed the work being audited.

4.13.2 Corrective Action

When audit findings cast doubt on the effectiveness of the operation or on the correctness or validity of the laboratory's test results, corrective action is undertaken according to the corrective action procedure.

The customer is notified if investigations show that non-conformances related to audit results also have affected work performed for the customer. This notification is documented.

4.13.3 Audit Records

The area of activity audited, the audit findings, and corrective action that arise from them are recorded according the audit procedure.

4.13.4 Follow-up Audit Activities

Follow-up audit activities are conducted to verify and record the implementation and effectiveness of the corrective action taken. This follow-up is included as part of the management review process.

4.13.5 Related Procedures

Insert references to procedures that are specific to this section.

4.14 Management Reviews

4.14.1 General

The management review procedure includes the schedule for conducting management reviews. This review is conducted by the laboratory's executive management to ensure continuing fitness for use and effectiveness of the management system and to introduce needed changes or improvements.

The management review addresses the elements of the management system and includes but is not limited to the following elements:

- Suitability of policies and procedures
- Reports from managerial and supervisory personnel
- Outcome of recent internal audits
- Corrective and preventive actions
- Assessments by external bodies
- Results of interlaboratory comparisons, proficiency test, and quality control
- Changes in the volume and type of work
- Customer feedback
- Complaints
- Other factors, such as quality control activities, resources and staff training

The findings and the actions that arise from the review are recorded according to the management review procedure. Each action includes a target date for resolution.

4.14.2 Related Procedures

Insert references to procedures that are specific to this section.

4.15 Improvement

The effectiveness of the management system is improved by using the following activities: internal audits; management reviews; analysis of quality control data; corrective actions; preventive actions; the quality policy; and the quality objectives.

4.15.1 Related Procedures
Insert references to procedures that are specific to this section.

5 Technical Requirements

5.1 General

The sections following below address the factors affecting the correctness and reliability of the tests performed by a laboratory. These factors include contributions from:

- Personnel (5.2 Personnel: Training Procedure)
- Accommodation and environmental conditions (5.3 Facilities and Environmental Conditions)
- Test and calibration methods and method selection and validation (5.4 Test Methods and Validation)
- Equipment selection and calibration (4.6 Purchasing and Receipt; 5.5 Equipment)
- Measurement uncertainty and traceability (5.4 Test Methods and Validation; 5.6 Measurement Traceability)
- Handling of test and calibration items (5.8 Sample Management)

The procedures listed in each section address these factors.

5.1.1 Contribution to Total Uncertainty of Measurement
These factors are considered in determining total measurement uncertainty and in developing uncertainty budgets. Additionally, these factors are considered by the laboratory when developing test procedures, in the training and qualification of personnel, and in the selection of the equipment utilized.

5.1.2 Related Procedures
Insert references to procedures that are specific to this section.

5.2 Personnel

5.2.1 Personnel Competence
The **AGENCY NAME** management ensures that laboratory personnel have the knowledge, skills, and abilities to perform their duties. Competence is based on education, experience, demonstrated skills, and training. Staff records contain the documentation of personnel education, experience, skills, and training for the position held.

Trainees undergo a training program in accordance with the analytical section's training procedure. A senior analyst serves as the trainer. Trainees perform procedures when training is completed and competency has been demonstrated. The documented demonstration of competence is an exercise that the trainee performs independent of supervision. The trainee is considered competent after the specified criteria have been successfully met.

5.2.2 Goals for Education, Training and Skills

The individual and management are jointly responsible for the setting, the pursuit, and achievement of educational goals for professional advancement. The annual performance evaluation process can be used by the individual to discuss career advancement and training possibilities. By using this process, individuals have the opportunity to identify areas of study and request training oriented towards the attainment of their goals.

Training needs are identified in the technical methods manual of each analytical discipline. In-house training is conducted according to analytical section's training procedure. Present and anticipated tasks of the laboratory are addressed in the planning of special training modules.

Skills of personnel are based upon demonstration of competence. This demonstration is to be completed successfully before analysts generate data independently. The effectiveness of personnel training is documented in but not limited to management reviews, internal audits, external assessments, proficiency testing, and performance evaluations.

5.2.3 Employees and Contracted Personnel

The **AGENCY NAME** may utilize the skills and talent of both full-time employees and contract personnel. The requirements of the management system are administered equally to both categories. No differentiation is made between the two categories of workers. Supervision, training, and competence are documented for all technical and key support personnel.

5.2.4 Job Descriptions

The **AGENCY NAME** maintains active job descriptions for managerial, technical, and key support personnel involved in tests. Job descriptions are established according to procedures of the **UMBRELLA OGANIZATION NAME**.

5.2.5 Management Authorization

The Laboratory Director authorizes identified personnel to:

- Perform testing and calibration
- Issue test reports
- Give opinions and interpretations
- Operate particular types of equipment

Records of authorizations, demonstration of competence, education, training, and experience are maintained by the laboratory and dated. Training files are maintained and include these records.

5.2.6 Related Procedures

Insert references to procedures that are specific to this section.

5.3 Accommodation and Environmental Conditions

5.3.1 Facilities and Environmental Conditions

The laboratory environmental conditions facilitate the correct performance of analytical testing. Test methods used by the laboratory include instructions addressing applicable environmental conditions. Examples of environmental influences are energy sources, lighting, biological sterility,

dust, humidity, and temperature. The laboratory monitors critical environmental conditions to ensure that results and the quality of the measurement are not adversely affected or invalidated.

In the event mobile labs are deployed, the laboratory is aware of and complies with all the environmental requirements and laws for the location. The technical needs for accommodation and environmental conditions that can affect the results of test are documented with the data generated.

5.3.2 Monitoring

Environmental conditions requiring monitoring include, but are not limited to:

- Room temperature and humidity
- Air flow rates for chemical fume hoods
- Biosafety hoods and laminar flow hoods
- Metal contamination on benches and hoods in laboratories performing metal analysis
- Microbiological contamination on bench surfaces and hoods in microbiology laboratories
- Air sampling for microbiological contamination in microbiology areas

Where environmental controls are needed, the environmental conditions are recorded.

Testing activities are stopped when the environmental conditions invalidate the test results or adversely affect quality control. Monitoring activities are conducted as part of the laboratory test or calibration methods.

5.3.3 Cross-contamination

Separate areas are maintained for incompatible activities. Measures taken to prevent cross-contamination include but are not limited to:

- Chemistry laboratories are separated from microbiology laboratories
- Sample receiving and storage are conducted in designated areas
- Separate storage for standards and reference materials and cultures
- Microbiology media preparation and sterilization are separated from work areas

5.3.4 Access

Laboratories are limited access areas. Access is controlled by but is not limited to:

- Issuance of keycards for entrance
- Escorting visitors
- Issuance of identification badges
- The use of security guards

5.3.5 Housekeeping

Laboratory areas are maintained clean and orderly to prevent contamination of samples and to facilitate the efficiency of laboratory operations. The laboratory's Chemical Hygiene Plan and Hazardous Waste Management Plan include measures taken to ensure good housekeeping in the laboratory.

5.3.6 Related Procedures

Insert references to procedures that are specific to this section.

5.4 Test Methods and Method Validation

5.4.1 General

The scope of test technologies and associated method source routinely used are identified in the **AGENCY NAME's** accreditation program documentation.

The estimation of the uncertainty of measurement is addressed in Subsection 5.4.6 and Section 5.9 of this manual describes the quality control processes, including the application of statistical techniques, for supporting test and calibration data.

The laboratory instructions for the use and operation of equipment called for by the laboratory methods is either a laboratory procedure identified on the master list or as equipment manuals. Procedures for the handling of items for testing are addressed in Section 5.8. Equipment manuals and standards for the laboratory's scope of testing technologies are controlled as external documents according to Section 4.3. Deviations from test methods are documented, technically justified, authorized, and where circumstances call for it, accepted by the customer according to Section 5.10.

5.4.2 Selection of Methods

Standard methods are those published by international, regional or national standards-writing bodies; by reputable technical organizations; in legal references; and **AGENCY NAME** published methods.

AGENCY NAME "official" methods are documented in the technical methods manuals of the individual analytical section.

Laboratory methods are selected to meet the customer's need as addressed in Section 4.4. The laboratory methods are controlled as external documents according to Section 4.3.

When the customer does not specify the method to be used, a standard method is preferred for use. If a standard method is not found the laboratory may use either a non-standard method or modify a method for use with the concurrence of the customer. The non-standard or modified method is validated according to Subsection 5.4.5.

The laboratory informs the customer when the method proposed by the customer is considered to be the incorrect choice or the incorrect revision for the intended purpose. This is done as part of contract review addressed in Section 4.4.

5.4.3 Laboratory Developed Methods

If an analytical section develops methods for its own use, the analytical section has its own procedure for its introduction. This procedure provides the planned activities, identification of qualified personnel, and resources. Plans are revised as method development proceeds and effective communication amongst all personnel involved is strongly encouraged. The analytical section developed methods adopted by the laboratory are used if they are validated according to Subsection 5.4.5.

5.4.4 Non-standard Methods

Non-standard methods are those methods not taken from authoritative, validated sources. A non-standard method has not undergone validation, such as a collaborative study or process to evaluate the method's performance capabilities.

Non-standard methods are selected for use when a customer request cannot be addressed with the use of a standard method. Such methods are subject to agreement with the customer and a clear specification of the customer's work requests, including the purpose of the test, is made. This process is described for contract amendments in Subsection 4.4.5 with laboratory management concurrence. Non-standard methods are validated according to Subsection 5.4.5.

5.4.5 Validation of Methods

5.4.5.1 Definition Validation is the confirmation by examination and the provision of objective evidence that the particular specifications for an intended use are fulfilled.

5.4.5.2 Methods Requiring Validation The analytical section validates non-standard methods, analytical section developed methods, and modified standard methods including use outside the intended scope and applications. Validation is conducted to confirm that the methods are fit for the intended use. The validation is documented.

5.4.5.3 Process The validation process addresses the needs of the given application or field of application. The laboratory analyst records the results obtained. The validation results include a statement as to whether the method is fit for the intended use. The needs of the customer define the intended use of the method. The attributes and data quality objectives include but are not limited to:

- Accuracy
- Precision
- Specificity
- Detection limit
- Limit of quantitation
- Linearity
- Range
- Ruggedness or robustness

If all the data quality objectives are met as indicated by the data collected, the method is considered as validated.

5.4.6 Estimation of Uncertainty of Measurement

5.4.6.1 Procedure for Calibration Activities **The AGENCY NAME** does not perform calibration activities. At such time that calibration activities are performed, the **AGENCY NAME** will address the requirements of ISO/IEC 17025, 5.4.6.1.

5.4.6.2 Procedure for Testing Activities The laboratory has a procedure to estimate the uncertainty of measurement for testing activities.

The application of details in cases where the nature of the test method may preclude rigorous, metrologically and statistically valid, calculation of uncertainty of measurement is addressed in the procedure.

An attempt is made to identify all the components of uncertainty and make a reasonable estimation of the measurement uncertainty. This estimation is based on knowledge, experience, and validation data of the performance of the method and on the measurement scope. If needed as a part of the laboratory data, the uncertainty estimation is reported.

5.4.6.3 Uncertainty Components When estimating the uncertainty of measurement, all important uncertainty components are recorded in the uncertainty records for each determination and test technology.

5.4.7 Control of Data

5.4.7.1 Data Transfers Calculations and data transfers are reviewed before the data is reported. All changes are identified and verified where they occur. This process is detailed in the procedure for laboratory quality control identified in Section 5.9 Assuring the Quality of Test Results**.**

5.4.7.2 Computer Use When computers or automated equipment are used for the acquisition, processing, recording, reporting, storage or retrieval of test data, the laboratory follows the process in the laboratory's data protection procedure.

- If computer software is developed by the user, its development is documented in detail and algorithms are validated.
- The laboratory's data protection procedure addresses the protection of the data to include, but not limited to data integrity, data confidentiality during entry, collection, storage, transmission and processing.
- Computers and automated equipment are maintained to ensure proper functioning and are provided with the environmental and operating conditions to maintain the integrity of test and data.

5.4.8 Related Procedures

Insert references to procedures that are specific to this section.

5.5 Equipment

5.5.1 Laboratory Equipment

The **AGENCY NAME** has sample preparation, measurement and test equipment for the correct performance of the tests and calibrations. The **AGENCY NAME** also has ancillary equipment for processing samples and for processing data.

The **AGENCY NAME** purchases the equipment used by the laboratory. Maintenance contracts are established as needed. In those cases where the laboratory leases equipment it has direct control concerning its use. Leased equipment is managed in the same manner as purchased equipment according to the management system requirements.

The **AGENCY NAME** maintains an equipment inventory of all laboratory equipment used to perform regulatory testing.

5.5.2 Equipment Capability

Equipment and its software used for testing are to achieve the accuracy expected and comply with specifications of the testing concerned. **AGENCY NAME** equipment that has a significant effect on the results has a calibration schedule. The equipment performance is verified and verification records are maintained. Equipment is to meet the laboratory's testing parameters and conform to standard specifications before being placed into service.

5.5.3 Authorized Operation

Personnel are authorized to operate equipment according to Subsection 5.2.5. Authorization is based on work assignment, training, experience and demonstrated proficiency. Equipment manuals and maintenance procedures are maintained and supplied to laboratory personnel as described in Subsection 4.3.1.

5.5.4 Equipment Identification

Each item of equipment used for testing has an **AGENCY NAME** property number or an identification number that is unique to each instrument.

5.5.5 Equipment Records

Records are maintained of each item of equipment and its software significant to the tests or calibrations performed.

The records include at least the following items:

- Identity of the item of equipment and its software
- Manufacturer's name, type identification, and serial number or other unique identification
- Performance checks that equipment conforms to testing parameters and acceptance criteria
- Location of the equipment
- Manufacturer's instructions
- Dates, results and copies of reports and certificates of calibrations, adjustments, acceptance criteria, and the due date of next calibration
- Maintenance plan and maintenance carried out to date
- Any damage, malfunction, modification or repair to the equipment

5.5.6 Management of Equipment

The **AGENCY NAME** has a procedure for the safe handling, transport, storage, use and planned maintenance of measuring equipment to ensure proper functioning and to prevent contamination or deterioration.

5.5.7 Out of Service

Equipment that has been subjected to overloading or mishandling, gives suspect results, or has been shown to be defective or outside specified limits, is taken out of service. It is isolated and clearly labeled or marked as being "Out of Service" to prevent its use until it has been repaired and shown by calibration or test to perform correctly.

5.5.7.1 5.5.7.2 Retesting and Calibration **AGENCY NAME** personnel examine the effect of quality control analyses that indicate the defect or departure from specified limits on previous tests according to Section 4.9.

5.5.8 Calibration Status

Equipment under the control of the laboratory and requiring calibration is labeled or coded to indicate the calibration status, including the date when last calibrated and the date due for recalibration. Alternatively, equipment calibration status may be identified in an associated record to indicate the status of calibration.

5.5.9 Equipment Leaving the Laboratory

If for any reason equipment leaves the direct control of the laboratory, the function and calibration status of the equipment is checked upon return and shown to be satisfactory before the equipment is returned to service.

5.5.10 Calibration Confirmation

Intermediate calibration confirmation checks are performed to maintain confidence in the calibration status of the equipment. These checks are conducted according to the procedure in Section 5.9.

5.5.11 Correction Factors

Where calibrations give rise to a set of correction factors, these factors are communicated to users.

5.5.12 Safeguards

Test and calibration equipment, including both hardware and software, are safeguarded from adjustments that would invalidate the test or calibration results. Safeguards are provided using access control to the laboratory.

5.5.13 Related Procedures

Insert references to procedures that are specific to this section.

5.6 Measurement Traceability

5.6.1 General

AGENCY NAME equipment is calibrated before being placed into service, as scheduled and following repairs**.**

5.6.2 Specific Requirements

5.6.2.1 Calibration

5.6.2.1.1 Measurement Traceability The program for calibration of equipment demands that calibrations and measurements made by the laboratory are traceable to the International System of Units. The scheduling of calibration activities is defined in the technical methods manual of each analytical section.

AGENCY NAME analytical sections are to provide evidence of measurement traceability of its own measurement standards and measuring instrument to the SI. This is done by means of an unbroken chain of calibration or comparisons linking them to primary standards of the SI units of measurement. Such primary standards are those used by national measurement standards.

The measurement traceability to SI units may be achieved by measurements related to national measurement standards. National measurement standards may be used as primary standards that are primary realizations of the SI units or agreed representations of SI units. National measurement standards based on fundamental physical constants, or standards calibrated by another national metrological institute may be use as primary standards.

AGENCY NAME analytical sections are to provide documentation demonstrating measurement capability and competence to perform the calibration services.

5.6.2.1.2 Non-traceability of Reference Standards to SI Units Calibrations that cannot provide strict measurement traceability to SI units are conducted such that the calibration results can provide confidence in the measurements made in the course of the analyses. Traceability alternatives to SI units are described in the technical methods manuals of each analytical section.

5.6.2.1.3 Interlaboratory Comparisons The **AGENCY NAME** participates in the following national or international proficiency programs:

Insert the names of the proficiency testing programs

5.6.2.2 Testing

5.6.2.2.1 Testing and Calibration Activities The requirements of Subsection 5.6.2.1 are included in the **AGENCY NAME's** calibration program for equipment that has a significant contribution from its calibration to the total measurement uncertainty. Contributions are considered significant if they are greater than a fifth of the largest contributor.

The measurement of uncertainty is determined and recorded according to the procedures outlined in the technical methods manual of the individual analytical section.

Equipment that does not contribute appreciably to the total uncertainty of the test result is exempt from the activities described in Subsection 5.6.2.1.

5.6.2.2.2 Non-traceability to SI Units Where measurement traceability for testing and calibration activities to SI units is not possible, the policies stated in Subsection 5.6.2.1 are followed.

5.6.3 Reference Standards and Reference Materials

5.6.3.1 Reference Standards The laboratory calibrates its reference standards as described in the technical method manual of the individual analytical section.

The reference standards are used for calibration only.

5.6.3.2 Reference Materials A reference material is a homogenous and well characterized substance used for standardization of equipment used in the testing process. Reference materials are traceable to national or international standard reference materials (SRMs), such as National Institute of Standards and Technology (NIST), or certified reference materials (CRMs) from competent suppliers of reference materials.

The measurement integrity of internal reference materials generated by the laboratory is evaluated against either standard reference materials or certified reference materials from an independent source when it is technically and economically possible.

5.6.3.3 Intermediate Confirmation of Calibration Status Confirmation for reference standards and reference materials included in the calibration program is conducted according to a schedule addressed in the technical method manual of the individual analytical section. The confirmation is conducted to maintain confidence in the calibration status of reference standards and reference materials.

5.6.3.4 Transport and Storage The procedure found in the technical method manual of the individual analytical section**,** addresses the safe handling, transport, storage and use of reference standards and reference materials. These activities are established in order to prevent contamination, deterioration, and to protect the integrity of reference standards and reference materials.

5.6.4 Related Procedures
Insert references to procedures that are specific to this section.

5.7 Sampling Operations

5.7.1 Procedure
The **AGENCY NAME** does not routinely perform sampling in the sense of collecting a representative sample from a product lot to represent the whole.

Sample collection is the customer's responsibility. **AGENCY NAME** personnel may be consulted about sampling parameters such as sample type or size or guidance for a particular sampling or analytical need. The **AGENCY NAME**, however, exerts no direct control over such sampling and do not have responsibility for sampling.

Sampling conducted by **AGENCY NAME** personnel involves for the most part those analyses that call for a portion or aliquot of the total sample received by the laboratory to be analyzed. Generally, this calls for mixing or preparing of samples to assure homogeneity before portions are taken for analysis. Sample preparation and subsampling protocols are found in the analytical methods, compliance programs, and assignments.

5.7.2 Related Procedures
Insert references to procedures that are specific to this section.

5.8 Handling of Samples

5.8.1 Protection of Samples
The technical methods manual of each analytical section, describes the receipt, processing, protection, storage, retention and disposal of samples. This procedure addresses the laboratory activities conducted to protect sample integrity.

5.8.2 Identification of Samples
The **AGENCY NAME** has a system for uniquely identifying samples. The sample number is used to track its progress from the time the sample is collected in the field until the analysis is completed and the sample is disposed. The sample number is also used to provide traceability between the sample and the data. The numbering system also provides traceability during transfer of samples within the **AGENCY NAME**. The identification system is described in **AGENCY NAME** sample control manual.

5.8.3 Departures, Additions or Exclusions
Upon receipt of the sample, abnormalities or departures from normal or specified conditions, for example contract specifications, analysis requested, and chain of custody, are recorded according to the **AGENCY NAME** sample control manual.

When samples received do not meet established acceptance criteria laboratory personnel will consult the customer for further instructions before proceeding. Communication with the customer is documented.

5.8.4 Protection of Samples during Processing and Storage

The procedure in the **AGENCY NAME** sample control manual, provides the details for protecting test items from deterioration, loss or damage during storage and processing. The **AGENCY NAME** has arrangements for storage and security that protect the condition and integrity of samples. Sample security arrangements apply both in the laboratory and in the custodial areas.

5.8.4.1 Processing Instructions Handling instructions provided with the sample are followed, as well as the instructions in the **AGENCY NAME** sample control manual.

5.8.4.2 Monitoring of Environmental Conditions When samples are held under environmental conditions specified in the test method, those conditions are maintained, monitored and recorded. Monitoring records are collected according to established procedures. These activities are conducted according to the policies stated in Section 5.3.

5.8.5 Related Procedures

Insert references to procedures that are specific to this section.

5.9 Assuring the Quality of Test Results

5.9.1 Quality Control Procedures

The laboratory has quality control procedures to validate the results of tests undertaken.

The monitoring data is recorded in such a way that trends may be detected, for example, statistical process control charts. Monitoring activities are planned and evaluated. Monitoring techniques may include, but are not limited to, the following:

(a) Scheduled use of certified reference materials and internally generated reference materials
(b) Scheduled participation in interlaboratory comparison or proficiency-testing and calibration programs
(c) Replicate tests using the same or different methods
(d) Retesting of reference materials and retained customer samples
(e) Correlation of results from tests conducted for different characteristics of a sample

5.9.2 Quality Data Criteria

The **AGENCY NAME** has defined the criteria for quality control data and performs analysis by such means as control charting. When data is found to be outside the established criteria, action is taken in accordance with the laboratory's control of non-conforming work procedure.

5.9.3 Related Procedures

Insert references to procedures that are specific to this section.

5.10 Reporting the Results

5.10.1 General

Examination reports will be distributed in accordance with the **AGENCY NAME** document format and dissemination policies. These procedures give the details for reporting data using consistent reporting formats for laboratory worksheets. Reports are reviewed against acceptance criteria that address accuracy, clarity and objectivity.

5.10.2 Reporting Results

An examination report will be generated for every sample submitted for analysis. The report will accurately reflect the results of the analysis perform on each item. If no examination was performed on a sample the report will reflect that the sample was receive and not analyzed.

5.10.3 Additional Requirements for Worksheets

5.10.3.1 Specific Requirements The following information is included in test reports for the interpretation of the test results:

(a) Deviations from, additions to, or exclusions from the test method, and information on test conditions, such as environmental conditions
(b) A statement of conformance or non-conformance with specifications
(c) A statement of the estimated uncertainty of measurement when a customer requests it
(d) Opinions and interpretations as detailed in Section 5.10.5
(e) Additional information that may be requested by methods, customers or groups of customers

5.10.3.2 Sampling Results In addition to the instructions listed in Sections 5.10.2 and 5.10.3.1, sampling information will be incorporated into the report if sampling was part of the services performed.

5.10.4 Calibration Certificates

The **AGENCY NAME** does not conduct calibration activities and, therefore, do not issue calibration certificates.

5.10.5 Opinions and Interpretations

The **AGENCY NAME** management expresses its opinion and interpretation of the compliance or non-compliance of the results through the laboratory classification assigned to each sample.

5.10.6 Testing Results Obtained from Subcontractors

Subcontracting laboratories are not utilized by the **AGENCY NAME**, therefore, there is no such data found for incorporation in the analysis report to the customer.

5.10.7 Electronic Transmission of Results

In the case of transmission of test or calibration results by telephone, facsimile or other electronic means, such transmission is conducted under conditions that meet the criteria of Subsection 5.4.7.

5.10.8 Format of Worksheets

The format for laboratory worksheets is designed to accommodate the type of test conducted to minimize the possibility of misunderstanding or misuse. The worksheet format is described in the technical methods manual of the individual analytical sections.

5.10.9 Amendments to Worksheet

Material amendments to analytical findings after issue are made only in the form of an additional document. They are flagged "Additional Analyses" in accordance with procedure of the technical methods manual of the individual analytical sections.

5.10.10 Related Procedures

Insert references to procedures that are specific to this section.

6 Document History

Rev. #	Issue Date	Description of Changes
01	01/01/2009	Original Document

End of Document

Appendix F

Emergency Equipment Inspection Form

Date	Section	
Emergency Lighting	**Functional Yes/No**	**Comments**
Emergency Light 1		
Emergency Light 2		
Emergency Light 3		
Emergency Light 4		
Emergency Exit Light 1		
Emergency Exit Light 2		
Emergency Exit Light 3		
Emergency Exit Light 4		
Fire Extinguisher Location	**Functional Yes/No**	**Comments**
Fire Extinguisher 1		
Fire Extinguisher 2		
Fire Extinguisher 3		
Fire Extinguisher 4		
First Aid Kit	**Adequate Supplies Yes/No**	**Comments**
First Aid Kit		

Eye Wash Station Location	Functional Yes/No	Station Flushed	Comments
Eye Wash Station 1			
Eye Wash Station 2			
Eye Wash Station 3			
Eye Wash Station 4			
Emergency Shower Location	**Functional Yes/No**	**Station Flushed**	**Comments**
Emergency Shower 1			
Emergency Shower 2			
Emergency Shower 3			
Emergency Shower 4			

Emergency Equipment Inspection Completed

Unit Health and Safety Coordinator	**Date**
Health and Safety Program Manager	**Date**

Name	Title

Health and Safety Manual Orientation

Item	Trainee's Initials	Date Completed	Trainer's Initials	Date Reviewed
Health and Safety Manual Issued				
Safety Responsibility and Authority (Read/Reviewed)				
Safety Practices and Procedures (Read/Reviewed)				
Occupant Emergency Plan (Read/Reviewed)				
Personal Protective Equipment (Read/Reviewed)				
Blood borne Pathogen Exposure and Control (Read/Reviewed)				
Chemical Hygiene Plan (Read/Reviewed)				
Hazardous Waste Disposal (Read/Reviewed)				
Spill Control and Containment (Read/Reviewed)				
Laboratory Fume Hoods (Read/Reviewed)				
Ergonomics and Office Safety (Read/Reviewed)				
Forms (Read/Reviewed)				

Orientation / Training Successfully Completed

Supervisor	Date
Quality Assurance Manager	**Date**

Name	Title

Health and Safety Manual Review Checklist

Year	Item	Trainee Initials	Trainer Initials	Date Completed
	Reading the Safety Manual			
	Emergency procedures and exits			
	Emergency equipment and location			
	Emergency spill clean up			
	Bloodborne pathogen training, consent/ decline form			
	Reviewing content and location of MSDSs for their respective unit			
	Employee Signature/Date			
	Safety Officer Signature/Date			

Year	Item	Trainee Initials	Trainer Initials	Date Completed
	Reading the Safety Manual			
	Emergency procedures and exits			
	Emergency equipment and location			
	Emergency spill clean up			
	Bloodborne pathogen training, consent/decline form			
	Reviewing content and location of MSDSs for their respective unit			
	Employee Signature/Date			
	Safety Officer Signature/Date			

Hazardous Waste Disposal Log

Container #	Generator	Waste Type	Waste Category	Amount	Date Generated	Date Disposed

Waste Stream Information Form

Container #

Generator Information

Name		Date
Unit	**Room**	**Phone**

Waste Category

☐ Ignitable	☐ Corrosive	☐ Reactive	☐ Toxic	☐ Non-Hazard

Waste Type

☐ Solid	Weight gm	☐ Liquid	Volume ml
☐ Organic		☐ Aqueous	pH
☐ Inorganic		☐ Organic	☐ Flammable
☐ Carcinogen	☐ Mutagen		☐ Hydrocarbons
☐ PCBs	☐ Radioactive		☐ Halogenated
☐ Explosive	☐ Other		☐ Peroxide Forming

	Components	**Estimated % of Total**
1		
2		
3		
4		
5		
6		
7		
8		
9		
10		
11		
12		
13		
14		
15		
	TOTAL (Should = 100%)	

Ready for Disposal

Generator	**Date**
Health and Safety Program Manager	**Date**

RESPONSIBILITY AND AUTHORITY

General Responsibility

1 PURPOSE

This document defines the **AGENCY NAME's** general health and safety responsibility policy.

2 SCOPE

This policy applies to all **AGENCY NAME** personnel.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

The **AGENCY NAME** will establish and maintain a healthy and safe work environment.

The **AGENCY NAME** will establish and maintain a Health and Safety Manual that will be define the health and safety policies and procedures.

All **AGENCY NAME** personnel are responsible for complying with the health and safety policies and procedures established by the **AGENCY NAME**.

All **AGENCY NAME** personnel will notify **AGENCY NAME** senior management about health and safety risks and issues as soon as they are recognized.

The **AGENCY NAME** will act upon all health and safety risks and issues as soon as they are notified about their existence.

5 PROCEDURE

There are no procedures that are directly applicable to this policy.

6 APPROVAL

The signatures below recognize the above Administrative Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

RESPONSIBILITY AND AUTHORITY

Authority

1 PURPOSE

This document defines the **AGENCY NAME's** general health and safety authority policy.

2 SCOPE

This policy applies to all **AGENCY NAME** personnel.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

The authority to implement and enforce health and safety policies and procedures follows the established line of supervision, from Assistant Director, through management, to the employee.

4.1 ASSISTANT DIRECTOR

The Assistant Director's authority and responsibilities include:

- Provide the leadership and management to ensure that safe working conditions are maintained in the laboratory.
- Ensure that a system is in place to monitor compliance with mandated safety programs.
- Appoint a Health and Safety Program Manager.

4.2 SECTION CHIEFS

The Section Chief's authority and responsibilities include:

- Provide the leadership and management to ensure that safe working conditions are maintained in the section.
- Ensure that personnel within the section attend scheduled training.

4.3 UNIT CHIEFS

The Unit Chief's authority and responsibilities include:

- Ensure that unit personnel annually review the Health and Safety Manual.
- Documentation of this review will be maintained by the unit.
- Maintain safety awareness and encourage the use of safe work practices.

- Provide the necessary personal protective equipment and ensure that it is used by the employees.
- Ensure that employees attend all applicable safety training.
- Correct safety deficiencies in a timely manner.
- Schedule new employees to be included in scheduled safety training.
- Appoint a Unit Health and Safety Coordinator.

4.4 SUPERVISORS

The Supervisor's authority and responsibilities include:

- Safety of the employees under their supervision.
- Ensuring that employees are properly trained to perform laboratory procedures and related duties in a safe manner.
- Ensure that the mandatory safety practices described in this manual are followed.

When necessary, the Unit Chief will assist the supervisor in controlling and correcting unsafe work practices.

4.5 HEALTH AND SAFETY PROGRAM MANAGER

The Health and Safety Program Manager's authority and responsibilities include:

- Establish and maintain occupational health and safety programs.
- Promote laboratory safety by providing consultation, training, and exposure monitoring when necessary.
- Develop and implement chemical hygiene policies and practices.
- Act as the **AGENCY NAME** resource for information on chemicals and chemical products.
- Develops and implements policies and practices for the handling and disposal of hazardous chemicals and materials.
- Ensures compliance with hazardous waste and related environmental regulations.
- Ensuring compliance with the relevant guidelines, regulations and standards concerning the use and handling of radioactive materials.

4.6 UNIT HEALTH AND SAFETY COORDINATOR

The Unit Health and Safety Coordinator's authority and responsibilities include:

- Serve as a liaison on health and safety issues.
- Ensures unit compliance with applicable environmental and occupational health and safety regulations.
- Serves as a representative on the Environmental and Occupational Health and Safety Committee.

4.7 EMPLOYEES

The Employee's authority and responsibilities include:

- Comply with the practices and procedures described in this manual and safety practices found in unit protocols or procedures.
- Maintain a safe workplace for themselves and their coworkers.

5 PROCEDURE

There are no procedures that are directly applicable to the implementation of this policy.

6 APPROVAL

The signatures below recognize the above Health and Safety Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

SAFETY PRACTICES

Awareness

1 PURPOSE

This document defines the **AGENCY NAME's** safety policy concerning awareness.

2 SCOPE

This policy applies to all **AGENCY NAME** personnel.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

Employees will:

- Determine potential hazards with all operations and observe all safety rules and procedures that apply.
- Be aware of the routes of exposure (inhalation, ingestion, skin contact, and injection) and recommended protective measures.
- Be familiar with the procedures for reporting injuries and exposures.
- Be alert to unsafe conditions and actions and call attention to them so that corrections can be made.
- Be encouraged to report unsafe or unhealthy work conditions.
- Have the right to examine and obtain a copy of their medical records and any chemical or biological exposure records.
    - Employee medical records will be maintained for 30 years.
    - Employees may obtain a copy of their records by submitting a written request that includes their name, social security number, service dates and signature.
- Think, act, and practice safety until it becomes a habit.

5 PROCEDURE

There are no procedures that are directly applicable to the implementation of this policy.

6 APPROVAL

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SAFETY PRACTICES

Eating and Drinking

1 PURPOSE

This document defines the **AGENCY NAME's** safety policy concerning eating and drinking.

2 SCOPE

This policy applies to all **AGENCY NAME** personnel.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

The Director of the **AGENCY NAME** will designate authorized eating and drinking areas.
It is prohibited to:

- Eat, drink, smoke, chew gum or apply cosmetics in areas where: chemicals, blood or other potentially infectious materials are present; or where evidence, that may be contaminated with chemicals, blood or other potentially infectious materials, is opened for examination.
- Store food and drink in refrigerators, freezers, shelves, cabinets or on countertops or bench tops where:
  - Chemicals, blood or other potentially infectious materials are present; or
  - Where evidence, that may be contaminated with chemicals, blood; or
  - Other potentially infectious materials are present.
- Handle or consume food or beverages out of glassware or utensils which are also used for laboratory operations.
- Wear lab coats in designated eating and drinking areas or in areas outside the laboratory space, except if there is a need to deliver or receive evidence.

Food and drink must be covered while carrying these items through designated laboratory space to designated eating and drinking areas.

5 PROCEDURE

There are no procedures that are directly applicable to the implementation of this policy.

6 APPROVAL

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SAFETY PRACTICES

Personal Hygiene

1 PURPOSE

This document defines the **AGENCY NAME's** safety policy concerning personal hygiene.

2 SCOPE

This policy applies to all **AGENCY NAME** personnel.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

All employees should:

- Never place personal effects where they may become contaminated with chemical or biological materials.
- Avoid touching the mouth or face with contaminated hands or gloves.
- Avoid contaminating clean surfaces such as drinking fountain handles, telephones, door knobs, and water faucets.
  - When appropriate, wash hands before eating, drinking, applying cosmetics or conducting any activities outside of designated laboratory space.
  - Wash hands thoroughly after removing gloves and prior to leaving the laboratory.
- Never pipette by mouth.
  - A pipette bulb, aspirator, or other mechanical device should be used to provide a vacuum.
- Never launder contaminated lab coats or other personal protective clothing at home.

5 PROCEDURE

There are no procedures that are directly applicable to the implementation of this policy.

6 APPROVAL

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SAFETY PRACTICES

Personal Protective Equipment

1 PURPOSE

This document defines the **AGENCY NAME's** safety policy concerning personal protective equipment.

2 SCOPE

This policy applies to all **AGENCY NAME** personnel.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

All employees should:

- Be familiar with the types of PPE for each procedure and its proper use.
- Wear eye protection in the laboratory whenever there is reasonable probability.
- Wear appropriate gloves when handling biological, chemical, other hazardous materials, and when there is a reasonable probability that evidence may be contaminated with these materials.
- Wear lab coats when working with or handling biological, chemical, other hazardous materials, and when there is a reasonable probability that evidence may be contaminated with these materials.
- Not wear open-toed shoes where biological or chemical hazards are present.

5 PROCEDURE

There are no procedures that are directly applicable to the implementation of this policy.

6 APPROVAL

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SAFETY PRACTICES

Biological Safety

1 PURPOSE

This document defines the **AGENCY NAME's** safety policy concerning biological safety.

2 SCOPE

This policy applies to all **AGENCY NAME** personnel.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

Employees will use Universal Precautions when handling biological materials.

5 PROCEDURE

There are no procedures that are directly applicable to the implementation of this policy.

6 APPROVAL

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SAFETY PRACTICES

Chemical Safety

1 PURPOSE

This document defines the **AGENCY NAME's** safety policy concerning chemical safety.

2 SCOPE

This policy applies to all **AGENCY NAME** personnel.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

Employees will:

- Know the location of Material Safety Data Sheets and how to interpret them.
- Be aware of incompatible materials.
- Be aware of the hazardous properties of the chemicals being used and recommended protective measures.
- Use a chemical fume hood for procedures involving carcinogens and hazardous materials.
- Conduct any potentially reactive experiment behind a safety shield inside a fume hood.
- Use bottle carriers when transporting glass containers of flammable or hazardous materials.
- Clean-up of all chemical spills in their unit.
  - Custodial personnel will not to clean chemical spills.
- Handle lacrimators (tear producers) or materials with offensive odors in a manner that prevents release into the laboratory environment, sewer systems, or trash receptacles.
- Write the date opened on the label of chemicals that- may form peroxides prior to opening the container.
- Not deface or remove the labels on hazardous chemical containers.
  - Any container used for the overnight storage of chemicals must be labeled with the identity of the material and hazard warnings associated with its handling.
- Combine reagents in the appropriate sequence to avoid violent reactions.
  - Avoid adding solids to hot liquids.
  - Pour more concentrated solutions into less concentrated solutions.
- Secure gas cylinders upright during use and storage.
  - Remove regulators and install cylinder caps before moving cylinders.

5 PROCEDURE

There are no procedures that are directly applicable to the implementation of this policy.

6 APPROVAL

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SAFETY PRACTICES

House Keeping

1 PURPOSE

This document defines the **AGENCY NAME's** safety policy concerning house keeping.

2 SCOPE

This policy applies to all **AGENCY NAME** personnel.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

Employees will:

- Keep their work area clean and orderly.
  - Floors, shelves, and tables should be free from dirt and general clutter.
- Not block access to eyewashes, safety showers and other emergency equipment.
- Flush eyewash stations for at least three minutes on a weekly basis.
- Keep all materials at least 18 inches from fire sprinkler heads.
- Keep the hood free of clutter.
  - Hoods should not be used for storage.
  - Only equipment and chemicals in use should be in the hood.
- Place equipment back from the edge of the lab bench to minimize injury from accidental bumping.
- Check their work area to ensure that heating devices are turned off and chemicals are properly stored before leaving the work area for the day.

5 PROCEDURE

There are no procedures that are directly applicable to the implementation of this policy.

6 APPROVAL

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SAFETY PRACTICES

Fire Prevention

1 PURPOSE

This document defines the **AGENCY NAME's** safety policy concerning fire prevention.

2 SCOPE

This policy applies to all **AGENCY NAME** personnel.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

In the event of a fire employees will notify the unit coordinator, notify other nearby occupants and evacuate.

In case of fire, personnel are expected to immediately exit the building.

Fire extinguishers will be provided in the each laboratory and other occupied area as require by the local fire code.

Employees trained in proper use of fire extinguishers may use one if required.

- The improper use of a fire extinguisher may make the problem worse and the extinguishers have a very limited capacity (i.e., for small fires).

5 PROCEDURE

There are no procedures that are directly applicable to the implementation of this policy.

6 APPROVAL

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SAFETY PRACTICES

Emergency Procedures

1 PURPOSE

This document defines the **AGENCY NAME's** safety policy concerning emergency procedures.

2 SCOPE

This policy applies to all **AGENCY NAME** personnel.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

Employees will:

- Report the location, nature, and extent of the fire should be related to security personnel.
- Stay out of the fire or emergency area unless required to provide assistance.
- Know the evacuation route from each work area and follow emergency evacuation procedures when notified to evacuate.
- Know the location of emergency equipment and how it is operated.
- Become familiar with the procedures needed to obtain help in an emergency.

5 PROCEDURE

There are no procedures that are directly applicable to the implementation of this policy.

6 APPROVAL

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SAFETY PRACTICES

Waste Disposal

1 PURPOSE

This document defines the **AGENCY NAME's** safety policy concerning waste disposal.

2 SCOPE

This policy applies to all **AGENCY NAME** personnel.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

Employees will:

- Dispose of all chemical, biological, and other hazardous material wastes in accordance with laboratory procedures.
- Dispose of sharp objects in a safe manner.
  - Scalpel blades, hypodermic needles, broken glass and syringes must be placed in designated puncture-resistant containers.
  - Never put broken glass, scalpel blades, or other sharp objects in the regular trash.
- Place uncontaminated broken glass in properly labeled glassware receptacles.
- Dispose of chemicals that may form peroxides upon storage within 90 days (three months) of opening.

5 PROCEDURE

There are no procedures that are directly applicable to the implementation of this policy.

6 APPROVAL

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SAFETY PRACTICES

Miscellaneous

1 PURPOSE

This document defines the **AGENCY NAME's** safety policy concerning miscellaneous safety practices.

2 SCOPE

This policy applies to all **AGENCY NAME** personnel.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

First aid kits shall be readily accessible and available in each unit.

Warning signs shall be posted where hazards such as radiation, laser operations, flammable materials, or biological hazards exist.

Laboratory equipment shall only be used for its designed purpose.

Work-related illnesses and injuries reported in an expeditious manner.

Children shall not enter the laboratory work areas where exposure to chemical and biological hazards may be encountered.

Custodial staff, maintenance personnel or visitors shall not be unnecessarily exposed to chemical, biological, or physical hazards.

5 PROCEDURE

There are no procedures that are directly applicable to the implementation of this policy.

6 APPROVAL

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OCCUPANT EMERGENCY PLAN

Guidelines

1 PURPOSE

This document defines the **AGENCY NAME's** occupant emergency plan guidelines.

2 SCOPE

This policy applies to all **AGENCY NAME** personnel.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

The Occupant Emergency Plan (OEP) is in place to ensure that all employees and visitors can safely evacuate the facility in a fire or other emergency.

When employees are notified that an emergency exists, they must immediately move to their assigned meeting location.

The Director of the **AGENCY NAME** shall appoint an Emergency Warden and appropriate personnel to act as Area Emergency Wardens and Unit Coordinators.

- The Emergency Warden will be responsible for maintaining the complete written emergency plan.
- The Emergency Warden will be responsible for the supervision of the OEP.
- Other duties will include planning, supervising, and expediting the organized and controlled movement of all building occupants in the event of an emergency.

Supervisors will ensure that new or transferred employees review the OEP upon reporting for duty. This review should be documented.

Employees should know who their Area Emergency Warden and Unit Coordinators are and be familiar with the emergency exits.

Fire drills are conducted periodically to ensure such familiarity with the OEP.

5 PROCEDURE

There are no procedures that are directly applicable to the implementation of this policy.

6 APPROVAL

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OCCUPANT EMERGENCY PLAN

Emergency Coordinators

1 PURPOSE

This document defines the **AGENCY NAME's** occupant emergency plan emergency coordinator responsibilities.

2 SCOPE

This policy applies to all **AGENCY NAME** personnel.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

4.1 EMERGENCY WARDEN

The Emergency Warden is responsible for supervising the planned and controlled movement in an emergency of all personnel and visitors assigned to **AGENCY NAME**.

The Emergency Warden's general duties include:

- Assuring that evacuation routes are clearly identified and known to the regular occupants in their section of the building.
- Assuring the evacuation procedures are known to all regular occupants.
- Making the decision to evacuate the space and issue the order to evacuate.
- Directing the orderly flow of personnel, during drills or actual emergencies, along the prescribed evacuation routes.
- Assuring that visitors and support personnel are evacuated in an emergency.
- Establishing a new route of evacuation if a bomb or suspicious item is discovered along the normal route of evacuation.
- Appointing a column leader to lead personnel along the prescribed routes to a pre-designated location outside the building.
- Coordinating the activities of the area wardens, stairwell monitors, elevator monitors, and disabled persons monitors.
- Assuring that all personnel know the location of fire alarms.
- Maintaining a current roster of personnel and their respective evacuation assignments.
  - The current roster will be posted in a common area employee review.
- Maintaining a list of the location of disabled individuals or individuals who may require assistance during and emergency evacuation.
- Reporting to the Command Center after the evacuation of their area has been completed.

4.2 AREA EMERGENCY WARDENS

Area Emergency Wardens are responsible for the training of personnel, readiness of emergency equipment, and orderly execution of the emergency plan in their departments or areas. They are specifically responsible for the assignment and training of all monitors and alternates in their area.

The Area Emergency Warden's general duties include:

- Performing all the general duties as described under Section 3.2.1 for the Emergency Warden.
- Assisting the Emergency Warden as needed to carry out the OEP.

4.3 UNIT COORDINATORS

One primary coordinator and one alternate person shall be designated for each unit. Unit Coordinators shall assist their Area Emergency Warden in training of personnel, readiness of emergency equipment, and maintaining current lists of monitors and alternates in their unit or assigned area.

The Unit Coordinator's general duties include:

- Reporting to the Emergency Warden.
- Coordinating all pertinent evacuation procedures within their assigned space as described under Section 3.2.1.
- Being familiar with any hazardous materials in their assigned space.
- The accountability of all employees and visitors in their assigned space.
- That all proper security procedures, as outlined in the OEP, are followed in their assigned space during an evacuation.
- Reporting all fire, explosion, and other hazardous conditions to the Emergency Warden (or Area Emergency Warden in their absence).
- Emergency procedures:
  - Activate the closest fire alarm pull station, advise security, with the exact location and nature of the emergency, and evacuate the immediate area.
- Non-emergency procedures:
  - Immediately contact the Division Emergency Warden before an evacuation decision is made.
- Assisting Area Emergency Wardens in training of all new and transferred employees as to the OEP.
- Maintain a roster of employees in their area of responsibility.
- Conducting periodic checks of fire extinguishers and other safety related items in the covered area including exit signs, emergency lights, and egress paths to exits.
- Contacting the appropriate parties when deficiencies are identified.

5 PROCEDURE

There are no procedures that are directly applicable to the implementation of this policy.

6 APPROVAL

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End of Document

OCCUPANT EMERGENCY PLAN

Emergency Evacuation Procedure

1 PURPOSE

This document defines the **AGENCY NAME's** occupant emergency plan emergency evacuation Procedure.

2 SCOPE

This policy applies to all **AGENCY NAME** personnel.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

The AGENCY NAME will establish an emergency evacuation procedure.

5 PROCEDURE

Employees will evacuate the area to the nearest stairwell when a life-threatening fire or emergency occurs.

- DO NOT USE ELEVATORS.
- Activate the alarm station upon your egress to the stairwell.
- When safe to do so, immediately notify security of the room, nature, and the extent of the emergency.

When the Fire Alarm System has been activated, all employees are to immediately evacuate the building and go to their outside meeting place.

Wardens, monitors, coordinators, and/or alternates are to perform their duties as described below:

- Insert duties

6 APPROVAL

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PERSONAL PROTECTIVE EQUIPMENT

General Guidelines

1 PURPOSE

This document defines the **AGENCY NAME's** personal protective equipment general guidelines.

2 SCOPE

This policy applies to all **AGENCY NAME** personnel.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

Personal protective equipment (PPE) is an important element in minimizing the potential for chemical or biological exposure.
Unit Chiefs and supervisors are responsible for ensuring that appropriate PPE is:

- Readily available.
- Used by employees when necessary.
- Maintained in a reliable condition. This includes, but is not limited to, gloves, lab coats, disposable coveralls or jumpsuits, eye and face protection, aprons and shoe covers or rubber boots, as appropriate.
- Ensure that PPE is repaired or replaced as needed to maintain its effectiveness.

PPE will not be worn in designated eating and drinking areas or in areas outside the laboratory, except if there is a need to deliver or receive evidence.

29 CFR 1910.132 will serve as the basis for the selection and use of personal protective equipment.

5 PROCEDURE

There are currently no procedures that directly impact the implementation of this policy.

6 APPROVAL

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PERSONAL PROTECTIVE EQUIPMENT

Eye and Face Protection

1 PURPOSE

This document defines the **AGENCY NAME's** personal protective equipment eye and face protections guidelines.

2 SCOPE

This policy applies to all **AGENCY NAME** personnel.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

Eye protection will be worn in the laboratory whenever there is the potential hazard of flying objects; splashing or spraying of chemicals, biological materials, or liquids; injurious radiation; or other injury to the eyes.

- This also applies to managers, supervisors, and visitors while they are in hazardous work areas.

Unit Chiefs and supervisors are responsible for enforcing the eye protection policy and for ensuring that appropriate eye protection is readily available and used by employees and visitors.

Eye protection should be selected based on the type and degree of the hazard encountered. Eye protection will meet the approval of the American National Standards Institute (ANSI) Z87.1-1989 requirements.

Safety glasses	For most laboratory work, safety glasses with side shields are adequate.
Safety goggles	Safety goggles are required where there is potential for splashing of chemicals or biological materials, or flying objects.
Face shields	Face shields are secondary protection only and must be worn in combination with safety glasses or goggles to provide full face protection.
Corrective lenses	Prescription eyeglasses may not provide adequate protection from injury to the eyes when working in the laboratory. Laboratory employees whose vision requires the use of corrective lenses must wear either prescription safety glasses with protective lenses or safety eyewear that can be worn over prescription glasses without disturbing the adjustment of the glasses.

UV eye protection	UV protective safety goggles or a face shield should be worn when using UV transilluminators.
Laser protective eyewear	Laser protective eyewear (e.g., goggles, face shields) using special filtered or reflective coatings or a combination of both must be worn when working with high powered lasers such as the Class IV Argon Laser. Laser safety eyewear must meet the requirements of the ANSI Z-136 Standard.
Contact lenses	Note: Contact lenses alone do not provide adequate eye protection. Therefore; eye protection must be chosen that fits snugly over the eyes and around the face.

29 CFR 1910.133 will serve as the basis for the selection and use of eye and face protection.

5 PROCEDURE

There are currently no procedures that directly impact the implementation of this policy.

6 APPROVAL

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PERSONAL PROTECTIVE EQUIPMENT

Protective Clothing

1 PURPOSE

This document defines the **AGENCY NAME's** personal protective equipment protective clothing guidelines.

2 SCOPE

This policy applies to all **AGENCY NAME** personnel.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

Lab coats will be worn when working with or handling biological, chemical or other hazardous materials.

A plastic or rubber apron may be worn over protective garments to provide additional protection against irritating and corrosive materials.

All protective clothing should be removed immediately when penetrated with hazardous chemicals.

5 PROCEDURE

There are currently no procedures that directly impact the implementation of this policy.

6 APPROVAL

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PERSONAL PROTECTIVE EQUIPMENT

Hand Protection

1 PURPOSE

This document defines the **AGENCY NAME's** personal protective equipment hand protection guidelines.

2 SCOPE

This policy applies to all **AGENCY NAME** personnel.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

Gloves will be worn when working with chemicals that are:

- Strong oxidizers
- Organic solvents
- Corrosive to skin
- Mutagenic
- Teratogenic
- Acutely toxic

Gloves will also be worn when working with any biohazard material such as: human blood, body fluids, or tissues or when physical injury is possible.

Gloves will be removed before touching objects in common areas, such as door knobs, light switches, or telephones.

Hands will be washed immediately after removing the gloves.

Glove selection will be based upon the chemical, biological, or physical hazards that will be encountered.

The following will be considered in the selection and use of gloves:

- Chemical permeation and degradation guides are available from glove manufacturers which provide information regarding the types of gloves required for various chemicals.
- All chemicals in a mixture.
- Chemical properties and the potential consequences of skin contact.
- The physical properties required of the glove necessary for the procedure.
    - Other considerations include glove length, thickness, and the use of liners to absorb moisture and reduce irritation.

Prior to donning plastic or rubber gloves:

- Check for imperfections, cracks, or pinholes.
- Remove all sharp jewelry that may pierce the glove.

29 CFR 1910.138 will serve as the basis for the selection and use of hand protection.

5 PROCEDURE

There are currently no procedures that directly impact the implementation of this policy.

6 APPROVAL

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PERSONAL PROTECTIVE EQUIPMENT

Foot Protection

1 PURPOSE

This document defines the **AGENCY NAME's** personal protective equipment foot protection guidelines.

2 SCOPE

This policy applies to all **AGENCY NAME** personnel.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

Employees are required to wear protective footwear, which completely covers and protects the foot, in areas where foot hazards are present.

Open-toed shoes should not be worn where biological or chemical hazards are present.

Foot hazards may be encountered:

- In areas where heavy or sharp objects may fall on or roll over the foot
- Where objects may pierce the sole of the shoe
- Where pallet carts and lift trucks are used
- At major crime scenes where a variety of physical hazards may be encountered

Unit Chiefs and supervisors are responsible for ensuring that safety shoes are available and used by unit employees who require them.

29 CFR 1910.136 will serve as the basis for the selection and use of foot protection.

5 PROCEDURE

There are currently no procedures that directly impact the implementation of this policy.

6 APPROVAL

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PERSONAL PROTECTIVE EQUIPMENT

Head Protection

1 PURPOSE

This document defines the **AGENCY NAME's** personal protective equipment head protection guidelines.

2 SCOPE

This policy applies to all **AGENCY NAME** personnel.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

Employees will wear head protection (hard hats) at major crime scenes where a variety of physical hazards may be encountered.

All head protection should meet or exceed the ANSI Z98.1-1986 requirement for impact and penetration resistance, as well as, meet appropriate voltage protection requirements.

29 CFR 1910.135 will serve as the basis for the selection and use of head protection.

5 PROCEDURE

There are currently no procedures that directly impact the implementation of this policy.

6 APPROVAL

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PERSONAL PROTECTIVE EQUIPMENT

Hearing Protection

1 PURPOSE

This document defines the **AGENCY NAME's** personal protective equipment hearing protection guidelines.

2 SCOPE

This policy applies to all **AGENCY NAME** personnel.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

Employees will utilize hearing protection during operations which may contribute to hearing loss.

Note: Operations or areas where conversation is difficult to hear when the speaker and listener face each other at a distance of two feet is considered suspect for the need of hearing protection.

Unit Chiefs and supervisors should advise the Assistant Director, of operations or areas where they suspect that hearing protection may be needed.

5 PROCEDURE

There are currently no procedures that directly impact the implementation of this policy.

6 APPROVAL

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PERSONAL PROTECTIVE EQUIPMENT

Respiratory Protection

1 PURPOSE

This document defines the **AGENCY NAME's** personal protective equipment respiratory protection guidelines.

2 SCOPE

The Respiratory Protection Program (RPP) applies to all employees who work in areas or perform tasks that may result in the exposure to airborne contaminants that require the use of respirators.

This program is designed to achieve and maintain compliance with 29 CFR 1910.134.

The RPP will be developed as a tiered program consisting of three phases.

- Phase 1 establishes the respiratory protection requirements and procedures.
- Phase 2 will include an assessment to identify work areas and functions where respiratory hazards may exist, with subsequent monitoring to determine if respirators are required.
- Phase 3 will be the provision of training for personnel in the proper selection and use of respirators.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

The AGENCY NAME will attempt to protect employees from exposure to contaminated air through the use of accepted engineering controls, such as ventilation, confinement of the operation, and substitution by a less hazardous substance.

Respirators will be used in emergency situations or when attempts to eliminate the hazard have been ineffective.

Employees will be aware that respirators have their limitations and are not a substitute for effective engineering controls or laboratory practices.

Employees covered under this program will use and maintain the respiratory equipment in accordance with the procedures outlined in this section.

4.1 MEDICAL EVALUATION

All employees will receive a medical evaluation prior to wearing a respirator.

- Employees will not be assigned tasks requiring the use of respirators unless it has been determined that they are physically able to perform the work while wearing a respirator.
- The medical status of the respirator user will be reviewed periodically as determined by the examining physician.

- A written report must be signed by the physician stating whether or not an employee is cleared to wear the selected respirator selected while performing their duties.
- The health care professional conducting the medical evaluation will complete a written report stating the evaluation results.
- The subsequent medical report will be maintained in accordance with section 4.8.8.

29 CFR 1910.134 and Appendix C outline the medical requirements for employee respirator use.

4.2 RESPONSIBILITIES

4.1.1 Assistant Director/Section Chief

The Assistant Director has the ultimate responsibility for the implementation and enforcement of all respiratory protection policies and procedures.

4.2.2 Unit Chief

The Unit Chief is responsible for:

- Identifying the hazards that require respiratory protection.
- Enforcing the use of respiratory protection in the areas where it is required.
- Ensuring that employees are aware of the respiratory requirements for the areas in which they work.
- Maintaining a work environment that ensures the protection for employees.
    - He may appoint an individual within the unit to act as the unit's RPP Coordinator (RPPC).

4.2.3 Occupational Health and Safety (OHS) Program Manager

The OHS Program Manager serves as the RPP administrator and is responsible for:

- The direction and scope of the program.
- Ensuring that the RPP complies with all applicable respiratory protection requirements and will issue guidelines and directives that initiate and update the program.
- Assisting the RPPC in implementing this program.

The OHS Program Manager will periodically evaluate program effectiveness by coordinating random audits of the RPP to ensure that employees have received appropriate training, and to ensure that respirators are properly selected, used, cleaned, and maintained.

The OHS Program Manager will periodically monitoring of laboratory operations where respiratory hazards may be present and advise the unit of potential hazards from current or proposed processes or operations.

4.2.4 Respiratory Protection Program Coordinator (RPPC)

The Unit Chief will appoint a Respiratory Protection Program Coordinator (RPPC) in units where respiratory protection is required.

The RPPC will have the authority to implement all aspects of the respiratory program within the unit.

The RPPC will receive specialized training in respiratory protection in order to be fully knowledgeable of the requirements and responsibilities associated with the RPP and have a complete working knowledge of the respirators assigned to their particular unit.

The RPPC will be responsible for:

- Preparing written plans for routine and emergency use of respirators.
- Ensuring that each employee assigned respiratory protective equipment is properly fitted and instructed in its use; and
- Cleaning, maintaining and storing all respirators not routinely used or not individually assigned. The written plans will include all information and guidance necessary for proper selection, use, care, and maintenance of the respirators.
- Maintaining fit test and training records for all unit personnel included in the respiratory program.
- Coordinating respirator selection and evaluation with the OHS Program Manager.

4.2.5 Employees

Employees will minimizing the use of hazardous chemicals and for utilize accepted engineering controls, such as ventilation, confinement of the operation, and substituting less hazardous substances, when possible.

Employees will use respiratory protective equipment when required and to follow established RPP practices and procedures when engineering controls are not possible or ineffective.

Each employee is responsible for cleaning, maintenance and storage of their assigned non-disposable respirators.

Employees will immediately notify the Unit Chief, RPPC and/or the OHS Program Manager of any conditions that may result in personal injury or illness.

4.3 HAZARD ASSESSMENT

The OHS Program Manager will coordinate a hazard assessment of appropriate units. Based on the results of this assessment, appropriate controls will be implemented.

When controls are not possible or ineffective, respiratory protection will be provided as required.

4.4 RESPIRATOR SELECTION AND USE

The following criteria will be used to in the selection of respiratory protection:

- The atmospheric oxygen concentration
- A contaminant's physical state (particulate, gas or vapor)
- Toxicity and concentration (immediately or not immediately dangerous to life or health)
- The presence of other contaminants
- Stress factors in the working environment
- Worker exposure time and susceptibility

The following procedures are provided to ensure consistency in the selection and use of respiratory protective equipment (Note: This section does not apply to the selection of atmosphere supplying respirators, see section 4.8.6).

4.4.1 Respirator Selection

Respirators will be selected on the basis of the hazards to which the employee may be exposed.

All respirators will be selected according to the type of activity for which they will be used and the potential air contaminants associated with these activities.

- Outside consultation, manufacturers' assistance, and information from other recognized authorities may be used as part of the selection process.

Respirators approved by the United States National Institute of Occupational Safety and Health (NIOSH)/Mine Safety and Health Administration (MSHA) should be used in accordance with the manufacturer's recommendation.

Non-disposable respirators will be assigned to individual employees for their exclusive use, where practicable.

- All non-disposable respirators used by more than one person will be cleaned and sanitized between each use.

Mixing of components between different types or makes of respirators is not permitted.

The use of disposable respirators may be authorized in units with limited respirator usage.

4.4.2 Air Purifying Respirators (APR) Use

In general, air-purifying cartridge or canister respirators will be allowed if:

- The contaminant(s) is known.
- The concentration(s) is known.
- The air-purifying element provides adequate protection for the air contaminant(s).
  - This type of respirator may be equipped with either chemical cartridges or a canister for protection against gases and vapors.
- The contaminant(s) has good warning (break through) properties.
  - The use of chemical cartridge respirators against substances with poor warning properties shall not be permitted unless its use is permitted in specific health standards.
  - Certain specific health standards permit the use of air-purifying respirators even though the chemical has poor or no warning properties.
- In this case, reliable information concerning the service life of the cartridge must be available. Since some reactive chemicals cannot be effectively adsorbed/absorbed by the sorbent, its use should also be restricted.

A partial (not all inclusive) list of air contaminants with poor odor warning properties or short breakthrough time follows:

acrolein
aniline
arsine
carbon monoxide
carbonyls
carbon disulfide
cyanogen
dimethylaniline
dimethyl sulfate
fluorine
hydrogen cyanide
hydrogen fluoride
hydrogen selenide
hydrogen sulfide
iodine
isocyanates: HDI, MDI, MIC and TDI
methanol
methyl bromide
methyl chloride
methyl iodine
nickel carbonyl
nitrocompounds: nitrobenzene, nitrogen oxides, nitroglycerine, and nitromethane ozone
bromine
boron hydrides
carbon dioxide
phosgene
phosphine
phosphorous
trichloride
stibine
sulfur
chloride
vinyl
chloride

HEPA filter cartridges will be replaced after a maximum of 40 hours use in a moderate to dusty workplaces or every 120 hours of use in low dust environments or whenever a significant increase in breathing resistance is noted by the user.

The date of installation will be marked on the cartridge.

Gas/vapor cartridges will be disposed of after each day's activities no matter how short those activities were.

- A day's activities begins when the cartridges is removed from the factory sealed container allowing the cartridges to be exposed to air.
- These cartridges, even if they are not exposed to a contaminated atmosphere, must be discarded.

4.4.3 Proper Fit

All users of respirators will be fit tested to determine which brand and size provides proper facepiece-to-face seal.

- The fit testing will take place before a respirator is issued and annually thereafter.
- Fit testing will be arranged and coordinated by the RPPC and the OHS Program Manager.

- The individual must wear only the respirator brand and size that was worn to pass the fit test.
- The use of a respirator that has not been fit tested is prohibited.

Respirator users will maintain personal grooming standards that will ensure proper facepiece-to-face seal.

Employees who have facial hair or wear objects that pass between the skin and the sealing surface will not be permitted to wear a negative-pressure air-purifying respirator.

Special mountings will be provided to hold corrective lenses inside full facepieces.

Once an employee has been fit tested and issued a respirator, the employee must perform a functional fit check each time a respirator is worn. The functional fit check is necessary to ensure that the face-to-mask seal is airtight and that the respirator is working properly. This can be accomplished by performing either a positive-pressure or negative-pressure check. Detailed instructions for performing the functional fit checks will be provided when the respirator is issued. Additional copies are available from the RPPC.

29 CFR 1910.134, Appendix A, Appendix B-1, and Appendix D outline the fit testing requirements for employee respirator use.

4.4.4 Respirator Storage

The following guidelines are necessary for maintaining a clean and sanitary respirator and to prevent damage to the respirator:

- Store chemical cartridge respirators in airtight, labeled containers between each use and labeled with the users name.
- Store respirators in a convenient, clean and sanitary space in order to protect from dust, sunlight, extreme cold, excess moisture, or damaging chemicals.
- Store respirators so that the facepiece and exhalation valve will rest in a normal position and so that the function will not be impaired by the elastomer setting in an abnormal position.
    - Do not store respirators by hanging them by the straps.

4.4.5 Maintenance and Inspection

4.4.5.1 Respirator Inspection

All respirators will be inspected by the wearer before and after each use to ensure that the respirator is in proper working order.

The wearer will perform the following inspection before each use of the respirator:

- Check the tightness of connections and the condition of the facepiece, head bands, valves, connecting tube, and canisters.
- Inspect rubber or elastomer parts for pliability and signs of deterioration.
- Replace defective parts with manufacturer's approved parts.

4.4.5.2 Cleaning and Disinfection of Respirators

Non-disposable respirators will be cleaned, disinfected and inspected after each use.

Employees will regularly clean their assigned respirators after each use by performing the following functions:

- Inspect respirators during cleaning.
- Remove canisters, filters, valves, straps, and speaking diaphragms from facepiece.
- Wash facepiece and accessories in warm soapy water or use a commercially available disinfection/decontamination solution, following the manufacturer's instructions.
  - Do not wash filters, cartridges, or canisters.
- Rinse parts thoroughly in clean water.
- Air dry in a clean place or wipe dry with a lint free cloth.
- Reassemble.

Non-disposable respirators will be inspected during routine cleaning, and worn or deteriorated parts will be replaced with approved parts according to the manufacturer's instructions.

Disposable respirators will be used until the cartridge or filter media requires replacement or when the facepiece is dirty.

The RPPC will verify that appropriate respiratory protection is readily available and is being used, inspected and maintained properly.

29 CFR 1910.134 and Appendix B-2 outline the maintenance and storage requirements for employee respirator use.

4.4.6 Atmosphere Suppling Respirators

Atmosphere supplying respirators, such as self-contained breathing apparatus (SCBA), will only be used by specially trained personnel. Contact the OHS Program Manager for information regarding this training.

1.5 TRAINING

The OHS Program Manager will ensure that a respiratory protection training program is available to all employees who are required to wear respirators.

It is the responsibility of the Unit Chief to ensure that employees participate in any required training program.

- Individuals required to wear respiratory protection will be instructed in its proper use, maintenance and limitations.
- Training will include handling the respirator, fit test, and actual use in a normal and a test atmosphere.
- The Unit Chief and the RPPC will receive training, regardless of whether or not they are issued a respirator.
- Training will be repeated as required.

29 CFR 1910.134, Appendix A, and Appendix B-1 and outline the fit testing requirements for employee respirator use.

1.6 RECORDS

The following records are to be maintained by each unit for the duration of each individual's assignment in that unit:

- Inspection dates and findings for respirators maintained for emergency use.
- A copy of the completed Respiratory Health Report.
- Training record showing employee name, date(s) trained, topics covered and name of trainer.
- Fit-test record showing date of test, type of test used, employee name, and respirator manufacturer and facepiece size.

These records will be maintained in accordance with 29 CFR 1910.134 and the AGENCY NAME document retention policy

4.7 RESPIRATORY PROTECTION PROGRAM EVALUATION

The adequacy of this program will be evaluated at least annually-by the OHS Program Manager with assistance from all Unit Chiefs and RPPCs. A report summarizing the findings of the evaluation will be submitted to the Assistant Director.

5 PROCEDURE

There are currently no procedures that directly impact the implementation of this policy.

6 APPROVAL

The signatures below recognize the above Health and Safety Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

BLOOD BORNE PATHOGEN EXPOSURE CONTROL

General Guidelines

1 PURPOSE

This document defines the **AGENCY NAME's** blood borne pathogen guidelines.

2 SCOPE

This policy applies to all **AGENCY NAME** personnel.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

Additional definitions include:

Contaminated	Refers to the presence or the reasonably anticipated presence of human blood or other potentially infectious materials on an item or surface.
Decontamination	Refers to the use of physical or chemical means to remove, inactivate, or destroy blood borne pathogens on a surface or an item rendering the surface or item safe for handling, use, or disposal.
Exposure Incident	Refers to a specific contact with the eye, mouth, or other mucous membrane, non-intact skin, or parenteral (needle stick) contact with human blood or other potentially infectious materials that results from the performance of an employee's duties.
Occupational Exposure	Refers to reasonably anticipated skin, eye, mucous membrane, or parenteral contact with human blood or potentially infectious materials that result from the performance of a employee's duties.

***Potentially Infectious Materials* (PIMs)**	Refers to the following human body fluids: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids. Also included are unfixed tissues or organs from a human (living or dead).
Sharps Container	Refers to a closable, puncture-resistant, and leak proof container designed for the disposal of needles and other sharp objects.

4 POLICY

All AGENCY NAME employees must comply with the appropriate procedures when handling evidence containing or contaminated with human blood (liquid or dried) or other potentially infectious materials.

Employees who handle these materials are required to develop a working knowledge of the procedures in this plan and incorporate them into their daily work routine.

29 CFR 1910.1030 will serve as the basis for the blood borne pathogen exposure control plan.

5 PROCEDURE

There are currently no procedures that directly impact the implementation of this policy.

6 APPROVAL

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BLOOD BORNE PATHOGEN EXPOSURE CONTROL

Universal Precautions

1 PURPOSE

This document defines the **AGENCY NAME's** blood borne pathogen universal precaution guidelines.

2 SCOPE

This policy applies to all **AGENCY NAME** personnel.

3 DEFINITIONS

The current revision of document APP-P101 and HAS-P501 will be used as a guide to define terms.

4 POLICY

The AGENCY NAME will take a Universal Precautions approach to infection control.

The AGENCY NAME will treat all human blood and certain body fluids as if they are known to be infected by HIV, HBV or other blood borne pathogens.

Employees will consider all evidence containing or contaminated with human blood or other PIMs as infectious regardless of the perceived status of the source individual or age of the material.

Employees will wear the appropriate personal protective equipment when handling items containing or contaminated with human blood or other PIMs.

5 PROCEDURE

There are currently no procedures that directly impact the implementation of this policy.

6 APPROVAL

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BLOOD BORNE PATHOGEN EXPOSURE CONTROL

Engineering Controls

1 PURPOSE

This document defines the **AGENCY NAME's** blood borne pathogen engineering controls guidelines.

2 SCOPE

This policy applies to all **AGENCY NAME** personnel.

3 DEFINITIONS

The current revision of document APP-P101 and HAS-P501 will be used as a guide to define terms.

4 POLICY

The **AGENCY NAME** will utilize engineering controls in an effort to isolate or remove the blood borne pathogen hazards from the employee.

Engineering controls may include:

- Biological safety cabinets
- Sharps containers
- Non-porous bench tops
- Enclosed centrifuges
- Plexiglas splatter shields

It is the responsibility of each unit to ensure that all appropriate engineering controls are in place, used and maintained in proper working order.

5 PROCEDURE

There are currently no procedures that directly impact the implementation of this policy.

6 APPROVAL

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BLOOD BORNE PATHOGEN EXPOSURE CONTROL

Personal Protective Equipment

1 PURPOSE

This document defines the **AGENCY NAME's** blood borne pathogen personal protective equipment guidelines.

2 SCOPE

This policy applies to all **AGENCY NAME** personnel.

3 DEFINITIONS

The current revision of document APP-P101 and HAS-P501 will be used as a guide to define terms.

4 POLICY

The **AGENCY NAME** will maintain an inventory of the PPE necessary to protect its employees from blood borne pathogen hazards.

Employees will utilize the PPE necessary to protect themselves from blood borne pathogen hazards.

PPE selection will be based upon the anticipated exposure to blood or other PIMs.

The PPE will be considered appropriate only if it does not permit blood or other PIMs to pass through or reach employees' clothing, skin, or mucous membranes of the eyes, nose and mouth.

PPE will be used in conjunction with engineering controls in order to provide an appropriate level of safety.

The following PPE is recommended and should be available for use by **AGENCY NAME** employees:

Disposable latex or nitrile gloves
Lab coats
Safety glasses with side shields
Safety goggles or face shields

5 PROCEDURE

There are currently no procedures that directly impact the implementation of this policy.

6 APPROVAL

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John Smith, Laboratory Director	Date
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BLOOD BORNE PATHOGEN EXPOSURE CONTROL

Safe Work Practices

1 PURPOSE

This document defines the **AGENCY NAME's** blood borne pathogen safe work practices guidelines.

2 SCOPE

This policy applies to all **AGENCY NAME** personnel.

3 DEFINITIONS

The current revision of document APP-P101and HAS-P501 will be used as a guide to define terms.

4 POLICY

Employees will strictly adhere to the following safe work practices:

- Eating, drinking, smoking, applying cosmetics or handling contact lenses will not be permitted in laboratory work areas.
- Food or drink will not be stored in refrigerators, freezers or cabinets where blood or other PIMs are stored.
- Pipeting by mouth is forbidden.
- Lab coats and eye and face protection will be worn whenever splashes, sprays, spatters, droplets, or aerosols may be generated.
  - Additional protection may be worn as required.
- Disposable (single use) latex or nitrile gloves will be worn when handling items that contain or are contaminated with human blood or other PIMs.
  - Gloves will be replaced gloves when visibly soiled, torn or punctured.
- Employees will wash the hands with soap and water immediately after removal of gloves and after visible contact with blood or other PIMs.
  - Antimicrobial antiseptic towelettes or gels may be used in the absence of hand-washing facilities.
- PPE will be removed immediately upon leaving the work area or when overtly contaminated.
  - Contaminated disposable PPE will be disposed of as biohazard waste.

- Employee will not shear, bend, break, recap or remove contaminated needles and other sharps, except as necessary for forensic examination purposes.
- Contaminated sharps such as scalpel blades and needles will be placed in a puncture resistant container for disposal as a biohazard waste.
- Mechanical means, such as a dustpan and brush, tongs, or forceps will be utilized to pick up contaminated, broken glassware, place in a puncture-resistant container and dispose of as a biohazard waste.
- Employees will use an approved biological safety cabinet when working with liquid blood or other PIMs that may result in splashing, spraying, or aerosolization of the sample.

5 PROCEDURE

There are currently no procedures that directly impact the implementation of this policy.

6 APPROVAL

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BLOOD BORNE PATHOGEN EXPOSURE CONTROL

Cleaning and Disinfecting

1 PURPOSE

This document defines the **AGENCY NAME's** blood borne pathogen cleaning and disinfecting guidelines.

2 SCOPE

This policy applies to all **AGENCY NAME** personnel.

3 DEFINITIONS

The current revision of document APP-P101 and HAS-P501 will be used as a guide to define terms.

4 POLICY

Employees will strictly adhere to the following safe work practices:

- Eating, drinking, smoking, applying cosmetics or handling contact lenses will not be permitted in laboratory work areas.
- Food or drink will not be stored in refrigerators, freezers or cabinets where blood or other PIMs are stored.
- Pipeting by mouth is forbidden.
- Lab coats and eye and face protection will be worn whenever splashes, sprays, spatters, droplets, or aerosols may be generated.
  - Additional protection may be worn as required.
- Disposable (single use) latex or nitrile gloves will be worn when handling items that contain or are contaminated with human blood or other PIMs.
  - Gloves will be replaced gloves when visibly soiled, torn or punctured.
- Employees will wash the hands with soap and water immediately after removal of gloves and after visible contact with blood or other PIMs.
  - Antimicrobial antiseptic towelettes or gels may be used in the absence of hand-washing facilities.
- PPE will be removed immediately upon leaving the work area or when overtly contaminated.
  - Contaminated disposable PPE will be disposed of as biohazard waste.

- Employee will not shear, bend, break, recap or remove contaminated needles and other sharps, except as necessary for forensic examination purposes.
- Contaminated sharps such as scalpel blades and needles will be placed in a puncture resistant container for disposal as a biohazard waste.
- Mechanical means, such as a dustpan and brush, tongs, or forceps will be utilized to pick up contaminated, broken glassware, place in a puncture-resistant container and dispose of as a biohazard waste.
- Employees will use an approved biological safety cabinet when working with liquid blood or other PIMs that may result in splashing, spraying, or aerosolization of the sample.

5 PROCEDURE

There are currently no procedures that directly impact the implementation of this policy.

6 APPROVAL

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BLOOD BORNE PATHOGEN EXPOSURE CONTROL

Biohazard Spills

1 PURPOSE

This document defines the **AGENCY NAME's** blood borne pathogen biohazard spill guidelines.

2 SCOPE

This policy applies to all **AGENCY NAME** personnel.

3 DEFINITIONS

The current revision of document APP-P101 and HAS-P501 will be used as a guide to define terms.

4 POLICY

The employees responsible for cleaning biohazard spills will wear the proper PPE.

- At a minimum the employee will wear latex or nitrile gloves, lab coat, and safety glasses or goggles.

5 PROCEDURE

The employees will utilize the following procedure when human blood or potentially infectious material is spilled:

- Close the spill area to traffic.
- Contain the spill with an absorbent material.
- Pour a freshly prepared 10% solution of chlorine bleach on the spill.
  - Let sit for 15 minutes to allow for disinfection.
  - Repeat the process until the spill has been removed.
- Place cleanup materials in a biohazard bag and dispose of as infectious waste.

6 APPROVAL

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Mary Doe, Quality Assurance Manager	Date

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BLOOD BORNE PATHOGEN EXPOSURE CONTROL

Infectious Waste Disposal

1 PURPOSE

This document defines the **AGENCY NAME's** blood borne pathogen infectious waste disposal guidelines.

2 SCOPE

This policy applies to all **AGENCY NAME** personnel.

3 DEFINITIONS

The current revision of document APP-P101 and HAS-P501 will be used as a guide to define terms.

4 POLICY

Protective coverings used to cover equipment and environmental surfaces, will be removed and replaced as soon as feasible when they become overtly contaminated.

Needles, broken glass, scalpel blades and other sharps should be placed in labeled, puncture-resistant, leak proof containers for disposal.

Contaminated waste must be placed in properly labeled, closeable, leak proof containers or color coded biohazard bags.

5 PROCEDURE

There are currently no procedures that directly impact the implementation of this policy.

6 APPROVAL

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BLOOD BORNE PATHOGEN EXPOSURE CONTROL

Hazard Communication

1 PURPOSE

This document defines the **AGENCY NAME's** blood borne pathogen hazard communication guidelines.

2 SCOPE

This policy applies to all **AGENCY NAME** personnel.

3 DEFINITIONS

The current revision of document APP-P101 and HAS-P501 will be used as a guide to define terms.

4 POLICY

Biohazard warning labels will be posted on entry doors of areas where potential infectious materials may be readily encountered or stored.

Biohazard warning labels will be affixed to waste receptacles and refrigerators or freezers containing blood or other potentially infectious material.

Individual packages or containers of blood or other potential infectious materials are exempt from the labeling requirement if the biohazard warning label is placed on the secondary container.

Contaminated blood vials, centrifuge tubes, and other materials which remain in the immediate work area need not be labeled if Universal Precautions are being used.

5 PROCEDURE

There are currently no procedures that directly impact the implementation of this policy.

6 APPROVAL

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BLOOD-BORNE PATHOGEN EXPOSURE CONTROL

Hepatitis Vaccination

1 PURPOSE

This document defines the **AGENCY NAME's** blood-borne pathogen Hepatitis vaccination guidelines.

2 SCOPE

This policy applies to all **AGENCY NAME** personnel.

3 DEFINITIONS

The current revision of document APP-P101 and HAS-P501 will be used as a guide to define terms.

4 POLICY

All employees who have potential exposure to blood-borne pathogens should obtain a Hepatitis B vaccination.

- The AGENCY NAME will provide such vaccinations as funding becomes available.
- Employees who decline the vaccination are required to sign a statement of declination.

Hepatitis A vaccinations should be obtained by employees at risk of exposure to contaminated food, especially during travel in developing areas of the world.

- The AGENCY NAME will provide such vaccinations as funding becomes available.
- Employees who decline the vaccination are required to sign a statement of declination.

Employees will be evaluated by a physician for percutaneous exposure to blood from a source known to be infected with Hepatitis C so consideration can be given to the use Immunoglobulin or Interferon therapy.

- Currently, there is no vaccine for Hepatitis C.

5 PROCEDURE

There are currently no procedures that directly impact the implementation of this policy.

6 APPROVAL

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BLOOD BORNE PATHOGEN EXPOSURE CONTROL

Post Exposure Evaluation and Follow-up

1 PURPOSE

This document defines the **AGENCY NAME's** blood-borne pathogen post exposure evaluation and follow-up guidelines.

2 SCOPE

This policy applies to all **AGENCY NAME** personnel.

3 DEFINITIONS

The current revision of document APP-P101 and HAS-P501 will be used as a guide to define terms.

4 POLICY

Employees who receive an occupational exposure to blood borne pathogens should immediately notify their supervisor who will document the exposure.

Employees who receive a documented occupational exposure to blood borne pathogens will be provided a medical evaluation and follow-up.

Employees with be provided a copy of the evaluating healthcare professional's written opinion within 15 days of receipt by the **AGENCY NAME**.

5 PROCEDURE

There are currently no procedures that directly impact the implementation of this policy.

6 APPROVAL

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BLOOD BORNE PATHOGEN EXPOSURE CONTROL

Training

1 PURPOSE

This document defines the **AGENCY NAME's** blood-borne pathogen training guidelines.

2 SCOPE

This policy applies to all **AGENCY NAME** personnel.

3 DEFINITIONS

The current revision of document APP-P101 and HAS-P501 will be used as a guide to define terms.

4 POLICY

Training will be provided to all employees with the potential for occupational exposure to blood borne pathogens.

The training will be provided during working hours and at no cost to the employee.
Training for new employees will be scheduled as soon as possible.
All employees will be provided annual refresher training.

5 PROCEDURE

There are currently no procedures that directly impact the implementation of this policy.

6 APPROVAL

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BLOOD BORNE PATHOGEN EXPOSURE CONTROL

Record Keeping

1 PURPOSE

This document defines the **AGENCY NAME's** blood borne pathogen record keeping guidelines.

2 SCOPE

This policy applies to all **AGENCY NAME** personnel.

3 DEFINITIONS

The current revision of document APP-P101 and HAS-P501 will be used as a guide to define terms.

4 POLICY

4.1 MEDICAL RECORDS

The **AGENCY NAME** will maintain records of each employee's blood borne pathogen status.

The employee's record will include:

- A copy of the employee's hepatitis B vaccination status
- Results of examinations, medical testing and follow-up procedures subsequent to a documented occupational exposure to a suspected blood borne pathogen
- Written opinion and information from healthcare professionals

All medical records will be maintained in the employee's personnel file for the duration of employment plus 30 years.

4.2 TRAINING RECORDS

The AGENCY NAME will maintain a record of training for each employee with potential occupational exposure to blood borne pathogens.

The training records will include:

- The date and the contents of the training
- The names and qualifications of the persons conducting the training
- The name and unit of the employee being trained

All training records will be maintained in the employee's personnel file for the duration of employment.

5 PROCEDURE

There are currently no procedures that directly impact the implementation of this policy.

6 APPROVAL

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John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

CHEMICAL HYGIENE PLAN

General Guide

1 PURPOSE

This document defines the **AGENCY NAME's** chemical hygiene plan general guidelines.

2 SCOPE

This policy applies to all **AGENCY NAME** personnel.

3 DEFINITIONS

The current revision of document APP-P101 and HAS-P501 will be used as a guide to define terms.

4 POLICY

The **AGENCY NAME** will develop and implement the provisions of a written Chemical Hygiene Plan (CHP).

The CHP will include specific provisions, policies, and practices capable of protecting employees from overexposure to chemicals in the laboratory.

5 PROCEDURE

There are currently no procedures that directly impact the implementation of this policy.

6 APPROVAL

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John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

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CHEMICAL HYGIENE PLAN

Flammable Materials

1 PURPOSE

This document defines the **AGENCY NAME's** chemical hygiene plan flammable material policy.

2 SCOPE

This policy applies to all **AGENCY NAME** personnel.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

Flammable materials are defined as a substance whose vapors will ignite when exposed to an ignition source at temperatures below 37.8°C (100 °F).

Combustible materials are defined as a substance must be heated above 37.8°C (100°F) in order to be ignited.

4 POLICY

4.1 HAZARD INFORMATION

Factory labels and Material Safety Data Sheet (MSDS) will be used to determine the substance's flammable or combustible characteristics.

4.2 STORAGE

Flammable and combustible materials will be stored under the following conditions:

- Flammable and combustible materials will be segregated from incompatible materials.
- Flammable and combustible materials will be stored in in a flammable storage cabinet.
  - Flammable and combustible materials that require refrigeration will be stored in a properly labeled explosion-proof refrigerator.
- Spill cleanup materials near chemical storage areas.
- Storage areas will be inspected periodically for proper and safe storage.

4.3 HANDLING

The following safe work practices will be observed when handling flammable or combustible materials:

- Exercise caution to minimize the production of vapors and the associated risk of ignition by flashback from a remote source.

- Quantities of flammable substances in work areas will be minimized.
- Flammable liquids will be dispensed in a fume hood or other well ventilated area and away from heat and ignition sources, when possible.
- Containers that are metal and electrically bonded and grounded will be utilized when transferring flammable solvents from bulk storage (such as a 55 gallon drum).
- Gloves and safety goggles will be worn when handling flammable liquids.
- Bottle carriers will be utilized when transporting flammable liquids outside the laboratory or between the stockroom and the laboratory.
- Flammable or combustible material spills will be cleaned up immediately, using the proper spill kit.
- Flammable or combustible liquids or mixtures will not be deposited into the sink or drain.

5 PROCEDURE

There are currently no procedures that directly impact the implementation of this policy.

6 APPROVAL

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CHEMICAL HYGIENE PLAN

Corrosive Material

1 PURPOSE

This document defines the **AGENCY NAME's** chemical hygiene plan corrosive material policy.

2 SCOPE

This policy applies to all **AGENCY NAME** personnel.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

Corrosive chemical is defined as a substance that causes visible destruction of, or irreversible alterations in, living tissue by chemical action at the site of contact.

- Severe corrosive reactions are often designated as chemical burns. Inhalation of vapors or mists of these substances can cause severe irritation of the upper respiratory tract.
- Examples of corrosives include acids, bases, and peroxides.

4 POLICY

4.1 HAZARD INFORMATION

Factory labels and Material Safety Data Sheet (MSDS) will be used to determine the substance's corrosive characteristics.

4.2 STORAGE

Corrosive materials will be stored under the following conditions:

- Mineral (inorganic) acids will be segregate from bases and from both organic and flammable materials.
- Corrosive materials will be stored near the floor to minimize the danger of falling from shelves.
- Corrosive materials will be stored in cool, dry, well-ventilated areas, away from sunlight.
- Corrosive materials will be stored in an area that is not subject to rapid temperature changes.

Handling:
The following safe work practices will be observed when handling corrosive materials:

- Personal protective equipment will be utilized to protect against skin and eye contact.
- Quantities of corrosive substances in work areas will be minimized.
- Operations utilizing corrosive substances will be isolated as much as possible by using fume hood sashes and shields.
- Occupation exposures to corrosive chemicals that result in skin or mucous membrane contact will be treated immediately.
- Wash the affected area with copious amounts of water.
- Eyes should be flushed with cool water for a minimum of 15 minutes.
- Medical help should be summoned promptly, particularly for eye exposure.

5 PROCEDURE

There are currently no procedures that directly impact the implementation of this policy.

6 APPROVAL

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CHEMICAL HYGIENE PLAN

Oxidizing Materials

1 PURPOSE

This document defines the **AGENCY NAME's** chemical hygiene plan oxidizing materials policy.

2 SCOPE

This policy applies to all **AGENCY NAME** personnel.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

Oxidizers are chemicals that react violently when in contact with organic substances, and therefore, represent a particular safety hazard.

Interactions between oxidizers and organic materials should be avoided.

Examples of oxidizers include:

- Fluorine
- Sulfuric acid
- Chlorine
- Chlorates
- Chlorites
- Perchlorates
- Oxygen
- Hydrogen peroxide
- Peroxides
- Iodine
- Nitric acid
- Nitrates
- Nitrites
- Permanganates

4 POLICY

4.1 HAZARD INFORMATION

Factory labels and Material Safety Data Sheet (MSDS) will be used to determine the substance's oxidizing characteristics.

4.2 STORAGE

Oxidizers will be segregated from reducing agents and combustibles.

4.3 HANDLING

The following safe work practices will be observed when handling oxidizing materials:

- Personal protective equipment will be utilized to protect against skin and eye contact.
- Quantities of oxidizing substances in work areas will be minimized.
- Operations utilizing oxidizing substances will be isolated as much as possible by using fume hood sashes and shields.

5 PROCEDURE

There are currently no procedures that directly impact the implementation of this policy.

6 APPROVAL

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CHEMICAL HYGIENE PLAN

Reactive Materials

1 PURPOSE

This document defines the **AGENCY NAME's** chemical hygiene plan reactive material policy.

2 SCOPE

This policy applies to all **AGENCY NAME** personnel.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

Reactivity refers to the hazard from chemicals or a combination of chemicals that react violently or explosively, releasing a large amount of energy or gas.

4 POLICY

4.1 HAZARD INFORMATION

Factory labels and Material Safety Data Sheet (MSDS) will be used to determine the substance's reactive characteristics.

4.2 STORAGE

Reactive chemicals will be segregated when storing.

4.3 HANDLING

The following safe work practices will be observed when handling reactive materials:

- Reactive chemicals will be handled with the proper safety precautions.
- Personal protective equipment will be utilized to protect against skin and eye contact.
- Quantities of reactive substances in work areas will be minimized.
- Operations utilizing reactive substances will be isolated as much as possible by using fume hood sashes and shields.

5 PROCEDURE

There are currently no procedures that directly impact the implementation of this policy.

6 APPROVAL

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CHEMICAL HYGIENE PLAN

Explosive Materials

1 PURPOSE

This document defines the **AGENCY NAME's** chemical hygiene plan explosive materials policy.

2 SCOPE

This policy applies to all **AGENCY NAME** personnel.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

Explosive materials are chemicals that cause an instantaneous release of large or small amounts of gas and heat, resulting in a dramatic pressure increase when subjected to sudden shock or high temperature.

Examples of explosives include:

- TNT
- Nitroglycerin
- Diazomethane
- Heavy metal azides
- Nitrogen trichloride
- Ammonium chlorate
- Acetone and ether peroxides
- Metal fulminates
- Cuprous acetylide
- Divinyl acetylene
- Silver diacetylide (explosive even when wet)

4 POLICY

4.1 HAZARD INFORMATION

Factory labels and Material Safety Data Sheet (MSDS) will be used to determine the substance's explosive characteristics.

4.2 STORAGE

Strong oxidizers that can facilitate explosions when combined with organic materials will be isolated from organic material. These compounds include:

- Perchlorates
- Nitrates
- Chlorates
- Chromates
- Chlorites
- Hypochlorites
- Permanganates

Appropriate measures will be taken to prevent the formation of unstable or explosive substances that result from chemical operations or prolonged storage.

4.3 HANDLING

The following safe work practices will be observed when handling explosive materials:

- Reactive chemicals will be handled with the proper safety precautions.
- Personal protective equipment will be utilized to protect against skin and eye contact.
- Quantities of reactive substances in work areas will be minimized.
- Operations utilizing reactive substances will be isolated as much as possible by using fume hood sashes and shields.
- Identifing the potential explosive hazards prior to the analysis of case evidence, including the stability of reactants/products from the analysis.

Employees will avoid handling potentially explosive chemicals in the following manner:

- Allowing picric acid to dry out
- Mixing flammable chemicals with oxidizers
- Flammable gas leaks
- Heating compressed or liquefied gas
- Uncontrollable fluctuating temperatures during experiments using explosive chemicals
- Bringing hot liquid into sudden contact with a material possessing a lower boiling point
- Contacting flammable materials with catalysts (i.e., acids or bases catalyze an explosive polymerization of acrolein)
- Allowing explosive peroxide decomposition products to build up in solvent containers during storage
- Mixing nitric acid with flammable solvents
- Distilling ethers unless free from peroxides

5 PROCEDURE

There are currently no procedures that directly impact the implementation of this policy.

6 APPROVAL

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CHEMICAL HYGIENE PLAN

Explosive Materials

1 PURPOSE

This document defines the **AGENCY NAME's** chemical hygiene plan explosive materials policy.

2 SCOPE

This policy applies to all **AGENCY NAME** personnel.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

Explosive materials are chemicals that cause an instantaneous release of large or small amounts of gas and heat, resulting in a dramatic pressure increase when subjected to sudden shock or high temperature.

Examples of explosives include:

- TNT
- Nitroglycerin
- Diazomethane
- Heavy metal azides
- Nitrogen trichloride
- Ammonium chlorate
- Acetone and ether peroxides
- Metal fulminates
- Cuprous acetylide
- Divinyl acetylene
- Silver diacetylide (explosive even when wet)

4 POLICY

4.1 HAZARD INFORMATION

Factory labels and Material Safety Data Sheet (MSDS) will be used to determine the substance's explosive characteristics.

4.2 STORAGE

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- Chlorates
- Chromates
- Chlorites
- Hypochlorites
- Permanganates

Appropriate measures will be taken to prevent the formation of unstable or explosive substances that result from chemical operations or prolonged storage.

4.3 HANDLING

The following safe work practices will be observed when handling explosive materials:

- Reactive chemicals will be handled with the proper safety precautions.
- Personal protective equipment will be utilized to protect against skin and eye contact.
- Quantities of reactive substances in work areas will be minimized.
- Operations utilizing reactive substances will be isolated as much as possible by using fume hood sashes and shields.
- Identifing the potential explosive hazards prior to the analysis of case evidence, including the stability of reactants/products from the analysis.

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- Uncontrollable fluctuating temperatures during experiments using explosive chemicals
- Bringing hot liquid into sudden contact with a material possessing a lower boiling point
- Contacting flammable materials with catalysts (i.e., acids or bases catalyze an explosive polymerization of acrolein)
- Allowing explosive peroxide decomposition products to build up in solvent containers during storage
- Mixing nitric acid with flammable solvents
- Distilling ethers unless free from peroxides

5 PROCEDURE

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CHEMICAL HYGIENE PLAN

Compressed Gas

1 PURPOSE

This document defines the **AGENCY NAME's** chemical hygiene plan compressed gas policy.

2 SCOPE

This policy applies to all **AGENCY NAME** personnel.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

The following guidelines will be observed for the safe handling and storage of compressed gases:

- Cylinders will be stored in a dry, well-ventilated area away from sources of ignition.
- Cylinders stored outdoors will be protected from weather extremes and direct sunlight.
- Cylinders will be stored in an upright position and harnessed to either a counter or the wall.
- The number of cylinders present within the laboratory will be maintained at an absolute minimum.
- Oxygen gas cylinders must be separated from flammable gas cylinders by at least 20 ft.
- Color coding will not be used to identify cylinder content.
- Valve protection caps will remain in place when cylinders are connected to dispensing equipment.
- Compressed gas cylinders will only be used with the correct regulator and fittings for each gas.
- Faulty cylinders or valves will not be used and promptly returned to the compressed gas vendor.
- The use of oil or grease to lubricate compressed gas fittings or valves is prohibited.
- All cylinders will be labeled "FULL" or "EMPTY."
- Abbreviations are not acceptable.

- When the pressure drops below the usable level, the cylinder should be marked "EMPTY" and recapped for return.
- All cylinders will be treated as if full at all times.

5 PROCEDURE

There are currently no procedures that directly impact the implementation of this policy.

6 APPROVAL

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CHEMICAL HYGIENE PLAN

Carcinogens

1 PURPOSE

This document defines the AGENCY NAME's chemical hygiene plan carcinogen policy.

2 SCOPE

This policy applies to all AGENCY NAME personnel.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

Carcinogens are Substances that increase the risk of the abnormal growth of tissue in humans or animals.

Examples of select carcinogens include:

- Acrylamide
- Benzene
- Acrylonitrile
- Benzidine
- Asbestos

Formaldehyde

4 POLICY

4.1 HAZARD INFORMATION

Factory labels and Material Safety Data Sheet (MSDS) will be used to determine the substance's carcinogenic characteristics.

4.2 STORAGE

Carcinogens will be stored using the following guidelines:

- Bulk storage of large quantities of carcinogenic compounds is prohibited.
- Minimum quantities of select carcinogens will be stored at an employee's work station.
- Carcinogens will be appropriately labeled, segregated and in designated, limited access areas.
- Plastic, glass or stainless steel trays, as appropriate, may be used for secondary containment.
- The compound's MSDS will provide additional storage instructions.

4.3 HANDLING

Employees are responsible for ensuring the safe use and proper disposal of carcinogenic chemicals and for taking the necessary precautions to minimize the risk.

All carcinogens will be handled in a manner which minimizes the chemical's contact with and prevents exposure to employees and the environment.

- Carcinogenic compounds will be handled with the proper safety precautions.
- Analytical methods manuals will establish safety procedures for examinations involving the use of suspected carcinogens.
- Operations utilizing carcinogenic compounds will be isolated as much as possible by using fume hood sashes and shields.
- The work areas which utilize suspected carcinogens must be posted with appropriate warning signs.
- Personal protective equipment will be utilized to protect against skin and eye contact.
- Quantities of carcinogenic compounds in work areas will be minimized.
- Identifying the potential carcinogenic hazards prior to the analysis of case evidence, including the stability of reactants/products from the analysis.

The following work practices will be used when working with carcinogens:

- Absorbent paper, spill trays, and other appropriate spill containment procedures will be used to minimize contamination of work surfaces.
- Work surfaces, equipment, and glassware will be decontaminated using a compatible solvent after the use of carcinogens.
- Employees should wear two disposable gloves on each hand.
  - The outer glove will be discarded when it becomes torn or contaminated.
- Handling or touching clean surfaces or equipment with contaminated gloves is prohibited.
- Gloves will be discarded upon completion of the analysis.
- The exposed area should be washed immediately if an occupational exposure to a suspect carcinogen occurs.
  - Employees should wash their hands upon completion of an analysis and before leaving the work area.

5 PROCEDURE

There are currently no procedures that directly impact the implementation of this policy.

6 APPROVAL

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CHEMICAL HYGIENE PLAN

Reproductive Toxins

1 PURPOSE

This document defines the **AGENCY NAME's** chemical hygiene plan reproductive toxin policy.

2 SCOPE

This policy applies to all **AGENCY NAME** personnel.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

Reproductive toxins are defined as chemicals which may adversely affect the reproductive capability of either men or women. These toxins fall into two categories: teratogens and mutagens.

Teratogens are chemical and physical agents that interfere with normal embryonic development. Damage to the fetus (embryo) is most likely to occur early in pregnancy, during the first 12 weeks.

The following are examples of substances that have been identified as teratogens:

- Formamide
- Dibromochloropropane
- Lead compounds
- Ethylene oxide

Mutagens are chemical and physical agents that induce mutations in DNA and in living cells, causing heritable changes in the genetic structure. Individuals exposed to chemicals with mutagenic properties may develop genetic damage to the extent that future offspring could be affected.

Examples of mutagens include:

- Arsenic compounds
- Ionizing radiation
- Ethidium Bromide
- Alkylating agents (e.g., dimethyl sulfate)

4 POLICY

The **AGENCY NAME** will reduce or eliminate exposure of pregnant women and women contemplating pregnancy to reproductive toxins.

- The **AGENCY NAME** reserves the right to temporarily change the work assignment of women who are pregnant or contemplating pregnancy to avoid the risk of exposure to reproductive toxins.

- Pregnant women and women contemplating pregnancy may request reassignment during their pregnancy to avoid the risk of exposure to reproductive toxins.
- Pregnant women and women contemplating pregnancy will consult their private physicians regarding their potential for occupational exposure.

4.1 HAZARD INFORMATION

Factory labels and Material Safety Data Sheet (MSDS) will be used to determine the substance's reproductive toxin characteristics.

4.2 STORAGE

Reproductive toxins will be stored using the following guidelines

- Bulk storage of large quantities of reproductive toxins is prohibited.
- Minimum quantities of select reproductive toxins will be stored at an employee's work station.
- Reproductive toxins will be appropriately labeled, segregated and in designated, limited access areas.
- Plastic, glass or stainless steel trays, as appropriate, may be used for secondary containment.
- The compound's MSDS will provide additional storage instructions.

4.3 HANDLING

Employees are responsible for ensuring the safe use and proper disposal of reproductive toxins and for taking the necessary precautions to minimize the risk.

All reproductive toxins will be handled in the following manner:

- Reproductive toxins will be handled with the proper safety precautions.
- Analytical methods manuals will establish safety procedures for examinations involving the use of suspected reproductive toxins.
- Operations utilizing reproductive toxins will be isolated as much as possible by using fume hood sashes and shields.
    - The work areas which utilize suspected carcinogens must be posted with appropriate warning signs.
- Personal protective equipment will be utilized to protect against occupational exposures to reproductive toxins.
- Quantities of reproductive toxins in work areas will be minimized.
- Identifying the potential reproductive toxin hazards prior to the analysis of case evidence, including the stability of reactants/products from the analysis.

The following work practices will be used when working with reproductive toxins:

- Handling of reproductive toxins will only occur in a posted, designated area such as a chemical fume hood.
- Absorbent paper, spill trays, and other appropriate spill containment procedures will be used to minimize contamination of work surfaces.
- Work surfaces, equipment, and glassware will be decontaminated using a compatible solvent after the use of reproductive toxins.
- Work surfaces will be decontaminated after every activity that involves a reproductive toxin.
- Employees should wear two disposable gloves on each hand.
  - The outer glove will be discarded when it becomes torn or contaminated.
- Handling or touching clean surfaces or equipment with contaminated gloves is prohibited.
- Gloves will be discarded upon completion of the analysis.
- The exposed area should be washed immediately if an occupational exposure to a suspect reproductive toxin occurs.
  - Employees should wash their hands upon completion of an analysis and before leaving the work area.

5 PROCEDURE

There are currently no procedures that directly impact the implementation of this policy.

6 APPROVAL

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CHEMICAL HYGIENE PLAN

Chemical Labeling

1 PURPOSE

This document defines the **AGENCY NAME's** chemical hygiene plan chemical labeling policy.

2 SCOPE

This policy applies to all **AGENCY NAME** personnel.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

The manufacturer's label must not be removed or defaced until the container is empty.

Employees will note on the label:

- The date received
- The date opened
- The expiration date, where appropriate

Chemicals transferred from the manufacturer's original container to a secondary container must be labeled to display the chemical identity and hazard warning.

- Secondary containers utilized for a single working session or less are only required the container's contents on the label.

Aliquots of test reagent solutions will be labeled with the reagent's name and the highest hazard level of chemicals in the solution

A separate "HAZARDOUS WASTE" label must be placed on the empty container before it is used for waste containment.

5 PROCEDURE

There are currently no procedures that directly impact the implementation of this policy.

6 APPROVAL

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CHEMICAL HYGIENE PLAN

Material Safety Data Sheet

1 PURPOSE

This document defines the **AGENCY NAME's** chemical hygiene plan material safety data sheet (MSDS) policy.

2 SCOPE

This policy applies to all **AGENCY NAME** personnel.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

The **AGENCY NAME** shall maintain a master file of all of the Material Safety Data Sheet (MSDS) for every substance that is received.

MSDS may be maintained as a paper copy of all incoming shipments or computer database of all available MSDS.

- One MSDS per chemical is sufficient to meet this requirement.
- An MSDS for every vendor supplying a specific chemical is not required.
- The MSDSs will be filed in a fashion that is conducive to ready access by **AGENCY NAME** employees.

All employees who work with chemicals are responsible for reading the MSDS for the chemicals that they use.

Each unit will maintain a file of the MSDSs of the chemicals it utilizes.

- One MSDS per chemical is sufficient to meet this requirement.
- An MSDS for every vendor supplying a specific chemical is not required.
- The MSDSs will be filed in a fashion that is conducive to ready access by unit employees.

The **AGENCY NAME** will generate an MSDS for any chemical substance or reagent solution provided to anyone outside the **AGENCY NAME.**

- The individual generating the MSDS will have a thorough knowledge of the properties and hazards associated with that chemical.

5 PROCEDURE

There are currently no procedures that directly impact the implementation of this policy.

6 APPROVAL

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CHEMICAL HYGIENE PLAN

Exposure Reduction

1 PURPOSE

This document defines the **AGENCY NAME's** chemical hygiene plan exposure reduction policy.

2 SCOPE

This policy applies to all **AGENCY NAME** personnel.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

Employees will take every reasonable precaution to prevent exposure to hazardous chemicals.

The **AGENCY NAME** will minimized exposure through the implementation of engineering controls, safe work practices, and the use of personal protective equipment.

29 CFR 1910.1000 will be used to as a basis to establish acceptable exposure limits for various chemicals used in the laboratory.

4.1 ENGINEERING CONTROLS

The **AGENCY NAME** will utilize engineering controls to isolate or contain hazards. (Examples of engineering controls are chemical fume hoods and glove boxes.)

4.2 SAFE WORK PRACTICES

Supervisors will ensure that employees are informed of any special or unusual hazards associated with procedures conducted in the unit.

A safety review will be conducted and safety procedures developed and incorporated into the written standard operating procedure (SOP) when new procedures involving the use of hazardous chemicals are introduced or developed.

Employees will utilize safe work practices and universal precautions when conducting examinations.

5 PROCEDURE

There are currently no procedures that directly impact the implementation of this policy.

6 APPROVAL

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CHEMICAL HYGIENE PLAN

Emergency Equipment

1 PURPOSE

This document defines the **AGENCY NAME's** chemical hygiene plan emergency equipment policy.

2 SCOPE

This policy applies to all **AGENCY NAME** personnel.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

The **AGENCY NAME** will provide and maintain equipment and training in its application.

Employees will be familiar with the location and use of the emergency equipment.

4.1 FIRST AID KITS

First aid kits will be readily accessible and available in each unit.

The Unit Health and Safety Coordinator is responsible for ensuring that the contents of first aid kits are maintained.

4.2 SAFETY SHOWERS

Safety showers should be readily accessible to employees, and the immediate area beneath the shower kept free from obstructions.

The location should be identified by a highly visible sign.

Safety showers should be located away from electrical panels or outlets.

The Unit Health and Safety Coordinator will conduct a monthly functionality check of the safety showers in his area of responsibility.

Documentation of the monthly functionality check will be forwarded to the Health and Safety Program Manager.

4.3 EYEWASH STATIONS

Eyewash stations will be readily accessible to employees and the location should be identified by a highly visible sign.

Protective covers must be kept on the eyewash nozzles when not in use.

The Unit Health and Safety Coordinator will conduct a monthly functionality check of the eye wash stations in his area of responsibility.

Eyewash stations connected to laboratory water system will be flushed monthly for a period not less than three minutes.

Portable eye wash stations that utilize disposable eyewash solutions do not require flushing.

Solution levels in portable eyewash stations will be monitored and documented during the monthly functionality check.

Documentation of the monthly functionality check will be forwarded to the Health and Safety Program Manager.

4.4 FIRE EXTINGUISHERS

Fire extinguishers will be provided in the laboratory.

In Case of fire employees are expected to immediately exit the building.

Employees trained in the proper use of the fire extinguishers in their work area my attempt extinguish the fire.

Employees may attempt to extinguish small fires with an inverted beaker.

The Unit Health and Safety Coordinator will conduct a monthly functionality check of the fire extinguishers in his area of responsibility.

Documentation of the monthly functionality check will be forwarded to the Health and Safety Program Manager.

4.5 EMERGENCY LIGHTING

The **AGENCY NAME** will install emergency lighting that will illuminate areas that do not receive ambient light during a power failure.

The **AGENCY NAME** will install emergency exit signage that will be illuminated during power failures.

The Unit Health and Safety Coordinator will conduct a monthly functionality check of the emergency lighting systems in his area of responsibility.

Documentation of the monthly functionality check will be forwarded to the Health and Safety Program Manager.

4.6 DOCUMENTATION

The Health and Safety Program Manager will create and maintain emergency equipment inspection files for each section of the laboratory.

The Unit Health and Safety Coordinator will perform a monthly inspection of the emergency equipment.

The Unit Health and Safety Coordinator will document his inspection using the Emergency Equipment Inspection Form.

The Health and Safety Program Manager will review and sign each unit's completed Emergency Equipment inspection Form prior to filing.

5 PROCEDURE

There are currently no procedures that directly impact the implementation of this policy.

6 APPROVAL

The signatures below recognize the above Health and Safety Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

CHEMICAL HYGIENE PLAN

Chemical Procurement and Receipt

PURPOSE

This document defines the **AGENCY NAME's** chemical hygiene plan chemical procurement and receipt policy.

SCOPE

This policy applies to all **AGENCY NAME** personnel.

DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

POLICY

The **AGENCY NAME** will only procure the amount of chemicals required to meet its immediate analytical needs.

- Employee will evaluate their respective laboratory operations to ensure that the appropriate quantities of chemicals are ordered.

Employees who purchase or receive shipments of chemicals must be trained in the safe handling of hazardous substances.

Employees who perform **AGENCY NAME** chemical receiving and supply function will:

- Compare the type and quantity of chemicals received to the procurement order.
  - Chemicals that are incorrectly ordered should be returned to the manufacturer.
- Not accept chemical container(s) or compressed gas cylinder(s) without an identifying label.
- File a copy of the chemical's MSDS in the AGENCY NAME's master MSDS file, if one does not already exist.
- Will enter the following information into the AGENCY NAME's master chemical inventory:
  - Chemical Name
  - Manufacturer
  - Lot Number
  - Original Amount
  - Expiration Date
  - Storage Location

- Forward the chemicals and their associated MSDSs received to the ordering unit or employees.
  - If a chemical is received without an MSDS, the unit ordering the chemical should attempt to obtain a copy of the MSDS.
  - MSDSs may be obtained upon request from the manufacturer.

Units receiving chemicals shall:

- File a copy of the chemical's MSDS in the Unit's MSDS file, if one does not already exist, and ensure that they are readily accessible to employees.
- Will enter the following information into the Unit's master chemical inventory:
  - Chemical Name
  - Manufacturer
  - Lot Number
  - Original Amount
  - Expiration Date
  - Storage Location

PROCEDURE

There are currently no procedures that directly impact the implementation of this policy.

APPROVAL

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John Smith, Laboratory Director	Date
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CHEMICAL HYGIENE PLAN

Chemical Storage

1 PURPOSE

This document defines the **AGENCY NAME's** chemical hygiene plan chemical storage policy.

2 SCOPE

This policy applies to all **AGENCY NAME** personnel.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

Chemicals should be segregated and stored according to their chemical properties.

- The chemical's label information and MSDS will be used to determine the chemical's storage location and method.
- Chemical storage areas will be labeled with signage indicating the chemical properties of the contents.

Incompatible chemicals will be segregated and stored in approved containers that are distinctly label with the content's chemical properties.

- Where incompatible materials must be stored together, they should be separated by a chemical-resistant physical barrier that will reduce or eliminate the potential for the materials to combine if a spill should occur.

Large containers of chemicals should not be stored above eye level.

4.1 STORAGE REQUIREMENTS

4.1.1 ACIDS

- Segregate all acids from alkali and other corrosives.
- Segregate mineral acids from organic acids.
- Segregate oxidizing acids from mineral acids and organic material.
- Acetic acid and nitric acid cannot be stored in the same cabinet.
- Store below eye level.

4.1.2 ALKALI

- Segregate from acids and other corrosives.
- Store below eye level.

4.1.3 FLAMMABLES

- Store in an approved cabinet.
- Segregate from oxidizers.
- Segregate from ignition sources.
- Segregate methanol and acetone from chloroform.
  - Chloroform is nonflammable and does not require a special storage cabinet.
- Quantities of flammable solvents in excess of daily needs shall be kept in approved cabinets.
  - Containers less than four liters are considered "useable quantities" and do not need to be stored in approved cabinets.
  - Working volumes can be stored in each unit in an appropriate area.

4.1.4 COMPRESSED GASES

- All compressed gas cylinders will be stored upright in a designated space against a wall or cabinet and strapped into a mounted bracket.
- When moving cylinders, the tops must be covered with the screw-on cap and a hand truck with a safety strap designed for this purpose must be used.

4.1.5 OXIDIZERS

- Segregate form organics, combustible materials, and flammable solvents.
- Segregate for reducing agents.

4.1.6 CARCINOGENS

- Distinctly Label all containers as "cancer causing agents," "mutagentic," "carcinogenic," or "teratogen."
- Store according to the hazardous nature of the chemical.

4.1.7 WATER-REACTIVE CHEMICALS

- Store in a cool, dry place.
- In case of fire, keep water away from these chemicals to avoid a reaction.

4.2 CHEMICAL INVENTORY REVIEW

The Health and Safety Program Manager will annually review the chemical inventory, inspect the chemical storage facilities and identify chemicals which are unfit for use by the AGENCY NAME.

Chemicals found to be unfit for use will be disposed of using the procedure outlined in the Health and Safety Manual.

5 PROCEDURE

There are currently no procedures that directly impact the implementation of this policy.

6 APPROVAL

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CHEMICAL HYGIENE PLAN

Chemical Transportation

1 PURPOSE

This document defines the **AGENCY NAME's** chemical hygiene plan chemical transportation policy.

2 SCOPE

This policy applies to all **AGENCY NAME** personnel.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

Bottle carriers will be used when transporting glass bottles of chemicals such as concentrated acids, flammable solvents, or other corrosives outside the laboratory or between the stockroom and the laboratory.

- Bottle carriers are not necessary if chemicals are in shatterproof containers.

Appropriate personal protective equipment will be worn when handling large quantities of corrosive or flammable liquids.

4.1.1

5 PROCEDURE

There are currently no procedures that directly impact the implementation of this policy.

6 APPROVAL

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CHEMICAL HYGIENE PLAN

Information and Training

1 PURPOSE

This document defines the **AGENCY NAME's** chemical hygiene plan information and training policy.

2 SCOPE

This policy applies to all **AGENCY NAME** personnel.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

Employees will be provided with the necessary information and training to comply with the requirements established within this manual.

- The Health and Safety Manual orientation will serve as the minimum training each employee will receive.
  - The orientation will be documented on the Health and Safety Manual orientation form.
- Employees will annually review the Health and Safety Manual.
  - The annual review will be documented on the Health and Safety Manual review form.
- Additional training will be provided as required.

Supervisors will provide training on unit specific safety practices and procedures.

All training records will be maintained in the employee's personnel file for the duration of employment.

5 PROCEDURE

There are currently no procedures that directly impact the implementation of this policy.

6 APPROVAL

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CHEMICAL HYGIENE PLAN

Exposure and Injury Notification

1 PURPOSE

This document defines the **AGENCY NAME's** chemical hygiene plan exposure and injury notification policy.

2 SCOPE

This policy applies to all **AGENCY NAME** personnel.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

All occupationally related injuries or exposures to hazardous or toxic substances will be reported immediately to the employee's supervisor.

The following conditions or symptoms should be reported to the Unit Chief/supervisor:

- Direct skin contact with a known hazardous substance.
- Chemical or foreign substance in the eye.
- Manifestation of health symptoms such as:
  - headache.
  - nausea.
  - dizziness.
  - cough; tearing.
  - irritation or redness of the eyes, nose, or throat.
  - skin rash; or
  - loss of motor dexterity or judgment which resembles intoxication while or after working with chemicals.

5 PROCEDURE

There are currently no procedures that directly impact the implementation of this policy.

6 APPROVAL

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CHEMICAL HYGIENE PLAN

Medical Consultation and Follow-up

1 PURPOSE

This document defines the **AGENCY NAME's** chemical hygiene plan medical consultation and follow-up policy.

2 SCOPE

This policy applies to all **AGENCY NAME** personnel.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

All employees who work with hazardous materials and have symptoms of exposure will be provided with an opportunity to receive medical attention, including follow-up examinations deemed necessary by the examining physician.

All medical examinations and consultations must be performed by, or under the direct supervision of, a licensed physician and will be provided at no cost to the employee, without loss of pay, and at a reasonable time and place.

When an exposure occurs, the following information shall be provided by the employee to the physician:

- The identity of the hazardous material(s) to which the employee may have been exposed and the MSDSs for those materials.
- A description of the conditions under which the exposure occurred.
- A description of the symptoms of exposure that the employee may manifest.

All medical consultations and examinations, including test results or written opinions, will be maintained in the employee's personnel file for the duration of employment plus 30 years.

Medical recordkeeping requirements will be kept, transferred, and made available in accordance with 29 CFR 1910.1020.

5 PROCEDURE

There are currently no procedures that directly impact the implementation of this policy.

6 APPROVAL

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HAZARDOUS WASTE DISPOSAL

Program Overview

1 PURPOSE

This document defines the **AGENCY NAME's** hazardous waste disposal program overview.

2 SCOPE

This policy applies to all **AGENCY NAME** personnel.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

Hazardous waste will be defined as any material (solid, semi-solid, liquid, or gas) that has been discarded or "abandoned" or sent for disposal by the generator.

Hazardous wastes include:

- Spent solvents.
- Unused reagents.
- Reaction products.
- Strong acid or alkaline solutions.
- Reactive materials.
- Flammable materials.
- Heavy metals.
- Photographic reagents.
- Polychlorinated biphenyls (PCBs).
- Cleaning fluids.
- Degreasers.
- Batteries.
- Printing inks.
- Some aerosol containers.
- Some ordinary office supplies that are unused and discarded, may be classified as hazardous waste.

4 POLICY

The **AGENCY NAME** will establish and maintain a hazardous waste program to minimize the impact of laboratory generated waste on the environment through pollution prevention, waste minimization, recycling, and reuse.

A hazardous waste is regulated as soon as it is "generated".

All employees who generate a hazardous waste are obligated to properly manage the hazardous waste in accordance with these regulations.

5 PROCEDURE

There are currently no procedures that directly impact the implementation of this policy.

6 APPROVAL

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HAZARDOUS WASTE DISPOSAL

Waste Characterization

1 PURPOSE

This document defines the **AGENCY NAME's** hazardous waste characterization policy.

2 SCOPE

This policy applies to all **AGENCY NAME** personnel.

3 DEFINITIONS

The current revision of document APP-P101 and HAS-P701 will be used as a guide to define terms.

4 POLICY

4.1 GENERAL

40 CFR 261 and Appendix VIII will serve as the basis for the characterization and handling of hazardous waste.

The generator must determine if the waste is listed as a hazardous waste or if the waste possesses the "characteristics" of a hazardous waste.

- This determination may be based on either the generator's knowledge of the material and the process which generates the waste or through testing by a qualified laboratory.
- The basis for determining if a waste is hazardous or non-hazardous should be documented.

Hazardous waste characterization should be carried out conservatively and waste should be classified as nonhazardous only when supported by the applicable regulations and sufficient data about the material and the process is available to make a reliable decision.

4.2 WASTE CHARACTERIZATION

The following Environmental Protection Agency classifications will be used to characterize wastes as hazardous:

Type F	Spent solvents and plating and metal-finishing wastes
Type K	Wastes produced by specific industrial processes
Type P	Acutely toxic
Type U	Unused chemical products, compounds or solutions

Listed wastes have been identified as such because they exhibit one of the characteristics of a hazardous waste or they contain a constituent that has been shown to be harmful to human health or the environment.

If a waste is not listed on one of the four lists, the generator must determine if the waste displays a "characteristic" that will cause it to be regulated.

The four characteristics are:

IGNITABLE	Wastes with a flash point less than 60°C (140°F) and carry the EPA waste identification number D001.
CORROSIVE	Wastes with a pH <2 or >12.5 and carry the EPA waste identification number D002.
REACTIVE	Wastes that are unstable, react violently with water or other materials or form potentially explosive mixtures with water. Reactive wastes may generate toxic gases, vapors or fumes when mixed with water. Examples include sodium metal, Class A or B explosives, cyanide plating wastes, waste bleaches, and other waste oxidizers. Reactive characteristic wastes carry the EPA waste identification number D003.
TOXIC	The toxicity characteristic relates to the hazards of a waste leaching toxic substances through soils and into the ground water. The United States Environmental Protection Agency (EPA) has listed 39 substances for which maximum toxicity concentrations have been established. (See 40 CFR 261.24 Table 1)

4.3 HAZARDOUS WASTE FROM LABORATORIES

The following list of laboratory generated hazardous waste that requires classification and disposal.

- F-listed spent halogenated and non-halogenated solvents from non-specific sources including solvent mixtures/blends used in cleaning, extraction, or other processes.
  - Halogenated solvents include tetrachloroethylene, methylene chloride, and carbon tetrachloride.
  - Non-halogenated solvents include xylene, pyridine, acetone, ethyl ether, methanol, and cyclohexanone.
- Commercial chemical products used in laboratories, including unused reagents that are no longer needed or are otherwise unusable.
  - These include U-listed products such as chloroform, phenol, benzene, acrylamide, methanol; and
  - P-listed compounds such carbon disulfide, sodium azide and most cyanide compounds.
- Concentrated known human carcinogens or reproductive toxins.
- Any substance identified as a known toxin or poison.

- Any compound or mixture having a flash point of less than 140°F (60°C) or which can undergo spontaneous combustion.
- Any oxidizer or oxidizing agent, defined as a compound that may cause or enhance the combustion of other materials.
    - Examples include chlorates, chromates, dichromates, nitric and sulfuric acid, peroxides, and permanganates.
- Any corrosive compound or aqueous solution having a pH < 2.0 or > 12.5.
- Any compound that reacts violently with air or water.
- Any explosive.
- Any liquid that is not water miscible.
- A solid or liquid waste containing any of the following metals:

Antimony	Arsenic	Barium	Beryllium	Cadmium	Chromium
Copper	Cobalt	Gallium	Germanium	Hafnium	Indium
Iridium	Lead	Manganese	Mercury	Nickel	Osmium
Platinum	Rhenium	Rhodium	Ruthenium	Selenium	Silver
Tellurium	Thallium	Tungsten	Zinc	Vanadium	

5 PROCEDURE

There are currently no procedures that directly impact the implementation of this policy.

6 APPROVAL

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HAZARDOUS WASTE DISPOSAL

Handling and Disposal

1 PURPOSE

This document defines the **AGENCY NAME's** hazardous waste handling and disposal policy.

2 SCOPE

This policy applies to all **AGENCY NAME** personnel.

3 DEFINITIONS

The current revision of document APP-P101 and HAS-P701 will be used as a guide to define terms.

4 POLICY

4.1 GENERAL

Except as noted, the hazardous waste handling and disposal procedures described in this section are to be followed by all personnel.

It is the responsibility of the employee generating the waste to properly identify and characterize all waste materials intended for disposal.

Non-hazardous waste will not be combined with a characteristic or F-, K-, P-, or U-listed hazardous waste.

Hazardous materials or waste will not be discharged into a sewer system except as allowed in the following procedures.

Solid chemicals will not be disposed of in laboratory waste bins or office waste baskets.

All unused or surplus hazardous chemicals will be stored in an area designated by the Health and Safety Program Manager until disposal can be arranged.

5 PROCEDURE

5.1 IN-LAB TREATMENT AND DISPOSAL

The following situation may allow treated hazardous waste to be discharged into the sewer system.

- Wastes that are hazardous only on the basis of their corrosive characteristics (pH < 2 or > 12.5) may be neutralized by the addition of bases or acids, as appropriate, producing waste that is no longer hazardous.
  - Once neutralized, this waste may be discharged into the sewer system.
  - Flushing a corrosive waste down the laboratory drain does not constitute neutralization.

- Note: If the waste is corrosive and contains a listed hazardous material, regardless of the concentration, it may not be discharged into the sewer system.
- Alcohol solutions may be discharged into the sewer system under the following conditions:
  - The solution is < 24% (v/v).
    - Undiluted, flammable materials may never be discharged into the sewer system.
  - The solution does not contain any P- or U- listed material.
  - The solution does not contain additional corrosive, reactive, or toxic components.

5.2 LIQUID HAZARDOUS WASTE

Liquid hazardous wastes will be stored and disposed of as follows:

- Compatible container for storage and disposal will be utilized.
  - Empty containers that previously contained new chemicals may be rinsed and used for liquid hazardous waste disposal.
  - Containers which previously held P-listed materials may not be used for this purpose.
- Containers will be clearly labeled with:
  - The words "Hazardous Waste."
  - The content's chemical characteristics.
  - EPA waste classification.
- Waste containers will be closed at all times, except when adding waste.
- Carcinogens and mutagens will be separated from other waste.
- Aqueous wastes will be separated from organic solvents.
- Halogenated solvents and wastes will be separated from non-halogenated solvents.
- Waste mercury and its compounds will be separated from all other waste.
- Store partially filled waste containers in a place where they will not be broken or contaminate the work area.
- Full waste containers will be stored in an area designated by the Health and Safety Program Manager until disposal can be arranged.
- A record of the name and amount of each chemical added to the waste container will be maintained.
  - Include the percentages of each chemical in the container and the date the container became full enough for disposal.
  - The percent column must total 100%.
  - A copy should accompany the waste container for disposal.

5.3 SOLID HAZARDOUS WASTE

Solid hazardous wastes will be stored and disposed of as follows:

- Material in the original container with the manufacturer's label affixed:
  - Place a hazardous waste label on the container - do not cover the manufacturer's label.

    - Stored in an area designated by the Health and Safety Program Manager until disposal can be arranged.
- Material that is no longer in its original container:
    - Place a hazardous waste label on the container.
    - Document the contents.
    - Stored in an area designated by the Health and Safety Program Manager until disposal can be arranged.
- Used and unused rechargeable and nonrechargeable batteries are subject to the **Resource Conservation and Recovery Act** (RCRA), hazardous waste regulations.
    - Create a container for used batteries.
        - A separate container for each type of battery should be created.
    - Place a hazardous waste label on the container.
    - Document the contents.
    - Stored in an area designated by the Health and Safety Program Manager until disposal can be arranged.
- Do not produce any mixed wastes which consist of a Characteristic, F-, K-, U-, or P- Listed hazardous waste and a radioactive waste.

5.4 HIGHLY VOLATILE AND PEROXIDE-FORMING COMPOUNDS

Highly volatile and peroxide forming hazardous wastes will be stored and disposed of as follows:

- Peroxide forming compounds listed in Section 6.3.1.6 of this manual will be disposed of using the following schedule:
    - 3 months after opening.
    - 12 months after receipt, if unopened.
- Material in the original container with the manufacturer's label affixed:
    - Place a hazardous waste label on the container - do not cover the manufacturer's label.
    - Stored in an area designated by the Health and Safety Program Manager until disposal can be arranged.
- Material that is no longer in its original container:
    - Place a hazardous waste label on the container.
    - Document the contents.
    - Stored in an area designated by the Health and Safety Program Manager until disposal can be arranged.

5.5 UNUSED/SURPLUS HAZARDOUS CHEMICALS

Documentation of container contents is not required for, unopened, unused or surplus chemicals, provided that the materials are in their original container have the manufacturer's label affixed.

Surplus or unused material is defined as a hazardous material must also be clearly marked or labeled with the words "HAZARDOUS WASTE".

5.6 DISPOSAL PROCEDURE

The Generator will take a properly filled container of hazardous waste to the location designated for storage by the Health and Safety Program Manager and perform the following tasks.

- Complete a Waste Stream Information Sheet (WSIF).
- Assign the container a hazardous waste container number and make an entry in the Hazardous Waster Disposal Log.
- Label the container with:
  - Container #.
  - "HAZARDOUS WASTE" Label.
  - Hazard Information.
- Store the container of hazardous waste in the place designated by the Health and Safety Program Manager.
- File the in the place designated by the Health and Safety Program Manager.

The Health and Safety Program Manager will:

- Contract with an authorized chemical waste disposal company to dispose of the hazardous waste.
  - Disposals will be conducted at regularly scheduled interval.
  - The contractor will lawfully dispose of the hazardous waste.
- Provide the chemical waste disposal contractor the information required to safely package and ship the hazardous waste.
- Update the Hazardous Waste Disposal log with the date that a container was removed by the chemical waste disposal company.
- File the copy of the shipping manifest from the chemical disposal company the folder containing the associated WSIFs.

5.6.1 7.3.7 DOCUMENTATION

All employees who generate hazardous waste for disposal MUST complete a "Waste Stream Information Form (WSIF)" for each container of hazardous waste generated.

Each container of hazardous waste stored for disposal will be assigned a unique container number using the following format HW-XX-YYY.

- **HW:** Hazardous Waste.
- **XX:** The last 2 digits of the year the waste was generated.
- **YYY:** A unique identification number for a given year. Numbering begins at 001 on 1 January.

The Health and Safety Program Manager will establish and maintain a log of filled hazardous waste containers that are store and disposed of. (Hazardous Waste Disposal Log)

The Health and Safety Program Manager will establish and maintain a file that contains relevant hazardous waste disposal information, to include but not be limited to:

- Waste Stream Information Sheets
- Hazardous Waste Disposal Logs
- Shipping manifests from chemical waste disposal companies

If more than one container of the same waste is sent for disposal, only a single WSP form needs to be prepared for that waste stream.

The original copy of the WSP form should be kept on file in the unit and a copy affixed to the waste container by a single piece of tape across the top of the label in such a way that it can be later removed.

6 APPROVAL

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John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

HAZARDOUS WASTE DISPOSAL

Empty Container Disposal

1 PURPOSE

This document defines the **AGENCY NAME's** empty container disposal policy.

2 SCOPE

This policy applies to all **AGENCY NAME** personnel.

3 DEFINITIONS

The current revision of document APP-P101 and HAS-P701 will be used as a guide to define terms.

4 POLICY

A container is "empty" when it is void of all material using the practices commonly employed to remove materials from that type of container.

Empty chemical containers, or container liners (except for those containing P-listed materials). must be rinsed in the laboratory sink to remove all residual material.

- If the material is not water soluble, the open, empty container should be placed in a laboratory fume hood and the residue allowed to completely evaporate.

All labels should be defaced or removed from containers once emptied well rinsed or evaporated.

Plastic containers can then be thrown in the trash and glass bottles into glass disposal boxes.

The labels of larger containers should be defaced, labeled, the container labeled "EMPTY", and taken directly to the trash disposal area.

Rinsed empty containers, except those previously holding P-listed materials, may also be used for waste collection.

Empty containers, or container liners, which previously held P-listed, acute hazardous wastes must be triple rinsed using a solvent capable of removing the residue.

- The rinsed containers must be clearly labeled "TRIPLE RINSED" and the rinsed container disposed of directly in an appropriate trash container.

The solvent used to rinse the containers must be collected and disposed as a hazardous waste.

Containers which previously held compressed gasses, such as aerosol cans, must be handled as hazardous wastes.

PROCEDURE

There are currently no procedures that directly impact the implementation of this policy.

APPROVAL

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John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

END OF DOCUMENT

HAZARDOUS WASTE DISPOSAL

Non Hazardous Chemical

1 PURPOSE

This document defines the **AGENCY NAME's** non hazardous chemical policy.

2 SCOPE

This policy applies to all **AGENCY NAME** personnel.

3 DEFINITIONS

The current revision of document APP-P101 and HAS-P701 will be used as a guide to define terms.

4 POLICY

Unused and surplus non-hazardous chemical waste will not be disposed of in local landfills and may not be disposed of in the regular trash.

Non-hazardous chemicals should be labeled "non-hazardous waste" and returned to area designated by the Health and Safety Program Manager until disposal can be arranged.

Non-hazardous, liquid waste that does not contain a hazardous material or other recognized known or suspected carcinogen and which do not meet the definition of a hazardous waste as defined in the Waster Characterization Policy, may be disposed of down the laboratory drain.

5 PROCEDURE

There are currently no procedures that directly impact the implementation of this policy.

6 APPROVAL

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HAZARDOUS WASTE DISPOSAL

Regular Trash Disposal

1 PURPOSE

This document defines the **AGENCY NAME's** regular trash disposal policy.

2 SCOPE

This policy applies to all **AGENCY NAME** personnel.

3 DEFINITIONS

The current revision of document APP-P101 and HAS-P701 will be used as a guide to define terms.

4 POLICY

Paper and cardboard boxes may be recycled if appropriate.

Broken glass and other sharps should be placed in boxes designated for glass or sharp disposal and should never be disposed of in regular trash cans.

- Boxes specifically for broken glass will be made available for this purpose.

Chemical or biological waste will not be placed into the regular office or laboratory waste baskets.

5 PROCEDURE

There are currently no procedures that directly impact the implementation of this policy.

6 APPROVAL

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HAZARDOUS WASTE DISPOSAL

Radioactive Waste Disposal

1 PURPOSE

This document defines the **AGENCY NAME's** radioactive waste disposal policy.

2 SCOPE

This policy applies to all **AGENCY NAME** personnel.

3 DEFINITIONS

The current revision of document APP-P101 and HAS-P701 will be used as a guide to define terms.

4 POLICY

The **AGENCY NAME** does not handle radioactive materials and does not generate radioactive waste.

There is currently no policy for the disposal of radioactive waste.

A radioactive waste disposal policy and related procedures will be developed prior to initiating procedures that require the use of radioactive materials and the subsequent generation of radioactive waste.

5 PROCEDURE

There are currently no procedures that directly impact the implementation of this policy.

6 APPROVAL

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HAZARDOUS WASTE DISPOSAL

Biological Waste Disposal

1 PURPOSE

This document defines the **AGENCY NAME's** biological waste disposal policy.

2 SCOPE

This policy applies to all **AGENCY NAME** personnel.

3 DEFINITIONS

The current revision of document APP-P101 and HAS-P701 will be used as a guide to define terms.

Biological waste includes, but is not limited to:

- Human blood
- Blood products
- Body fluids, and urine
- Materials stained with blood or body fluids
- Human organs, tissues, and body parts, including autopsy specimens

As used in this section, "sharps" mean needles, syringes, scalpels, glass, or other materials capable of producing a puncture of the skin.

4 POLICY

All biohazard materials will be deposited in red, biohazard bags clearly marked with the biohazard symbol and/or the word "Biohazard".

- These bags should be kept closed except when adding waste.
- The closed bags should be placed in designated locations in each unit.

Biological waste, or material contaminated with this biological waste will not be placed into the regular trash cans.

Biological products that are toxic to humans will be considered hazardous and disposed of accordingly.

Sharps that are contaminated with human biological material must be placed in either metal or plastic sharps containers that are labeled with the biohazard symbol.

- Sharp objects of any type should never be placed in trash containers or waste baskets.

Contaminated sharps must be disposed of as a biohazard waste.

The Health and Safety Program Manager will:

- Designate a location for the storage of biohazard waste that is waiting for disposal.
- Contract with an authorized biohazard waste disposal company to dispose of the AGENCY NAME biohazard waste.
  - Disposals will be conducted at regularly scheduled interval.
  - The contractor will lawfully dispose of the biohazard waste.
- Provide the biohazard waste disposal contractor the information required to safely package and ship the AGENCY NAME's hazardous waste.

5 PROCEDURE

There are currently no procedures that directly impact the implementation of this policy.

6 APPROVAL

The signatures below recognize the above Health and Safety Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

HAZARDOUS WASTE DISPOSAL

Waste Minimization

1 PURPOSE

This document defines the **AGENCY NAME's** waste minimization policy.

2 SCOPE

This policy applies to all **AGENCY NAME** personnel.

3 DEFINITIONS

The current revision of document APP-P101 and HAS-P701 will be used as a guide to define terms.

4 POLICY

The **AGENCY NAME** will establish and maintain a policy of waste minimization to reduce the volume of hazardous waste generated, reduce the degree of hazard of the waste, and reduce the associated cost of disposal.

4.1 WASTE MINIMIZATION THROUGH PURCHASING

Employees are authorized to purchase any substance or material necessary to perform their assigned mission.
The following practices should be implemented to meet the goal of waste minimization:

- Less toxic materials should be substituted whenever technically feasible.
- Use of materials already in stock.
- Order only the minimum quantity required for a project.
  - A maximum of a 12 month supply of any material will be ordered.
  - Research project purchases will be limited the amount needed.
- Consider the cost requirements for disposal of unused material or its associated wastes when ordering.
  - Note: The disposal cost may be 10-20 times the original purchase price.
- Purchase compressed gas cylinders, including lecture bottles, only from vendors who will accept the return of empty cylinders.
- Use chemicals with the oldest received date first.

5 PROCEDURE

The following practices should be implemented to meet the goal of waste minimization:

- Wherever possible, scale down laboratory procedures that produce hazardous waste.
- Determine if other units or operations may be able to use excess chemicals.
- Review procedures regularly (e.g., annually) to see if quantities of chemicals and/or chemical waste could be reduced.
- Consider the quantity and type of waste that may be generated when purchasing new equipment or implementing a new procedure.
- Examine the possibility of including detoxification and/or waste neutralization steps in the written laboratory procedures.
- Keep hazardous chemical waste separate from non-hazardous chemical waste.
  - Do not mix chemical waste with normal trash (paper, wood, etc.).
- Review the necessity to use highly toxic, reactive, carcinogenic or mutagenic materials.
  - Determine if safer alternatives are feasible.
- If possible, avoid the use of reagents containing barium, arsenic, cadmium, chromium, lead, mercury, selenium, and silver, which, due to their toxicity, have been identified as hazardous by the EPA.
- Avoid procedures that produce wastes that contain both a radioactive and a hazardous chemical waste.
- Eliminate the use of uranium and thorium compounds.
- Substitute red liquid (alcohol) thermometers (range up to 150 degrees C°) for mercury thermometers where possible.
- Use the least hazardous cleaning solutions and procedures for glassware.
- Eliminate the use of chromic acid.
- When necessary for cleaning purposes, use a spent solvent for initial cleaning and a fresh solvent for final cleaning.
- If possible, use detergent and hot water to clean parts instead of solvents.
- Precipitate silver out of solution. The resulting liquid must be tested prior to discharge into the sanitary sewer to confirm that the amount of any silver remaining in solution is below regulatory levels.
  - Records of such testing must be maintained. For those solutions where the silver cannot be effectively removed, the entire solution must be disposed of as hazardous waste.
- Keep halogenated solvent waste separate from non-halogenated solvent waste.
- Keep organic wastes separate from metal-containing or inorganic wastes.
- Keep highly toxic wastes (cyanides, etc) separated from all other wastes.
- Corrosive wastes (pH < 2 or >_ 12.5) that do not contain metals or other hazardous materials may be neutralized at the lab bench and disposed of down the laboratory drain.

6 APPROVAL

The signatures below recognize the above Health and Safety Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

SPILL CONTROL AND CONTAINMENT

General Policy

1 PURPOSE

This document defines the **AGENCY NAME's** spill control and containment general policy.

2 SCOPE

This policy applies to all **AGENCY NAME** personnel.

3 DEFINITIONS

The current revision of document APP-P101 and HAS-P701 will be used as a guide to define terms.

4 POLICY

All employees are responsible for the safe and timely clean-up of spilled materials.

Facility maintenance, engineering, or custodial service personnel should not be called for assistance.

The AGENCY NAME will procure commercial spill kits and place them in areas where chemicals or other hazardous materials may be encountered.

5 PROCEDURE

There are currently no procedures that directly impact the implementation of this policy.

6 APPROVAL

The signatures below recognize the above Health and Safety Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

SPILL CONTROL AND CONTAINMENT

Containment Procedures

1 PURPOSE

This document defines the **AGENCY NAME's** spill containment general procedure.

2 SCOPE

This policy applies to all **AGENCY NAME** personnel.

3 DEFINITIONS

The current revision of document APP-P101 and HAS-P701 will be used as a guide to define terms.

4 POLICY

The **AGENCY NAME** will establish and maintain spill containment procedures.

5 PROCEDURE

The following procedures will be used for spill containment.

5.1 LIQUID SPILLS

- Alert coworkers in the immediate area.
- If necessary, notify the unit safety representative.
- Assist contaminated persons to a safety shower or eyewash.
  - Administer first aid and summon help as needed.
- If necessary, evacuate nonessential personnel from the spill area.
- Avoid unnecessary contact or exposure to the spilled material.
- Assess the hazard.
  - Consult the Material Safety Data Sheet (MSDS).
- If the spilled material is flammable, eliminate ignition and heat sources within and near the spill area.
- Maintain or establish exhaust ventilation if it is safe to do so.
- Wear the recommended personal protective equipment (PPE) and clothing.
  - At minimum, wear gloves, lab coat, and safety goggles.

- Use absorbent materials from the spill control kit to confine or contain the spill to a small area.
  - Avoid letting it spread or spill into floor drains.
  - (Spills involving hydrofluoric acid require specific absorbent material).
- Place spill cleanup residue and absorbent materials in yellow plastic hazardous material disposal bags, seal and label as hazardous waste.
  - These materials should be placed in durable, closable, polyurethane containers and labeled as hazardous waste. Containers are available in the hazardous waste storage room.
- Dispose of residue and cleanup materials as hazardous waste according to the guidelines given in the Hazardous Waste Disposal section.

5.2 SOLID SPILLS

- Alert coworkers in the immediate area.
- If necessary, notify the unit safety representative.
- Assist contaminated persons to a safety shower or eyewash.
  - Administer first aid and summon help as needed.
- If necessary, evacuate nonessential personnel from the spill area.
- Avoid unnecessary contact or exposure to the spilled material.
- Wear the recommended PPE and clothing. At minimum, wear gloves, lab coat, and safety goggles.
- Assess the hazard (Consult the MSDS).
- Sweep spilled, non-carcinogenic solid materials of low toxicity into a dust pan and place in an appropriate container for disposal.
- Use a HEPA equipped vacuum cleaner for cleanup of spills of suspected or known, highly toxic and/or carcinogenic powders, flakes or granules.
- Dispose of the waste and cleanup materials as hazardous waste according to the guidelines given in the Hazardous Waste Disposal section.

5.3 MERCURY SPILLS

- All spills of mercury must be properly cleaned up.
- Units that use mercury, or equipment such as thermometers which contain mercury, should purchase mercury spill control kits.
- Report all mercury spills to supervisor.
- Follow steps a - f for Solid Spills.
- Follow the instructions in the spill kit and proceed with the spill cleanup.
- Residue from cleanup should be placed in a plastic bag, sealed to prevent vapor release, labeled and disposed of as hazardous waste (Refer to the Hazardous Waste Disposal section).

5.3.1 Leaking Compressed Gas Cylinders

- If a leak is suspected, use a gas leak detector, soapy water or other suitable solution to detect the leak.
- If the leak cannot be stopped by tightening a valve, contact the supplier for instructions.
  - Supplier phone numbers can be obtained from the MSDS and canister labels.
- If the leak is of minimum size and does not pose a serious safety hazard or exposure of personnel, the cylinder may be moved through populated portions of the building if a plastic bag or similar device is placed over the top of the cylinder and taped to the cylinder to confine the leaking gas.
- For flammable or oxidizing gases, move the cylinder to an isolated area away from combustible materials and ignition sources.
  - Post signs that describe the hazards and state warnings. Contact the supplier.
- For toxic or corrosive gases, move the cylinder to an isolated and well ventilated area. Post signs that describe the hazards and state warnings. Contact the supplier.
- For large or uncontrollable leaks that pose a life-threatening hazard, emergency evacuation procedures, as described in the Occupant Emergency Plan - Fire or Emergency Evacuation Procedures section, should be followed.

5.3.2 Biohazard Spills (Potentially Infectious Materials)

- Close off the spill area to traffic.
- Wear the proper PPE.
  - At a minimum wear latex or nitrile gloves, lab coat, and safety glasses or goggles.
- Contain the spill with paper towels.
- Pour a freshly prepared 10% solution of chlorine bleach on the spill.
  - Let set for 15 minutes to allow for disinfection.
  - Repeat the process until the entire spill has been removed.
- Place cleanup materials in a color-coded biohazard bag and dispose of as infectious waste (Refer to the Hazardous Waste Disposal section).

5.3.3 Radioactive Spills

- Notify the Radiation Safety Officer (RSO) or Assistant RSO.
- Monitor personal exposure before leaving the area to avoid contaminating other areas of the laboratory.
- Notify coworkers and close off spill area to traffic.
- Identify the extent of the spill using appropriate detecting equipment.
- Circle the affected areas using a marking pen or pencil.
- Spray the affected area with a high phosphate solution and absorb the spray and waste with absorbent material from a spill kit. Repeat this process until no significant radiation is detected.

- Place used absorbent materials in an appropriate container, and label accordingly.
- Dispose of all waste material as radioactive waste.

6 APPROVAL

The signatures below recognize the above Health and Safety Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

LABORATORY FUME HOODS

General Policy

1 PURPOSE

This document defines the **AGENCY NAME's** laboratory fume hood general procedure.

2 SCOPE

This policy applies to all **AGENCY NAME** personnel.

3 DEFINITIONS

The current revision of document APP-P101 and HAS-P701 will be used as a guide to define terms.

4 POLICY

The **AGENCY NAME** will provide fume hoods designed to remove hazardous air contaminants, contain explosions and fires, and provide general ventilation for the laboratory.

All chemical analyses will be conducted in a fume hood when feasible.

Employees will correctly use and maintain fume hoods to ensure that maximum protection is afforded.

5 PROCEDURE

There are currently no procedures that directly impact the implementation of this policy.

6 APPROVAL

The signatures below recognize the above Health and Safety Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

LABORATORY FUME HOODS

General Procedures

1 PURPOSE

This document defines the **AGENCY NAME's** laboratory fume hood general procedure.

2 SCOPE

This policy applies to all **AGENCY NAME** personnel.

3 DEFINITIONS

The current revision of document APP-P101 and HAS-P701 will be used as a guide to define terms.

4 POLICY

The **AGENCY NAME** will establish and maintain operational procedures for fume hoods utilized by laboratory personnel.

5 PROCEDURE

Personnel who conduct procedures within a fume hood should follow the safe practices outlined below:

5.1 FUME HOOD OPERATIONAL PERAMETERS

- Fume hoods should be evaluated before use to ensure adequate face velocities.
  - Tissue paper or strip of thin paper hung at the face of the hood may be used to provide a visible sign that air is flowing into the hood.
  - A vaneometer will be used to determine the face velocity of the air flow into the fume hood.
  - Fume hood malfunctions will be reported to the section supervisor.
  - If a fume hood is thought to be malfunctioning, relocate the procedure and any stored chemicals to another, properly operating fume hood.
    - A sign should be placed on the hood indicating that it is nonoperational.
- Hood face velocity should:
  - Average between 60 - 100 ft/min. when the sash is in the full open position.
  - The face velocity should be no greater than 125 ft/min. at any sash height opening.

5.2 FUME HOOD USE

- Consult the Material Safety Data Sheet and other available references regarding the physical and chemical properties of the materials to be used.
- When performing a procedure in a fume hood, lower the sash to approximately 18 inches or to a level low enough to protect the face of the user.
- All work in a fume hood should be conducted at least six inches back from the hood face.
  - Large equipment should be supported one to two inches off the bench top with small blocks of wood.
  - This allows air to flow under the equipment.
- Laboratory equipment should be located as far back in the hood as practicable.
  - If the air slots are blocked, the air flow may be reduced and hazardous air contaminants may enter the work area creating a health hazard.
  - Air slots at the back of the hood should be cleaned as needed to remove dust and debris and maintain proper hood operation.
- Employees should not allow paper, disposable gloves, or other debris to be drawn into the slots at the rear of the hood.
- Employees will avoid placing your head inside the hood while chemicals are present in the hood.
- Employees will not place electrical receptacles or other spark sources in the hood when flammable or explosive materials are present.
- Fume hoods will not be used for disposal of waste chemicals by evaporation.

6 APPROVAL

The signatures below recognize the above Health and Safety Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

END OF DOCUMENT

LABORATORY FUME HOODS

Storage in Fume Hoods

1 PURPOSE

This document defines the **AGENCY NAME's** laboratory fume hood storage policy.

2 SCOPE

This policy applies to all **AGENCY NAME** personnel.

3 DEFINITIONS

The current revision of document APP-P101 and HAS-P701 will be used as a guide to define terms.

4 POLICY

Employees will minimize chemical storage in fume hood.

- Only the materials being used during the process should be stored in the hood.

Containers of flammable liquids should not be stored in the fume hood.
Solvent waste bottles may be stored in a fume hood while they are being filled.

- Full waste bottles should be promptly disposed of according to the procedures outlined in the Hazardous Waste Disposal section.

5 PROCEDURE

There are currently no procedures that directly impact the implementation of this policy.

6 APPROVAL

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John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

LABORATORY FUME HOODS

Ductless Fume Hoods

1 PURPOSE

This document defines the **AGENCY NAME's** laboratory ductless fume hood policy.

2 SCOPE

This policy applies to all **AGENCY NAME** personnel.

3 DEFINITIONS

The current revision of document APP-P101 and HAS-P701 will be used as a guide to define terms.

4 POLICY

Ductless fume hoods may be used to provide personnel and the environment protection from contaminant fumes, vapors, odors, and particulates.

Ductless fume hood filter selection will depend on the type of contaminant to be removed.

Used ductless fume hood filters will be handled and disposed of as hazardous waste unless determined otherwise.

The manufacturer's recommendations will be used as a guide for appropriate operation and maintenance of ductless fume hoods.

5 PROCEDURE

There are currently no procedures that directly impact the implementation of this policy.

6 APPROVAL

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John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

LABORATORY FUME HOODS

Biological Safety Cabinets

1 PURPOSE

This document defines the **AGENCY NAME's** laboratory biological safety cabinet policy.

2 SCOPE

This policy applies to all **AGENCY NAME** personnel.

3 DEFINITIONS

The current revision of document APP-P101 and HAS-P701 will be used as a guide to define terms.

4 POLICY

The use of biological safety cabinets (BSCs) is authorized as effective primary containment devices in laboratories working with blood borne pathogens and potentially infectious materials.

Employees will utilize universal precautions, good laboratory techniques and properly maintained BSCs, to maximize the effective containment system for safe manipulation of potentially infectious materials.

BSCs will not be used with volatile or toxic chemicals and radionuclides.

Filters removed from BSCs will be handled and disposed of as infectious waste.

5 PROCEDURE

There are currently no procedures that directly impact the implementation of this policy.

6 APPROVAL

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John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

LABORATORY FUME HOODS

Glove Boxes

1 PURPOSE

This document defines the **AGENCY NAME's** laboratory glove box policy.

2 SCOPE

This policy applies to all **AGENCY NAME** personnel.

3 DEFINITIONS

The current revision of document APP-P101 and HAS-P701 will be used as a guide to define terms.

4 POLICY

Glove boxes will be operated and maintained according to the manufacturer's instructions.

5 PROCEDURE

There are currently no procedures that directly impact the implementation of this policy.

6 APPROVAL

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John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

ERGONOMICS AND OFFICE SAFETY

Ergonomics

1 PURPOSE

This document defines the **AGENCY NAME's** ergonomics policy.

2 SCOPE

This policy applies to all **AGENCY NAME** personnel.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

The **AGENCY NAME** will make the office setting as user-friendly as possible by offering common sense, practical solutions for changing work settings and work tasks to meet the comfort needs of workers.

The **AGENCY NAME** will strive to reduce or eliminate commonly reported occupational or ergonomic risk factors which include:

- Repetitive and sustained exertions
- Forceful exertions
- Awkward postures
- Mechanical stress concentrations
- Vibration
- Temperature extremes

5 PROCEDURE

There are currently no procedures that directly impact the implementation of this policy.

6 APPROVAL

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End of Document

ERGONOMICS AND OFFICE SAFETY

Laboratory Environment

1 PURPOSE

This document defines the **AGENCY NAME's** laboratory environment policy.

2 SCOPE

This policy applies to all **AGENCY NAME** personnel.

3 DEFINITIONS

The current revision of document APP-P101 and HAS-P701 will be used as a guide to define terms.

4 POLICY

Employees should attempt to reduce repeated and sustained exertions by:

- Organizing their work day to alternate between different types of activities.
- Performing stretching exercises.
- Pipetteing with both the left and right hand whenever possible.
- Using automatic pipettes.
- Using the computer mouse with both the left and right hand.
- Incorporate key commands with computer mouse usage, where possible.

Employees should attempt to reduce forceful exertions by:

- Using automatic pipettes.
- Using a tool to put on and snap off caps.
- Using the minimal amount of force necessary to use the mouse and to type.

Employees should attempt to reduce posture stresses by:

- Alternating work heights while working at the bench.
- Utilizing a test tube holder that brings the test tube up to eye level while extracting substances under the hood.
- Positioning the computer mouse close to edge of the keyboard when in use.
- Using an adjustable keyboard stand that can be positioned in front of the monitor to minimize posture stresses.
- Utilizing a document holder when appropriate to minimize forward bending of the neck.
- Alternating the position of the document holder and the mouse between your left and right.

Employees should attempt to reduce mechanical stress concentrations by:

- Utilizing a soft pad when resting your hands or elbows on a hard work bench surface.
- Utilizing a padded wrist rest so that your wrist and forearm are not resting on a hard surface.
- Choosing chair arm rests that have rounded edges and are adjustable.

5 PROCEDURE

There are currently no procedures that directly impact the implementation of this policy.

6 APPROVAL

The signatures below recognize the above Health and Safety Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

ERGONOMICS AND OFFICE SAFETY

Office Environment

1 PURPOSE

This document defines the **AGENCY NAME's** office environment policy.

2 SCOPE

This policy applies to all **AGENCY NAME** personnel.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

Employees should attempt to reduce repeated and sustained exertions by:

- Taking short breaks or alternate activities other than keying every hour.
- Performing stretching exercises.
- Using the mouse with both the left and right hands.
- Incorporate key commands with computer mouse usage where possible.
- Organizing their work day to alternate between different types of activities.

Employees should attempt to reduce posture stresses by:

- Positioning the computer mouse close to the edge of the keyboard when in use.
- Using an adjustable keyboard stand that can be positioned in front of the monitor to minimize posture stresses.
- Utilizing a document holder when appropriate to minimize forward bending of the neck.
- Alternating the position of the document holder and the computer mouse between their left and right.

Employees should attempt to reduce mechanical stress concentrations by:

- Utilizing a padded wrist rest so that your wrist and forearm are not resting on a hard surface.
- Using a sit-stand chair if both standing and seated work are to be performed at the same work station.
    - If primarily seated work is to be completed at a workstation, then a traditional office chair is more desirable.
- Office chairs should have the following features:
    - Easily movable and on casters.

- Easily adjustable seat height and angle (adjust while seated).
- Adjustable backrest position and angle.
- Adjustable height of backrest.
- Arm rests should have rounded edges and should be adjustable.

5 PROCEDURE

There are currently no procedures that directly impact the implementation of this policy.

6 APPROVAL

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Mary Doe, Quality Assurance Manager	Date

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ERGONOMICS AND OFFICE SAFETY

Office Environment

1 PURPOSE

This document defines the **AGENCY NAME's** office environment policy.

2 SCOPE

This policy applies to all **AGENCY NAME** personnel.

3 DEFINITIONS

The current revision of document APP-P101 will be used as a guide to define terms.

4 POLICY

4.1 GENERAL CONSIDERATIONS

Aisles should be less than 33 inches wide and exits should comply with fire codes.

Desks and equipment should be located in a manner which does not block exits and emergency equipment.

Desks, files, and other office equipment should be located so employees can work with them safely.

Video display terminals should be located in a manner that eliminates glare, provides enough light for reading and reduces fatigue.

Wires and cables should be properly anchored under desks, on walls, or in cable trays.

Wires and cables should be kept off the floor near walking areas and they should not be stretched between equipment.

- If cables must be located on floors, they should be covered with rubber trip guards.

4.2 PROPER LIFTING TECHNIQUES

Employees should utilize the following steps for safe and easy lifting:

- Face the object and get as close to it as you can.
- Balance yourself with your feet slightly apart.
- Squat down, bending your knees. Keep your back as straight and upright as possible.
- Grip the object firmly.
- Tighten your abdomen.
- Use your legs to bring to attain a standing position, keeping your back straight.
- Do not twist your body when lifting or setting an object down.

4.2.1 Tripping Hazards

Employees should utilize the following steps to avoid tripping hazards:

- Walking areas should be kept free of loose rugs.
- Walking areas should be kept clear of trash, boxes, files, and any other materials that do not belong in the aisles.
- Tripping hazards that cannot be removed should be brightly marked to warn other employees.

4.2.2 Fall Hazards

Employees should utilize the following steps to avoid fall haxards:

- Ladders or step stools should be provided when access to overhead storage is required. Employees should never stand on chairs, desks, or other office equipment to gain access to overhead storage.
- Plastic floor pads should be provided for rolling chairs if office carpet makes moving chairs difficult.
- Broken chairs should be immediately removed from service.
- File cabinets and shelves that could tip over should be properly anchored to the wall or other cabinets.

4.2.3 Safe Work Practices

Employees should utilize the following safe work practives:

- Office personnel should never try to repair electrical equipment.
  - Malfunctioning equipment should be reported to the supervisor or the appropriate equipment vendor.
- To prevent accidental scalding, coffee makers should not be placed and operated on shelves.
  - Coffee makers should be turned off and unplugged at the end of each work day to prevent fires.
- Employees should not attempt to move objects that are too heavy for them to handle safely.

5 PROCEDURE

There are currently no procedures that directly impact the implementation of this policy.

6 APPROVAL

The signatures below recognize the above Health and Safety Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

Appendix G

Health and Safety Policy Manual

(Revision XX)

This document represents the Health and Safety policies of the **AGENCY NAME**. All additions, deletions and modifications to this document are done in accordance with the policy preparation policy. This document is the property of the **AGENCY NAME** and cannot be reproduced without authorization.

Official revisions are incorporated annually. Interim modifications will be documented and implemented in accordance to the document modification policy. A copy of the interim modification will be distributed and inserted into the appropriate portion of each printed section of this manual.

The signatures below recognize the total volume as the official health and safety policy of the **AGENCY NAME** effective **DATE**.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

CONTENTS

1 Safety Responsibility/Authority

1.1 Scope

The policies, practices and procedures outlined in this manual apply to all **AGENCY NAME** personnel.

1.2 Responsibility for Safety

The responsibility for safety at the **AGENCY NAME** personnel follows the established line of supervision, from Assistant Director, through management, to the employee.

1.2.1 Assistant Director

The Assistant Director's responsibilities include:

- Provide the leadership and management to ensure that safe working conditions are maintained in the laboratory.
- Ensure that a system is in place to monitor compliance with mandated safety programs.
- Appoint a Health and Safety Program Manager.

1.2.2 Section Chiefs

The Section Chief's responsibilities include:

- Provide the leadership and management to ensure that safe working conditions are maintained in the section.
- Ensure that personnel within the section attend scheduled training.

1.2.3 Unit Chiefs

The Unit Chief's responsibilities include:

- Ensure that unit personnel annually review the Health and Safety Manual.
- Documentation of this review will be maintained by the unit.
- Maintain safety awareness and encourage the use of safe work practices.
- Provide the necessary personal protective equipment and ensure that it is used by the employees.
- Ensure that employees attend all applicable safety training.
- Correct safety deficiencies in a timely manner.
- Schedule new employees to be included in scheduled safety training.
- Appoint a Unit Health and Safety Coordinator.

1.2.4 Supervisors

The Supervisor's responsibilities include:

- Safety of the employees under their supervision.
- Ensuring that employees are properly trained to perform laboratory procedures and related duties in a safe manner.
- Ensure that the mandatory safety practices described in this manual are followed.

When necessary, the Unit Chief will assist the supervisor in controlling and correcting unsafe work practices.

1.2.5 Health and Safety Program Manager

The Health and Safety Program Manager's responsibilities include:

- Establish and maintain occupational health and safety programs.
- Promote laboratory safety by providing consultation, training, and exposure monitoring when necessary.
- Develop and implement chemical hygiene policies and practices.
- Act as the **AGENCY NAME** resource for information on chemicals and chemical products.
- Develops and implements policies and practices for the handling and disposal of hazardous chemicals and materials.
- Ensures compliance with hazardous waist and related environmental regulations.
- Ensuring compliance with the relevant guidelines, regulations and standards concerning the use and handling of radioactive materials.

1.2.6 Unit Health and Safety Coordinator

The Unit Health and Safety Coordinator's responsibilities include:

- Serve as a liaison on health and safety issues.
- Ensures unit compliance with applicable environmental and occupational health and safety regulations.
- Serves as a representative on the Environmental and Occupational Health and Safety Committee.

1.2.7 Employees

The Employee's responsibilities include:

- Comply with the practices and procedures described in this manual and safety practices found in unit protocols or procedures.
- Maintain a safe workplace for themselves and their coworkers.

2 Safety Practices and Procedures

Laboratory employees are responsible for complying with the following:

Awareness
Employees will:

- Determine potential hazards with all operations and observe all safety rules and procedures that apply.
- Be aware of the routes of exposure (inhalation, ingestion, skin contact, and injection) and recommended protective measures.
- Be familiar with the procedures for reporting injuries and exposures.
- Be alert to unsafe conditions and actions and call attention to them so that corrections can be made.
- Be encouraged to report unsafe or unhealthy work conditions.
- Have the right to examine and obtain a copy of their medical records and any chemical or biological exposure records.
    - Employee medical records will be maintained for 30 years.
    - Employees may obtain a copy of their records by submitting a written request that includes their name, social security number, service dates and signature.
- Think, act, and practice safety until it becomes a habit.

Eating and Drinking
The Director of the **AGENCY NAME** will designate authorized eating and drinking areas.
It is prohibited to:

- Eat, drink, smoke, chew gum or apply cosmetics in areas where: chemicals, blood or other potentially infectious materials are present; or where evidence, that may be contaminated with chemicals, blood or other potentially infectious materials, is opened for examination.
- Store food and drink in refrigerators, freezers, shelves, cabinets or on countertops or bench tops where: chemicals, blood or other potentially infectious materials are present; or where evidence, that may be contaminated with chemicals, blood or other potentially infectious materials is present.
- Handle or consume food or beverages out of glassware or utensils which are also used for laboratory operations.
- Wear lab coats in designated eating and drinking areas or in areas outside the laboratory space, except if there is a need to deliver or receive evidence.

Food and drink must be covered while carrying these items through designated laboratory space to designated eating and drinking areas.

Personal Hygiene
- Never place personal effects where they may become contaminated with chemical or biological materials.
- Avoid touching the mouth or face with contaminated hands or gloves. Also, avoid contaminating clean surfaces such as drinking fountain handles, telephones, door knobs, and water faucets.

    - When appropriate, wash hands before eating, drinking, applying cosmetics or conducting any activities outside of designated laboratory space.
    - Wash hands thoroughly after removing gloves and prior to leaving the laboratory.
- Pipetting by mouth is forbidden. A pipette bulb, aspirator, or other mechanical device should be used to provide a vacuum.
- Contaminated lab coats or other personal protective clothing should not be laundered at home.

Personal Protective Equipment (PPE)
Employees will:

- Be familiar with the types of PPE for each procedure and its proper use.
- Wear eye protection in the laboratory whenever there is reasonable probability.
- Wear appropriate gloves when handling biological, chemical, other hazardous materials, and when there is a reasonable probability that evidence may be contaminated with these materials.
- Wear lab coats when working with or handling biological, chemical, other hazardous materials, and when there is a reasonable probability that evidence may be contaminated with these materials.
- Not wear open-toed shoes where biological or chemical hazards are present.

Biological Safety
Employees will use Universal Precautions when handling biological materials.

Chemical Safety
Employees will:

- Know the location of Material Safety Data Sheets and how to interpret them.
- Be aware of incompatible materials.
- Be aware of the hazardous properties of the chemicals being used and recommended protective measures.
- Use a chemical fume hood for procedures involving carcinogens and hazardous materials.
- Conduct any potentially reactive experiment behind a safety shield inside a fume hood.
- Use bottle carriers when transporting glass containers of flammable or hazardous materials.
- Clean-up of all chemical spills in their unit.
    - Custodial personnel will not to clean chemical spills.
- Handle lacrimators (tear producers) or materials with offensive odors in a manner that prevents release into the laboratory environment, sewer systems, or trash receptacles.
- Write the date opened on the label of chemicals that may form peroxides prior to opening the container.
- Not deface or remove the labels on hazardous chemical containers.
    - Any container used for the overnight storage of chemicals must be labeled with the identity of the material and hazard warnings associated with its handling.

- Combine reagents in the appropriate sequence to avoid violent reactions.
  - Avoid adding solids to hot liquids.
  - Pour more concentrated solutions into less concentrated solutions.
- Secure gas cylinders upright during use and storage.
  - Remove regulators and install cylinder caps before moving cylinders.

Housekeeping
Employees will:

- Keep units clean and orderly.
  - Floors, shelves, and tables should be free from dirt and general clutter.
- Not block access to eyewashes, safety showers and other emergency equipment.
- Flush eyewash stations for at least three minutes on a weekly basis.
- Keep all materials at least 18 inches from fire sprinkler heads.
- Keep the hood free of clutter.
  - Hoods should not be used for storage.
  - Only equipment and chemicals in use should be in the hood.
- Place equipment back from the edge of the lab bench to minimize injury from accidental bumping.
- Check their work area to ensure that heating devices are turned off and chemicals are properly stored before leaving the work area for the day.

Fire Prevention
In the event of a fire in your work area, it is your responsibility to notify the unit coordinator, notify other nearby occupants and evacuate.

- Fire extinguishers are provided in the Laboratory.
- In case of fire, personnel are expected to immediately exit the building.
- However, employees trained in it's proper use, you may use one of the fire extinguishers available in your area.
  - Keep in mind that the improper use of a fire extinguisher may make the problem worse and the extinguishers have a very limited capacity (i.e., for small fires).

Emergency Procedures
Employees will:

- Report all fires to security.
  - Information regarding the location, nature, and extent of the fire should be related to security personnel.
- Stay out of the fire or emergency area unless it is your responsibility to provide assistance.
- Know the evacuation route from each work area.
  - Follow emergency evacuation procedures when notified to evacuate.
- Know the location of emergency equipment and how it is operated.
  - Become familiar with the procedures needed to obtain help in an emergency.

Waste Disposal
Employees will:

- Dispose of all chemical, biological, and other hazardous material wastes in accordance with laboratory procedures.
- Dispose of sharp objects in a safe manner.
  - Scalpel blades, hypodermic needles, broken glass and syringes must be placed in designated puncture-resistant containers.
  - Never put broken glass, scalpel blades, or other sharp objects in the regular trash.
- Place uncontaminated broken glass in properly labeled glassware receptacles.
- Dispose of chemicals that may form peroxides upon storage within 90 days (three months) of opening.

Miscellaneous
- First aid kits should be readily accessible and available in each unit.
- Post warning signs where hazards such as radiation, laser operations, flammable materials, or biological hazards exist.
- Use laboratory equipment only for its designed purpose.
- Report work-related illnesses and injuries.
- Do not bring children into the laboratory work areas where exposure to chemical and biological hazards may be encountered.
- Do not expose the custodial staff, maintenance personnel or visitors to chemical, biological, or physical hazards.

3 Occupant Emergency Plan

3.1 Guidelines

The Occupant Emergency Plan (OEP) is in place to ensure that all employees and visitors can safely evacuate the facility in a fire or other emergency. When employees are notified that an emergency exists, they must immediately move to their assigned meeting location.

The Director of the **AGENCY NAME** shall appoint an Emergency Warden and appropriate personnel to act as Area Emergency Wardens and Unit Coordinators.

- The Emergency Warden will be responsible for maintaining the complete written emergency plan.
- The Emergency Warden will be responsible for the supervision of the OEP.
- Other duties will include planning, supervising, and expediting the organized and controlled movement of all building occupants in the event of an emergency.

Supervisors will ensure that new or transferred employees review the OEP upon reporting for duty. This review should be documented.

Employees should know who their Area Emergency Warden and Unit Coordinators are and be familiar with the emergency exits.

Fire drills are conducted periodically to ensure such familiarity with the OEP.

3.2 Emergency Coordinators

3.2.1 Emergency Warden

The Emergency Warden is responsible for supervising the planned and controlled movement in an emergency of all personnel and visitors assigned to **AGENCY NAME**.

The Emergency Warden's general duties include:

- Assuring that evacuation routes are clearly identified and known to the regular occupants in their section of the building.
- Assuring the evacuation procedures are known to all regular occupants.
- Making the decision to evacuate the space and issue the order to evacuate.
- Directing the orderly flow of personnel, during drills or actual emergencies, along the prescribed evacuation routes.
- Assuring that visitors and support personnel are evacuated in an emergency.
- Establishing a new route of evacuation if a bomb or suspicious item is discovered along the normal route of evacuation.
- Appointing a column leader to lead personnel along the prescribed routes to a pre-designated location outside the building.
- Coordinating the activities of the area wardens, stairwell monitors, elevator monitors, and disabled persons monitors.
- Assuring that all personnel know the location of fire alarms.
- Maintaining a current roster of personnel and their respective evacuation assignments.
  - The current roster will be posted in a common area employee review.
- Maintaining a list of the location of disabled individuals or individuals who may require assistance during and emergency evacuation.
- Reporting to the Command Center after the evacuation of their area has been completed.

3.2.2 Area Emergency Wardens

Area Emergency Wardens are responsible for the training of personnel, readiness of emergency equipment, and orderly execution of the emergency plan in their departments or areas. They are specifically responsible for the assignment and training of all monitors and alternates in their area.

The Area Emergency Warden's general duties include:

- Performing all the general duties as described under Section 3.2.1 for the Emergency Warden.
- Assisting the Emergency Warden as needed to carry out the OEP.

3.2.3 Unit Coordinators

One primary coordinator and one alternate person shall be designated for each unit. Unit Coordinators shall assist their Area Emergency Warden in training of personnel, readiness of emergency equipment, and maintaining current lists of monitors and alternates in their unit or assigned area.

The Unit Coordinator's general duties include:

- Reporting to the Emergency Warden.
- Coordinating all pertinent evacuation procedures within their assigned space as described under Section 3.2.1.
- Being familiar with any hazardous materials in their assigned space.

- The accountability of all employees and visitors in their assigned space.
- That all proper security procedures, as outlined in the OEP, are followed in their assigned space during an evacuation.
- Reporting all fire, explosion, and other hazardous conditions to the Emergency Warden (or Area Emergency Warden in their absence).
- Emergency procedures:
  - Activate the closest fire alarm pull station, advise security, with the exact location and nature of the emergency, and evacuate the immediate area.
- Non-emergency procedures:
  - Immediately contact the Division Emergency Warden before an evacuation decision is made.
- Assisting Area Emergency Wardens in training of all new and transferred employees as to the OEP.
- Maintain a roster of employees in their area of responsibility.
- Conducting periodic checks of fire extinguishers and other safety related items in the covered area including exit signs, emergency lights, and egress paths to exits.
- Contacting the appropriate parties when deficiencies are identified.

3.3 Fire or Emergency Evacuation Procedures

When a life-threatening fire or emergency occurs, evacuate the area to the nearest stairwell.

- DO NOT USE ELEVATORS.
- Activate the alarm station upon your egress to the stairwell.
- When safe to do so, immediately notify security of the room, nature, and the extent of the emergency.

When the Fire Alarm System has been activated, all employees are to immediately evacuate the building and go to their outside meeting place.

Wardens, monitors, coordinators, and/or alternates are to perform their duties as described in this manual.

4 Personal Protective Equipment Policy

4.1 Background

Personal protective equipment (PPE) is an important element in minimizing the potential for chemical or biological exposure.

Unit Chiefs and supervisors are responsible for ensuring that appropriate PPE is:

- Readily available.
- Used by employees when necessary.
- Maintained in a reliable condition. This include, but is not limited to, gloves, lab coats, disposable coveralls or jumpsuits, eye and face protection, aprons and shoe covers or rubber boots, as appropriate.
- Ensure that PPE is repaired or replaced as needed to maintain its effectiveness.

PPE will not be worn in designated eating and drinking areas or in areas outside the laboratory, except if there is a need to deliver or receive evidence.

29 CFR 1910.132 will serve as the basis for the selection and use of personal protective equipment.

4.2 Eye and Face Protection

Eye protection will be worn in the laboratory whenever there is the potential hazard of flying objects; splashing or spraying of chemicals, biological materials, or liquids; injurious radiation; or other injury to the eyes.

- This also applies to managers, supervisors, and visitors while they are in hazardous work areas.

Unit Chiefs and supervisors are responsible for enforcing the eye protection policy and for ensuring that appropriate eye protection is readily available and used by employees and visitors.

Eye protection should be selected based on the type and degree of the hazard encountered. Eye protection will meet the approval of the American National Standards Institute (ANSI) Z87.1-1989 requirements.

Safety Glasses	For most laboratory work, safety glasses with side shields are adequate.
Safety Goggles	Safety goggles are required where there is potential for splashing of chemicals or biological materials, or flying objects.
Face Shields	Face shields are secondary protection only and must be worn in combination with safety glasses or goggles to provide full face protection.
Corrective Lenses	Prescription eyeglasses may not provide adequate protection from injury to the eyes when working in the laboratory. Laboratory employees whose vision requires the use of corrective lenses must wear either prescription safety glasses with protective lenses or safety eyewear that can be worn over prescription glasses without disturbing the adjustment of the glasses.
UV Eye Protection	UV protective safety goggles or a face shield should be worn when using UV transilluminators.
Laser Protective Eyewear	Laser protective eyewear (e.g., goggles, face shields) using special filtered or reflective coatings or a combination of both must be worn when working with high powered lasers such as the Class IV Argon Laser. Laser safety eyewear must meet the requirements of the ANSI Z-136 Standard.
Contact Lenses	Note: Contact lenses alone do not provide adequate eye protection. Therefore; eye protection must be chosen that fits snugly over the eyes and around the face.

29 CFR 1910.133 will serve as the basis for the selection and use of eye and face protection.

4.3 Protective Clothing

Lab coats will be worn when working with or handling biological, chemical or other hazardous materials.

A plastic or rubber apron may be worn over protective garments to provide additional protection against irritating and corrosive materials.

All protective clothing should be removed immediately when penetrated with hazardous chemicals.

4.4 Hand Protection

Gloves will be worn when working with chemicals that are:

- Strong oxidizers
- Organic solvents
- Corrosive to skin
- Mutagenic
- Teratogenic
- Acutely toxic

Gloves will also be worn when working with any biohazard material such as: human blood, body fluids, or tissues or when physical injury is possible.

Gloves will be removed before touching objects in common areas, such as door knobs, light switches, or telephones.

Hands will be washed immediately after removing the gloves.

Glove selection will be based upon the chemical, biological, or physical hazards that will be encountered.

The following will be considered in the selection and use of gloves:

- Chemical permeation and degradation guides are available from glove manufacturers which provide information regarding the types of gloves required for various chemicals.
- All chemicals in a mixture.
- Chemical properties and the potential consequences of skin contact.
- The physical properties required of the glove necessary for the procedure.
    - Other considerations include glove length, thickness, and the use of liners to absorb moisture and reduce irritation.

Prior to donning plastic or rubber gloves:

- Check for imperfections, cracks, or pinholes.
- Remove all sharp jewelry that may pierce the glove.

29 CFR 1910.138 will serve as the basis for the selection and use of hand protection.

4.5 Foot Protection

Employees are required to wear protective footwear, which completely covers and protects the foot, in areas where foot hazards are present.

Open-toed shoes should not be worn where biological or chemical hazards are present.

Foot hazards may be encountered:

- In areas where heavy or sharp objects may fall on or roll over the foot
- Where objects may pierce the sole of the shoe
- Where pallet carts and lift trucks are used
- At major crime scenes where a variety of physical hazards may be encountered

Unit Chiefs and supervisors are responsible for ensuring that safety shoes are available and used by unit employees who require them.

29 CFR 1910.136 will serve as the basis for the selection and use of foot protection.

4.6 Head Protection

Employees will wear head protection (hard hats) at major crime scenes where a variety of physical hazards may be encountered.

All head protection should meet or exceed the ANSI Z98.1-1986 requirement for impact and penetration resistance, as well as, meet appropriate voltage protection requirements.

29 CFR 1910.135 will serve as the basis for the selection and use of head protection.

4.7 Hearing Protection

Employees will utilize hearing protection during operations which may contribute to hearing loss.

- Note: Operations or areas where conversation is difficult to hear when the speaker and listener face each other at a distance of two feet is considered suspect for the need of hearing protection.

Unit Chiefs and supervisors should advise the Assistant Director, of operations or areas where they suspect that hearing protection may be needed.

4.8 Respiratory Protection

4.8.1 Scope

The Respiratory Protection Program (RPP) applies to all employees who work in areas or perform tasks that may result in the exposure to airborne contaminants that require the use of respirators.

This program is designed to achieve and maintain compliance with 29 CFR 1910.134.

The RPP will be developed as a tiered program consisting of three phases.

- Phase 1 establishes the respiratory protection requirements and procedures.
- Phase 2 will include an assessment to identify work areas and functions where respiratory hazards may exist, with subsequent monitoring to determine if respirators are required.
- Phase 3 will be the provision of training for personnel in the proper selection and use of respirators.

4.8.2 Purpose

The purpose of the RPP is to protect employees who may have the potential for inhaling harmful air contaminants resulting from job-related activities.

The **AGENCY NAME** will attempt to protect employees from exposure to contaminated air through the use of accepted engineering controls, such as ventilation, confinement of the operation, and substitution by a less hazardous substance.

Respirators will be used in emergency situations or when attempts to eliminate the hazard have been ineffective.

Employees will be aware that respirators have their limitations and are not a substitute for effective engineering controls or laboratory practices.

Employees covered under this program will use and maintain the respiratory equipment in accordance with the procedures outlined in this section.

4.8.3 Responsibilities

Assistant Director/Section Chief

The Assistant Director has the ultimate responsibility for the implementation and enforcement of all respiratory protection policies and procedures.

Unit Chief

The Unit Chief is responsible for:

- Identifying the hazards that require respiratory protection.
- Enforcing the use of respiratory protection in the areas where it is required.
- Ensuring that employees are aware of the respiratory requirements for the areas in which they work.
- Maintaining a work environment that ensures the protection for employees.
    - He may appoint an individual within the unit to act as the unit's RPP Coordinator (RPPC).

Occupational Health and Safety (OHS) Program Manager

The OHS Program Manager serves as the RPP administrator and is responsible for:

- The direction and scope of the program.
- ensuring that the RPP complies with all applicable respiratory protection requirements and will issue guidelines and directives that initiate and update the program.
- Assisting the RPPC in implementing this program.

The OHS Program Manager will periodically evaluate program effectiveness by coordinating random audits of the RPP to ensure that employees have received appropriate training, and to ensure that respirators are properly selected, used, cleaned, and maintained.

The OHS Program Manager will periodically monitoring of laboratory operations where respiratory hazards may be present and advise the unit of potential hazards from current or proposed processes or operations.

Respiratory Protection Program Coordinator (RPPC)

The Unit Chief will appoint a Respiratory Protection Program Coordinator (RPPC) in units where respiratory protection is required.

The RPPC will have the authority to implement all aspects of the respiratory program within the unit.

The RPPC will receive specialized training in respiratory protection in order to be fully knowledgeable of the requirements and responsibilities associated with the RPP and have a complete working knowledge of the respirators assigned to their particular unit.

The RPPC will be responsible for:

- Preparing written plans for routine and emergency use of respirators.
- Ensuring that each employee assigned respiratory protective equipment is properly fitted and instructed in its use.
- Cleaning, maintaining and storing all respirators not routinely used or not individually assigned. The written plans will include all information and guidance necessary for proper selection, use, care, and maintenance of the respirators.
- Maintaining fit test and training records for all unit personnel included in the respiratory program.
- Coordinating respirator selection and evaluation with the OHS Program Manager.

Employees

Employees will minimizing the use of hazardous chemicals and for utilize accepted engineering controls, such as ventilation, confinement of the operation, and substituting less hazardous substances, when possible.

Employees will use respiratory protective equipment when required and to follow established RPP practices and procedures when engineering controls are not possible or ineffective.

Each employee is responsible for cleaning, maintenance and storage of their assigned non-disposable respirators.

Employees will immediately notify the Unit Chief, RPPC and/or the OHS Program Manager of any conditions that may result in personal injury or illness.

4.8.4 Hazard Assessment

The OHS Program Manager will coordinate a hazard assessment of appropriate units. Based on the results of this assessment, appropriate controls will be implemented.

When controls are not possible or ineffective, respiratory protection will be provided as required.

4.8.5 Respirator Selection and Use

The following criteria will be used to in the selection of respiratory protection:

- The atmospheric oxygen concentration
- A contaminant's physical state (particulate, gas or vapor)
- Toxicity and concentration (immediately or not immediately dangerous to life or health)
- The presence of other contaminants
- Stress factors in the working environment
- Worker exposure time and susceptibility

The following procedures are provided to ensure consistency in the selection and use of respiratory protective equipment (Note: This section does not apply to the selection of atmosphere supplying respirators, see Section 4.8.6):

4.8.5.1 Respirator Selection Respirators will be selected on the basis of the hazards to which the employee may be exposed.

All respirators will be selected according to the type of activity for which they will be used and the potential air contaminants associated with these activities.

- Outside consultation, manufacturers' assistance, and information from other recognized authorities may be used as part of the selection process.

Respirators approved by the United States National Institute of Occupational Safety and Health (NIOSH)/Mine Safety and Health Administration (MSHA) should be used in accordance with the manufacturer's recommendation.

Non-disposable respirators will be assigned to individual employees for their exclusive use, where practicable.

- All non-disposable respirators used by more than one person will be cleaned and sanitized between each use.

Mixing of components between different types or makes of respirators is not permitted.

The use of disposable respirators may be authorized in units with limited respirator usage.

4.8.5.2 Respirator Use

Air Purifying Respirators (APR)

In general, air-purifying cartridge or canister respirators will be allowed if:

- The contaminant(s) is known.
- The concentration(s) is known.
- The air-purifying element provides adequate protection for the air contaminant(s).
  - This type of respirator may be equipped with either chemical cartridges or a canister for protection against gases and vapors.
- The contaminant(s) has good warning (break through) properties.
  - The use of chemical cartridge respirators against substances with poor warning properties shall not be permitted unless its use is permitted in specific health standards.
  - Certain specific health standards permit the use of air-purifying respirators even though the chemical has poor or no warning properties.
  - In this case, reliable information concerning the service life of the cartridge must be available. Since some reactive chemicals cannot be effectively adsorbed/absorbed by the sorbent, its use should also be restricted.

A partial (not all inclusive) list of air contaminants with poor odor warning properties or short breakthrough time follows:

- acrolein
- aniline
- arsine
- bromine
- boron hydrides
- carbon dioxide

- carbon monoxide
- carbonyls
- carbon disulfide
- cyanogen
- dimethylaniline
- dimethyl sulfate
- fluorine
- hydrogen cyanide
- hydrogen fluoride
- hydrogen selenide
- hydrogen sulfide
- iodine
- isocyanates: HDI, MDI, MIC, and TDI
- methanol
- methyl bromide
- methyl chloride
- methyl iodine
- nickel carbonyl
- nitrocompounds: nitrobenzene, nitrogen oxides, nitroglycerine, and nitromethane
- ozone
- phosgene
- phosphine
- phosphorous trichloride
- stibine
- sulfur chloride
- vinyl chloride

HEPA filter cartridges will be replaced after a maximum of 40 hours use in a moderate to dusty workplaces or every 120 hours of use in low dust environments or whenever a significant increase in breathing resistance is noted by the user.

The date of installation will be marked on the cartridge.

Gas/vapor cartridges will be disposed of after each day's activities no matter how short those activities were.

- A day's activities begins when the cartridges is removed from the factory sealed container allowing the cartridges to be exposed to air.
- These cartridges, even if they are not exposed to a contaminated atmosphere, must be discarded.

4.8.5.3 Medical Evaluation All employees will receive a medical evaluation prior to wearing a respirator.

- Employees will not be assigned tasks requiring the use of respirators unless it has been determined that they are physically able to perform the work while wearing a respirator.
- The medical status of the respirator user will be reviewed periodically as determined by the examining physician.

- A written report must be signed by the physician stating whether or not an employee is cleared to wear the selected respirator selected while performing their duties.
- The health care professional conducting the medical evaluation will complete a written report stating the evaluation results.
- The subsequent medical report will be maintained in accordance with section 4.8.8.

29 CFR 1910.134 and Appendix C outline the medical requirements for employee respirator use.

4.8.5.4 Fit Testing All users of respirators will be fit tested to determine which brand and size provides proper facepiece-to-face seal.

- The fit testing will take place before a respirator is issued and annually there after.
- Fit testing will be arranged and coordinated by the RPPC and the OHS Program Manager.
- The individual must wear only the respirator brand and size that was worn to pass the fit test.
- The use of a respirator that has not been fit tested is prohibited.

Respirator users will maintain personal grooming standards that will ensure proper facepiece-to-face seal.

Employees who have facial hair or wear objects that pass between the skin and the sealing surface will not be permitted to wear a negative-pressure air-purifying respirator.

Special mountings will be provided to hold corrective lenses inside full facepieces.

Once an employee has been fit tested and issued a respirator, the employee must perform a functional fit check each time a respirator is worn. The functional fit check is necessary to ensure that the face-to-mask seal is airtight and that the respirator is working properly. This can be accomplished by performing either a positive-pressure or negative-pressure check. Detailed instructions for performing the functional fit checks will be provided when the respirator is issued. Additional copies are available from the RPPC.

29 CFR 1910.134, Appendix A, Appendix B-1 and Appendix D outline the fit testing requirements for employee respirator use.

4.8.5.5 Respirator Storage The following guidelines are necessary for maintaining a clean and sanitary respirator and to prevent damage to the respirator:

- Store chemical cartridge respirators in airtight, labeled containers between each use and labeled with the users name.
- Store respirators in a convenient, clean and sanitary space in order to protect from dust, sunlight, extreme cold, excess moisture, or damaging chemicals.
- Store respirators so that the facepiece and exhalation valve will rest in a normal position and so that the function will not be impaired by the elastomer setting in an abnormal position.
    - Do not store respirators by hanging them by the straps.

4.8.5.6 Maintenance and Inspection

Respirator Inspection

All respirators will be inspected by the wearer before and after each use to ensure that the respirator is in proper working order.

The wearer will perform the following inspection before each use of the respirator:

- Check the tightness of connections and the condition of the facepiece, head bands, valves, connecting tube, and canisters.
- Inspect rubber or elastomer parts for pliability and signs of deterioration.
- Replace defective parts with manufacturer's approved parts.

Cleaning and Disinfection of Respirators
Non-disposable respirators will be cleaned, disinfected and inspected after each use.

Employees will regularly clean their assigned respirators after each use by performing the following functions:

- Inspect respirators during cleaning.
- Remove canisters, filters, valves, straps, and speaking diaphragms from facepiece.
- Wash facepiece and accessories in warm soapy water or use a commercially available disinfection/decontamination solution, following the manufacturer's instructions.
  - Do not wash filters, cartridges, or canisters.
- Rinse parts thoroughly in clean water.
- Air dry in a clean place or wipe dry with a lint free cloth.
- Reassemble.

Non-disposable respirators will be inspected during routine cleaning, and worn or deteriorated parts will be replaced with approved parts according to the manufacturer's instructions.

Disposable respirators will be used until the cartridge or filter media requires replacement or when the facepiece is dirty.

The RPPC will verify that appropriate respiratory protection is readily available and is being used, inspected and maintained properly.

29 CFR 1910.134 and Appendix B-2 outline the maintenance and storage requirements for employee respirator use.

4.8.6 Atmosphere Suppling Respirators

Atmosphere supplying respirators, such as self-contained breathing apparatus (SCBA), will only be used by specially trained personnel. Contact the OHS Program Manager for information regarding this training.

4.8.7 Training

The OHS Program Manager will ensure that a respiratory protection training program is available to all employees who are required to wear respirators.

It is the responsibility of the Unit Chief to ensure that employees participate in any required training program.

- Individuals required to wear respiratory protection will be instructed in its proper use, maintenance and limitations.
- Training will include handling the respirator, fit test, and actual use in a normal and a test atmosphere.

- The Unit Chief and the RPPC will receive training, regardless of whether or not they are issued a respirator.
- Training will be repeated as required.

29 CFR 1910.134, Appendix A and Appendix B-1 and outline the fit testing requirements for employee respirator use.

4.8.8 Records

The following records are to be maintained by each unit for the duration of each individual's assignment in that unit:

- Inspection dates and findings for respirators maintained for emergency use.
- A copy of the completed Respiratory Health Report.
- Training record showing employee name, date(s) trained, topics covered and name of trainer.
- Fit-test record showing date of test, type of test used, employee name, and respirator manufacturer and facepiece size.

These records will be maintained in accordance with 29 CFR 1910.134 and the **AGENCY NAME** document retention policy.

4.8.9 Respiratory Protection Program Evaluation

The adequacy of this program will be evaluated at least annually-by the OHS Program Manager with assistance from all Unit Chiefs and RPPCs. A report summarizing the findings of the evaluation will be submitted to the Assistant Director.

5 Blood Borne Pathogen Exposure Control Plan

5.1 Background

The United States Occupational Safety and Health Administration (OSHA) established 29 CFR 1910.1030 (Occupational Exposure to Blood borne Pathogens) in an attempt to minimize or eliminate occupational exposure to potentially infectious blood borne pathogens. These pathogens include, but are not limited to, the human immunodeficiency (HIV) and hepatitis B (HBV) viruses.

A set of rules and practices collectively defined as Universal Precautions have been established to the elimination of exposure blood borne pathogens. Under the Universal Precautions concept, all human blood, blood products, and certain body fluids should be treated as if they are contaminated with blood borne pathogens.

In addition to Universal Precautions, the rule mandates specific actions the employer must take to minimize occupational exposure to blood borne pathogens. These actions include:

- Written Exposure Control Plan
- Exposure determination
- Hepatitis B vaccine program
- Medical policies
- Training program

5.2 Scope and Application

All **AGENCY NAME** employees are included in the blood borne pathogen exposure control plan.

All **AGENCY NAME** employees must comply with the appropriate procedures when handling evidence containing or contaminated with human blood (liquid or dried) or other potentially infectious materials.

Employees who handle these materials are required to develop a working knowledge of the procedures in this plan and incorporate them into their daily work routine.

29 CFR 1910.1030 will serve as the basis for the blood borne pathogen exposure control plan.

5.3 Definitions

Contaminated	Refers to the presence or the reasonably anticipated presence of human blood or other potentially infectious materials on an item or surface.
Decontamination	Refers to the use of physical or chemical means to remove, inactivate, or destroy blood borne pathogens on a surface or an item rendering the surface or item safe for handling, use, or disposal.
Exposure Incident	Refers to a specific contact with the eye, mouth, or other mucous membrane, non-intact skin, or parenteral (needle stick) contact with human blood or other potentially infectious materials that results from the performance of an employee's duties.
Occupational Exposure	Refers to reasonably anticipated skin, eye, mucous membrane, or parenteral contact with human blood or potentially infectious materials that result from the performance of a employee's duties.
Potentially Infectious Materials (PIMs)	Refers to the following human body fluids: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids. Also included are unfixed tissues or organs from a human (living or dead).
Sharps Container	Refers to a closable, puncture-resistant, and leak proof container designed for the disposal of needles and other sharp objects.

5.4 Universal Precautions

The **AGENCY NAME** will take a Universal Precautions approach to infection control.

The **AGENCY NAME** will treat all human blood and certain body fluids as if they are known to be infected by HIV, HBV or other blood borne pathogens.

Employees will consider all evidence containing or contaminated with human blood or other PIMs as infectious regardless of the perceived status of the source individual or age of the material.

Employees will wear the appropriate personal protective equipment when handling items containing or contaminated with human blood or other PIMs.

5.5 Engineering Controls

The AGENCY NAME will utilize engineering controls in an effort to isolate or remove the blood borne pathogen hazards from the employee.

Engineering controls used in the Laboratory may include:

- Biological safety cabinets
- Sharps containers
- Non-porous bench tops
- Enclosed centrifuges; or
- Plexiglas splatter shields

It is the responsibility of each unit to ensure that all appropriate engineering controls are in place, used and maintained in proper working order.

5.6 Personal Protective Equipment (PPE)

The AGENCY NAME will maintain an inventory of the PPE necessary to protect its employees from blood borne pathogen hazards.

AGENCY NAME employees will utilize the PPE necessary to protect themselves from blood borne pathogen hazards.

- PPE selection will be based upon the anticipated exposure to blood or other PIMs.
- The PPE will be considered appropriate only if it does not permit blood or other PIMs to pass through or reach employees' clothing, skin, or mucous membranes of the eyes, nose and mouth.

PPE will be used in conjunction with engineering controls in order to provide an appropriate level of safety.

The following PPE is recommended and should be available for use by AGENCY NAME employees:

- Disposable latex or nitrile gloves
- Lab coats
- Safety glasses with side shields
- Safety goggles or face shields

5.7 Safe Work Practices

Employees will strictly adhere to the following safe work practices:

- Eating, drinking, smoking, applying cosmetics or handling contact lenses will not be permitted in laboratory work areas.
- Food or drink will not be stored in refrigerators, freezers or cabinets where blood or other PIMs are stored.
- Pipeting by mouth is forbidden.

- Lab coats and eye and face protection will be worn whenever splashes, sprays, spatters, droplets, or aerosols may be generated.
  - Additional protection may be worn as required.
- Disposable (single use) latex or nitrile gloves will be worn when handling items that contain or are contaminated with human blood or other PIMs.
  - Gloves will be replaced gloves when visibly soiled, torn or punctured.
- Employees will wash the hands with soap and water immediately after removal of gloves and after visible contact with blood or other PIMs.
  - Antimicrobial antiseptic towelettes or gels may be used in the absence of hand-washing facilities.
- PPE will be removed immediately upon leaving the work area or when overtly contaminated.
  - Contaminated disposable PPE will be disposed of as biohazard waste.
- Employee will not shear, bend, break, recap or remove contaminated needles and other sharps, except as necessary for forensic examination purposes.
- Contaminated sharps such as scalpel blades and needles will be placed in a puncture resistant container for disposal as a biohazard waste.
- Mechanical means, such as a dustpan and brush, tongs, or forceps will be utilized to pick up contaminated, broken glassware, place in a puncture-resistant container and dispose of as a biohazard waste.
- Employees will use an approved biological safety cabinet when working with liquid blood or other PIMs that may result in splashing, spraying, or aerosolization of the sample.

5.8 Cleaning and Disinfection

All equipment and work surfaces that have had contact with blood or other potentially infectious materials will be cleaned and decontaminated under the following timetable:

- When surfaces are overtly contaminated
- After any spill of blood or other infectious materials
- Between samples
- At the end of the workday

Employees will utilize appropriate PPE when cleaning or disinfecting work surfaces or equipment. A 10% solution of chlorine bleach can be used as a disinfectant for work surfaces.

- Since bleach may become deactivated depending on the length of storage, bleach solutions set aside for spill response must be kept fresh.
- Non-corrosive disinfectants should be used on laboratory equipment that may be damaged by bleach.

Absorbent paper will be used to cover work surfaces where potentially infectious materials may be handled or examined.

- Absorbent paper will be replaced when visibly contaminated or at the end of the work session.

Absorbent paper and the cleaning materials will be treated as infectious waste and disposed of in a biohazard bag.

Trash containers used for infectious waste will be cleaned when visibly contaminated.

Laboratory equipment will be cleaned and decontaminated prior to shipment to a company for servicing.

- If the equipment cannot be completely decontaminated, it will be labeled with a biohazard warning label.
- The label will state which portion of the equipment remains contaminated.

5.9 Biohazard Spills

The employees responsible for cleaning biohazard spills will wear the proper PPE.

- At a minimum, wear latex or nitrile gloves, lab coat, and safety glasses or goggles.

The employees will utilize the following procedure when human blood or potentially infectious material is spilled:

- Close the spill area to traffic.
- Contain the spill with an absorbent material.
- Pour a freshly prepared 10% solution of chlorine bleach on the spill.
  - Let sit for 15 minutes to allow for disinfection.
  - Repeat the process until the spill has been removed.
- Place cleanup materials in a biohazard bag and dispose of as infectious waste.

5.10 Infectious Waste Disposal

Protective coverings used to cover equipment and environmental surfaces, will be removed and replaced as soon as feasible when they become overtly contaminated.

Needles, broken glass, scalpel blades and other sharps should be placed in labeled, puncture-resistant, leak proof containers for disposal.

Contaminated waste must be placed in properly labeled, closeable, leak proof containers or color coded biohazard bags.

5.11 Communication of Hazards

Biohazard warning labels will be posted on entry doors of areas where potential infectious materials may be readily encountered or stored.

Biohazard warning labels will be affixed to waste receptacles and refrigerators or freezers containing blood or other potentially infectious material.

Individual packages or containers of blood or other potential infectious materials are exempt from the labeling requirement if the biohazard warning label is placed on the secondary container.

Contaminated blood vials, centrifuge tubes, and other materials which remain in the immediate work area need not be labeled if Universal Precautions are being used.

5.12 Hepatitis B Vaccination

All employees who have potential exposure to blood borne pathogens should obtain a Hepatitis B vaccination.

- The **AGENCY NAME** will provide such vaccinations as funding becomes available.
- Employees who decline the vaccination are required to sign a statement of declination.

Hepatitis A vaccinations should be obtained by employees at risk of exposure to contaminated food, especially during travel in developing areas of the world.

- The **AGENCY NAME** will provide such vaccinations as funding becomes available.
- Employees who decline the vaccination are required to sign a statement of declination.

Employees will be evaluated by a physician for percutaneous exposure to blood from a source known to be infected with Hepatitis C so consideration can be given to the use Immunoglobulin or Interferon therapy.

- Currently, there is no vaccine for Hepatitis C.

5.13 Post-exposure Evaluation and Follow-up

Employees who receive an occupational exposure to blood borne pathogens should immediately notify their supervisor who will document the exposure.

Employees who receive a documented occupational exposure to blood borne pathogens will be provided a medical evaluation and follow-up.

Employees with be provided a copy of the evaluating healthcare professional's written opinion within 15 days of receipt by the **AGENCY NAME**.

5.14 Training

Training will be provided to all employees with the potential for occupational exposure to blood borne pathogens.

The training will be provided during working hours and at no cost to the employee.

Training for new employees will be scheduled as soon as possible.

All employees will be provided annual refresher training.

5.15 Recordkeeping

5.15.1 Medical

The **AGENCY NAME** will maintain records of each employee's blood borne pathogen status.

The employee's record will include:

- A copy of the employee's hepatitis B vaccination status
- Results of examinations, medical testing and follow-up procedures subsequent to a documented occupational exposure to a suspected blood borne pathogen
- Written opinion and information from healthcare professionals

All medical records will be maintained in the employee's personnel file for the duration of employment plus 30 years.

5.15.2 Training

The **AGENCY NAME** will maintain a record of training for each employee with potential occupational exposure to blood borne pathogens.

The training records will include:

- The date and the contents of the training
- The names and qualifications of the persons conducting the training
- The name and unit of the employee being training

All training records will be maintained in the employee's personnel file for the duration of employment.

6 Chemical Hygiene Plan

6.1 Background

The **AGENCY NAME** will develop and implement the provisions of a written Chemical Hygiene Plan (CHP).

The CHP will include specific provisions, policies, and practices capable of protecting employees from overexposure to chemicals in the laboratory.

6.2 Scope

The CHP applies to all employees who use chemicals or chemical products.

The purpose of the CHP is to provide employees with the information necessary to protect them and others from hazards associated with the use of chemicals in the laboratory.

The safety guidelines and procedures set forth in this CHP should not be considered all inclusive.

Employees working with a hazardous, or potentially hazardous, material are responsible for its safe handling.

Link to (29 CFR 1910.1450) will serve as the basis for the Chemical Hygiene Plan.

6.3 Hazards

6.3.1 Chemicals Hazards

6.3.1.1 Flammable Materials Flammable materials are defined as a substance whose vapors will ignite when exposed to an ignition source at temperatures below 37.8°C (100°F).

Combustible materials are defined as a substance must be heated above 37.8°C (100°F) in order to be ignited.

Hazard Information:
Factory labels and Material Safety Data Sheet (MSDS) will be used to determine the substance's flammable or combustible characteristics.

Storage:

- Flammable and combustible materials will be segregated from incompatible materials.
- Flammable and combustible materials will be stored in in a flammable storage cabinet.
  - Flammable and combustible materials that require refrigeration will be stored in a properly labeled explosion-proof refrigerator.
- Spill cleanup materials near chemical storage areas.
- Storage areas will be inspected periodically for proper and safe storage.

Handling:

The following safe work practices will be observed when handling flammable or combustible materials:

- Exercise caution to minimize the production of vapors and the associated risk of ignition by flashback from a remote source.
- Quantities of flammable substances in work areas will be minimized.
- Flammable liquids will be dispensed in a fume hood or other well-ventilated area and away from heat and ignition sources, when possible.
- Containers that are metal and electrically bonded and grounded will be utilized when transferring flammable solvents from bulk storage (such as a 55 gallon drum).
- Gloves and safety goggles will be worn when handling flammable liquids.
- Bottle carriers will be utilized when transporting flammable liquids outside the laboratory or between the stockroom and the laboratory.
- Flammable or combustible material spills will be cleaned up immediately, using the proper spill kit.
- Flammable or combustible liquids or mixtures will not be deposited into the sink or drain.

6.3.1.2 Corrosive Materials Corrosive chemical is defined as a substance that causes visible destruction of, or irreversible alterations in, living tissue by chemical action at the site of contact. Severe corrosive reactions are often designated as chemical burns. Inhalation of vapors or mists of these substances can cause severe irritation of the upper respiratory tract. Examples of corrosives include acids, bases, and peroxides.

Hazard Information:

Factory labels and Material Safety Data Sheet (MSDS) will be used to determine the substance's corrosive characteristics.

Storage:

- Mineral (inorganic) acids will be segregate from bases and from both organic and flammable materials.
- Corrosive materials will be stored near the floor to minimize the danger of falling from shelves.
- Corrosive materials will be stored in cool, dry, well-ventilated areas, away from sunlight.
- Corrosive materials will be stored in an area that is not subject to rapid temperature changes.

Handling:
The following safe work practices will be observed when handling corrosive materials:

- Personal protective equipment will be utilized to protect against skin and eye contact.
- Quantities of corrosive substances in work areas will be minimized.
- Operations utilizing corrosive substances will be isolated as much as possible by using fume hood sashes and shields.
- Occupation exposures to corrosive chemicals that result in skin or mucous membrane contact will be treated immediately.
  - Wash the affected area with copious amounts of water.
  - Eyes should be flushed with cool water for a minimum of 15 minutes.
  - Medical help should be summoned promptly, particularly for eye exposure.

6.3.1.3 Oxidizing Materials Oxidizers are chemicals that react violently when in contact with organic substances, and therefore, represent a particular safety hazard. For this reason, avoid interactions between oxidizers and organic materials.

Examples of oxidizers include:
- fluorine
- sulfuric acid
- chlorine
- oxygen
- hydrogen peroxide
- iodine
- nitric acid
- permanganates

Hazard Information:
Factory labels and Material Safety Data Sheet (MSDS) will be used to determine the substance's oxidizing characteristics.

Storage:

- Segregate oxidizers from reducing agents and combustibles.

Handling:
The following safe work practices will be observed when handling oxidizing materials:

- Personal protective equipment will be utilized to protect against skin and eye contact.
- Quantities of oxidizing substances in work areas will be minimized.
- Operations utilizing oxidizing substances will be isolated as much as possible by using fume hood sashes and shields.

6.3.1.4 Reactive Materials Reactivity refers to the hazard from chemicals or a combination of chemicals that react violently or explosively, releasing a large amount of energy or gas.

Hazard Information:
Factory labels and Material Safety Data Sheet (MSDS) will be used to determine the substance's reactive characteristics.

Storage:
- Reactive chemicals will be segregated when storing.

Handling:
The following safe work practices will be observed when handling reactive materials:

- Reactive chemicals will be handled with the proper safety precautions.
- Personal protective equipment will be utilized to protect against skin and eye contact.
- Quantities of reactive substances in work areas will be minimized.
- Operations utilizing reactive substances will be isolated as much as possible by using fume hood sashes and shields.

6.3.1.5 Explosives Explosive materials are Chemicals that cause an instantaneous release of large or small amounts of gas and heat, resulting in a dramatic pressure increase when subjected to sudden shock or high temperature.

Examples of explosives include:
- TNT
- Nitroglycerin
- Diazomethane
- Heavy metal azides
- Nitrogen trichloride
- Ammonium chlorate
- Acetone and ether peroxides
- Metal fulminates
- Cuprous acetylide
- Divinyl acetylene
- Silver diacetylide (explosive even when wet)

Hazard Information:
Factory labels and Material Safety Data Sheet (MSDS) will be used to determine the substance's explosive characteristics.

Storage:
Strong oxidizers that can facilitate explosions when combined with organic materials will be isolated from organic material. These compounds include:

- Perchlorates
- Nitrates
- Chlorates
- Chromates
- Chlorites
- Hypochlorites
- Permanganates

Appropriate measures will be taken to prevent the formation of unstable or explosive substances that result from chemical operations or prolonged storage.

Handling:
The following safe work practices will be observed when handling explosive materials:

- Reactive chemicals will be handled with the proper safety precautions.
- Personal protective equipment will be utilized to protect against skin and eye contact.
- Quantities of reactive substances in work areas will be minimized.
- Operations utilizing reactive substances will be isolated as much as possible by using fume hood sashes and shields.
- Identifing the potential explosive hazards prior to the analysis of case evidence, including the stability of reactants/products from the analysis.

Employees will avoid handling potentially explosive chemicals in the following manner:

- Allowing picric acid to dry out
- Mixing flammable chemicals with oxidizers
- Flammable gas leaks
- Heating compressed or liquefied gas
- Uncontrollable fluctuating temperatures during experiments using explosive chemicals
- Bringing hot liquid into sudden contact with a material possessing a lower boiling point
- Contacting flammable materials with catalysts (i.e., acids or bases catalyze an explosive polymerization of acrolein)
- Allowing explosive peroxide decomposition products to build up in solvent containers during storage
- Mixing nitric acid with flammable solvents
- Distilling ethers unless free from peroxides

6.3.1.6 Peroxide Forming Compounds Under improper storage conditions, and in the absence of safety precautions, peroxide-forming chemicals can pose a serious hazard to personnel

Every effort will be made to abate any hazard related to peroxide forming compounds.

The following list of materials is representative of those compounds which form peroxides (Emergency Technical Services Corp., Newfoundland, NJ):

Peroxide Hazard on Storage
These compounds form peroxides that may explode even without being concentrated:

- Isopropyl ether
- Divinyl acetylene
- Potassium metal
- Potassium amide
- Sodium amide (sodamide)
- Vinylidene chloride

Peroxide Hazard on Concentration
These compounds form peroxides during distillation or upon evaporation:

- Dioxane
- Ethyl ether
- Tetrahydrofuran (THF)
- Acetal
- Cumene
- Cyclohexene
- Cyclopentene
- Diacetylene
- Dicyclopentadiene
- Ethylene glycol dimethyl ether (glyme)
- Furan
- Methyl acetylene
- Methylcyclopentane
- Methyl-i-butyl ketone
- Tetralin (Tetrahydronaphthalene)
- Vinyl ethers

Hazard due to Peroxide Initiation of Polymerization
The following substances will be considered as a peroxide hazard when stored as a liquid.

- Butadiene
- Chlorobutadiene (chloroprene)
- Chlorotrifluoroethylene
- Styrene
- Tetrafluoroethylene
- Vinyl acetate
- Vinyl acetylene
- Vinyl chloride
- Vinyl pyridine

Hazard Information:
Factory labels and Material Safety Data Sheet (MSDS) will be used to determine the substance's peroxide forming characteristics.

Storage:
The following safety procedures for the handling, storage and disposal of peroxide forming compounds will be instituted and followed by all units:

- Bulk storage of large quantities of peroxide-forming compounds is prohibited.
- The purchase or storage of peroxide-forming compounds in glass containers having screw-cap lids or glass stoppers, is prohibited.
    - Cases in which particular analysis requires that glass bottles be used are exempt form this requirement.

- Peroxide-forming compounds will be stored in cool, dry areas, away from powerful oxidizers.
- All peroxide-forming compound containers will be clearly mark as to the date received and date opened.
- Storage of open containers of peroxide forming compounds for more than 3 months is prohibited.
- Storage of unopened containers of peroxide-forming compounds for more than 12 months is prohibited.

Handling:
The following safe work practices will be observed when handling explosive materials:

- Peroxide forming compounds will be handled with the proper safety precautions.
- Personal protective equipment will be utilized to protect against skin and eye contact.
- Quantities of peroxide forming compounds in work areas will be minimized.
- Operations utilizing peroxide forming compounds will be isolated as much as possible by using fume hood sashes and shields.
- Identify the potential peroxide forming hazards prior to the analysis of case evidence, including the stability of reactants/products from the analysis.
- Limit the amount of peroxide forming compounds to the minimum amount needed for routine use.
- Open containers of peroxide forming substances should be tested for peroxides prior to use.
    - Test strips are commercially available to check for the presence of peroxides.
    - These test strips may be obtained from Lab Safety Supply and will detect peroxides at levels of 0.5 to 25 ppm (catalog # 7A-1162) and 0 to 100 ppm (catalog # 7A-27173).

6.3.1.7 Compressed Gases

The following guidelines will be observed for the safe handling and storage of compressed gases:

- Cylinders will be stored in a dry, well-ventilated area away from sources of ignition.
- Cylinders stored outdoors will be protected from weather extremes and direct sunlight.
- Cylinders will be stored in an upright position and harnessed to either a counter or the wall.
- The number of cylinders present within the laboratory will be maintained at an absolute minimum.
- Oxygen gas cylinders must be separated from flammable gas cylinders by at least 20 ft.
- Color coding will not be used to identify cylinder content.
- Valve protection caps will remain in place when cylinders are connected to dispensing equipment.
- Compressed gas cylinders will only be used with the correct regulator and fittings for each gas.
- Faulty cylinders or valves will not be used and promptly returned to the compressed gas vendor.
- The use of oil or grease to lubricate compressed gas fittings or valves is prohibited.

- All cylinders will be labeled "FULL" or "EMPTY."
  - Abbreviations are not acceptable.
  - When the pressure drops below the usable level, the cylinder should be marked "EMPTY" and recapped for return.
  - All cylinders will be treated as if full at all times.

6.3.1.8 Carcinogens Carcinogens are Substances that increase the risk of the abnormal growth of tissue in humans or animals.

Examples of select carcinogens include:
- Acrylamide
- Benzene
- Acrylonitrile
- Benzidine
- Asbestos
- Formaldehyde

Hazard Information:
Factory labels and Material Safety Data Sheet (MSDS) will be used to determine the substance's carcinogenic characteristics.

Storage:
- Bulk storage of large quantities of carcinogenic compounds is prohibited.
- Minimum quantities of select carcinogens will be stored at an employee's work station.
- Carcinogens will be appropriately labeled, segregated and in designated, limited access areas.
- Plastic, glass or stainless steel trays, as appropriate, may be used for secondary containment.
- The compound's MSDS will provide additional storage instructions.

Handling:
The employee is responsible for ensuring the safe use and proper disposal of carcinogenic chemicals and for taking the necessary precautions to minimize the risk.

All carcinogens will be handled in a manner which minimizes the chemical's contact with and prevents exposure to employees and the environment.

- Carcinogenic compounds will be handled with the proper safety precautions.
- Analytical methods manuals will establish safety procedures for examinations involving the use of suspected carcinogens.
- Operations utilizing carcinogenic compounds will be isolated as much as possible by using fume hood sashes and shields.
  - The work areas which utilize suspected carcinogens must be posted with appropriate warning signs.
- Personal protective equipment will be utilized to protect against skin and eye contact.
- Quantities of carcinogenic compounds in work areas will be minimized.
- Identifying the potential carcinogenic hazards prior to the analysis of case evidence, including the stability of reactants/products from the analysis.

The following work practices will be used when working with carcinogens:

- Absorbent paper, spill trays, and other appropriate spill containment procedures will be used to minimize contamination of work surfaces.
- Work surfaces, equipment, and glassware will be decontaminated using a compatible solvent after the use of carcinogens.
- Employees should wear two disposable gloves on each hand.
  - The outer glove will be discarded when it becomes torn or contaminated.
- Handling or touching clean surfaces or equipment with contaminated gloves is prohibited.
- Gloves will be discarded upon completion of the analysis.
- The exposed area should be washed immediately if an occupational exposure to a suspect carcinogen occurs.
  - The employee should wash his/her hands upon completion of an analysis and before leaving the work area.

6.3.1.9 Reproductive Toxins Reproductive toxins are defined as chemicals which may adversely affect the reproductive capability of either men or women. These toxins fall into two categories: teratogens and mutagens.

Teratogens are chemical and physical agents that interfere with normal embryonic development. Damage to the fetus (embryo) is most likely to occur early in pregnancy, during the first 12 weeks.

- The following are examples of substances that have been identified as teratogens:
  - Formamide
  - Dibromochloropropane
  - Lead compounds
  - Ethylene oxide

Mutagens are chemical and physical agents that induce mutations in DNA and in living cells, causing heritable changes in the genetic structure. Individuals exposed to chemicals with mutagenic properties may develop genetic damage to the extent that future offspring could be affected.

- Examples of mutagens include:
  - Arsenic compounds
  - Ionizing radiation
  - Ethidium Bromide
  - Alkylating agents (e.g., dimethyl sulfate)

The **AGENCY NAME** will reduce or eliminate exposure of pregnant women and women contemplating pregnancy to reproductive toxins.

- The **AGENCY NAME** reserves the right to temporarily change the work assignment of women who are pregnant or contemplating pregnancy to avoid the risk of exposure to reproductive toxins.
- Pregnant women and women contemplating pregnancy may request reassignment during their pregnancy to avoid the risk of exposure to reproductive toxins.

Pregnant women and women contemplating pregnancy will consult their private physicians regarding their potential for occupational exposure.

Hazard Information:
Factory labels and Material Safety Data Sheet (MSDS) will be used to determine the substance's reproductive toxin characteristics.

Storage:

- Bulk storage of large quantities of reproductive toxins is prohibited.
- Minimum quantities of select reproductive toxins will be stored at an employee's work station.
- Reproductive toxins will be appropriately labeled, segregated and in designated, limited access areas.
- Plastic, glass or stainless steel trays, as appropriate, may be used for secondary containment.
- The compound's MSDS will provide additional storage instructions.

Handling:
The employee is responsible for ensuring the safe use and proper disposal of reproductive toxins and for taking the necessary precautions to minimize the risk.

All reproductive toxins will be handled in the following manner:

- Reproductive toxins will be handled with the proper safety precautions.
- Analytical methods manuals will establish safety procedures for examinations involving the use of suspected reproductive toxins.
- Operations utilizing reproductive toxins will be isolated as much as possible by using fume hood sashes and shields.
    - The work areas which utilize suspected carcinogens must be posted with appropriate warning signs.
- Personal protective equipment will be utilized to protect against occupational exposures to reproductive toxins.
- Quantities of reproductive toxins in work areas will be minimized.
- Identifying the potential reproductive toxin hazards prior to the analysis of case evidence, including the stability of reactants/products from the analysis.

The following work practices will be used when working with reproductive toxins:

- Handling of reproductive toxins will only occur in a posted, designated area such as a chemical fume hood.
- Absorbent paper, spill trays, and other appropriate spill containment procedures will be used to minimize contamination of work surfaces.
- Work surfaces, equipment, and glassware will be decontaminated using a compatible solvent after the use of reproductive toxins.
- Work surfaces will be decontaminated after every activity that involves a reproductive toxin.
- Employees should wear two disposable gloves on each hand.
    - The outer glove will be discarded when it becomes torn or contaminated.

- Handling or touching clean surfaces or equipment with contaminated gloves is prohibited.
- Gloves will be discarded upon completion of the analysis.
- The exposed area should be washed immediately if an occupational exposure to a suspect reproductive toxin occurs.
    - The employee should wash his/her hands upon completion of an analysis and before leaving the work area.

6.3.2 Radiation Hazards

There are two types of radiation: ionizing and non-ionizing. Ionizing radiation is found in medical x-rays, radionuclides, nuclear power plants, radon from soil, and natural cosmic rays. Since radionuclides are used in the LD in some examinations of forensic evidence, it is imperative that every employee be knowledgeable of the safety rules and procedures and regulatory requirements. Non-ionizing radiation is found in infrared or ultraviolet light, radio waves, microwaves, or visible light lasers.

6.4 Identifying Hazards

6.4.1 Chemical Labels

The manufacturer's label must not be removed or defaced until the container is empty.

Employees will note on the label:

- The date received
- The date opened
- The expiration date, where appropriate

Chemicals transferred from the manufacturer's original container to a secondary container must be labeled to display the chemical identity and hazard warning.

- Secondary containers utilized for a single working session or less are only required the container's contents on the label.

Aliquots of test reagent solutions will be labeled with the reagent's name and the highest hazard level of chemicals in the solution.

A separate "HAZARDOUS WASTE" label must be placed on the empty container before it is used for waste containment.

6.4.2 Material Safety Data Sheets

The **AGENCY NAME** shall maintain a master file of all of the Material Safety Data Sheet (MSDS) for every substance that is received.

MSDS may be maintained as a paper copy of all incoming shipments or computer database of all available MSDS.

- One MSDS per chemical is sufficient to meet this requirement.
- An MSDS for every vendor supplying a specific chemical is not required.
- The MSDSs will be filed in a fashion that is conducive to ready access by **AGENCY NAME** employees.

All employees who work with chemicals are responsible for reading the MSDS for the chemicals that they use.

Each unit will maintain a file of the MSDSs of the chemicals it utilizes.

- One MSDS per chemical is sufficient to meet this requirement.
- An MSDS for every vendor supplying a specific chemical is not required.
- The MSDSs will be filed in a fashion that is conducive to ready access by unit employees.

The **AGENCY NAME** will generate an MSDS for any chemical substance or reagent solution provided to anyone outside the **AGENCY NAME**.

- The individual generating the MSDS will have a thorough knowledge of the properties and hazards associated with that chemical.

6.5 Measures to Reduce Exposures

Employees will take every reasonable precaution to prevent exposure to hazardous chemicals.

The **AGENCY NAME** will minimized exposure through the implementation of engineering controls, safe work practices, and the use of personal protective equipment.

29 CFR 1910.1000 will be used to as a basis to establish acceptable exposure limits for various chemicals used in the laboratory.

6.5.1 Engineering Controls

The **AGENCY NAME** will utilize engineering controls to isolate or contain hazards.

- Examples of engineering controls are chemical fume hoods and glove boxes.

6.5.2 Safe Work Practices

Supervisors will ensure that employees are informed of any special or unusual hazards associated with procedures conducted in the unit.

A safety review will be conducted and safety procedures developed and incorporated into the written standard operating procedure (SOP) when new procedures involving the use of hazardous chemicals are introduced or developed.

Employees will utilize safe work practices and universal precautions when conducting examinations.

6.6 Emergency Equipment

The **AGENCY NAME** will provide and maintain equipment and training in its application.

Employees will be familiar with the location and use of the emergency equipment.

6.6.1 First Aid Kits

First aid kits will be readily accessible and available in each unit.

The Unit Health and Safety Coordinator is responsible for ensuring that the contents of first aid kits are maintained.

6.6.2 Safety Showers

Safety showers should be readily accessible to employees, and the immediate area beneath the shower kept free from obstructions.

The location should be identified by a highly visible sign.

Safety showers should be located away from electrical panels or outlets.

The Unit Health and Safety Coordinator will conduct a monthly functionality check of the safety showers in his area of responsibility.

- Documentation of the monthly functionality check will be forwarded to the Health and Safety Program Manager.

6.6.3 Eyewash Stations

Eyewash stations will be readily accessible to employees and the location should be identified by a highly visible sign.

Protective covers must be kept on the eyewash nozzles when not in use.

The Unit Health and Safety Coordinator will conduct a monthly functionality check of the eye wash stations in his area of responsibility.

- Eyewash stations connected to laboratory water system will be flushed monthly for a period not less than three minutes.
- Portable eye wash stations that utilize disposable eyewash solutions do not require flushing.
- Solution levels in portable eyewash stations will be monitored and documented during the monthly functionality check.
- Documentation of the monthly functionality check will be forwarded to the Health and Safety Program Manager.

6.6.4 Fire Extinguishers

Fire extinguishers will be provided in the laboratory.

In case of fire employees are expected to immediately exit the building.

- Employees trained in the proper use of the fire extinguishers in their work area my attempt extinguish the fire.
- Employees may attempt to extinguish small fires with an inverted beaker.

The Unit Health and Safety Coordinator will conduct a monthly functionality check of the fire extinguishers in his area of responsibility.

- Documentation of the monthly functionality check will be forwarded to the Health and Safety Program Manager.

6.6.5 Emergency Lighting

The **AGENCY NAME** will install emergency lighting that will illuminate areas that do not receive ambient light during a power failure.

The **AGENCY NAME** will install emergency exit signage that will be illuminated during power failures.

The Unit Health and Safety Coordinator will conduct a monthly functionality check of the emergency lighting systems in his area of responsibility.

- Documentation of the monthly functionality check will be forwarded to the Health and Safety Program Manager.

6.6.6 Documentation

The Health and Safety Program Manager will create and maintain emergency equipment inspection files for each section of the laboratory.

The Unit Health and Safety Coordinator will perform a monthly inspection of the emergency equipment.

The Unit Health and Safety Coordinator will document his inspection using the Emergency Equipment Inspection Form.

The Health and Safety Program Manager will review and sign each unit's completed Emergency Equipment inspection Form prior to filing.

6.7 Chemical Procurement and Receipt

The **AGENCY NAME** will only procure the amount of chemicals required to meet its immediate analytical needs.

- Employee will evaluate their respective laboratory operations to ensure that the appropriate quantities of chemicals are ordered.

Employees who purchase or receive shipments of chemicals must be trained in the safe handling of hazardous substances.

Employees who perform **AGENCY NAME** chemical receiving and supply function will:

- Compare the type and quantity of chemicals received to the procurement order.
  - Chemicals that are incorrectly ordered should be returned to the manufacturer.
- Will not accept chemical container(s) or compressed gas cylinder(s) without an identifying label.
- File a copy of the chemical's MSDS in the **AGENCY NAME** master MSDS file, if one does not already exist.
- Will enter the following information into the **AGENCY NAME** master chemical inventory:
  - Chemical Name.
  - Manufacturer.
  - Lot Number.
  - Original Amount.
  - Expiration Date.
  - Storage Location.

- Forward the chemicals and their associated MSDSs received to the ordering unit or employees.
  - If a chemical is received without an MSDS, the unit ordering the chemical should attempt to obtain a copy of the MSDS.
  - MSDSs may be obtained upon request from the manufacturer.

Units receiving chemicals shall:

- File a copy of the chemical's MSDS in the Unit's MSDS file, if one does not already exist, and ensure that they are readily accessible to employees.
- Will enter the following information into the Unit's master chemical inventory:
  - Chemical Name.
  - Manufacturer.
  - Lot Number.
  - Original Amount.
  - Expiration Date.
  - Storage Location.

6.8 Chemical Storage

Chemicals should be segregated and stored according to their chemical properties.

- The chemical's label information and MSDS will be used to determine the chemical's storage location and method.
- Chemical storage areas will be labeled with signage indicating the chemical properties of the contents.

Incompatible chemicals will be segregated and stored in approved containers that are distinctly label with the content's chemical properties.

- Where incompatible materials must be stored together, they should be separated by a chemical-resistant physical barrier that will reduce or eliminate the potential for the materials to combine if a spill should occur.

6.8.1 Storage Requirements

Acids

- Segregate all acids from alkali and other corrosives.
- Segregate mineral acids from organic acids.
- Segregate oxidizing acids from mineral acids and organic material.
  - Acetic acid and nitric acid cannot be stored in the same cabinet.
- Store below eye level.

Alkali
- Segregate from acids and other corrosives.
- Store below eye level.

Flammables
- Store in an approved cabinet.
- Segregate from oxidizers.
- Segregate from ignition sources.
- Segregate methanol and acetone from chloroform.
  - Chloroform is nonflammable and does not require a special storage cabinet.
- Quantities of flammable solvents in excess of daily needs shall be kept in approved cabinets.
  - Containers less than four liters are considered "useable quantities" and do not need to be stored in approved cabinets.
  - Working volumes can be stored in each unit in an appropriate area.

Compressed Gases
- All compressed gas cylinders will be stored upright in a designated space against a wall or cabinet and strapped into a mounted bracket.
- When moving cylinders, the tops must be covered with the screw-on cap and a hand truck with a safety strap designed for this purpose must be used.

Oxidizers
- Segregate form organics, combustible materials, and flammable solvents.
- Segregate for reducing agents.

Carcinogens
- Distinctly Label all containers as "cancer causing agents," "mutagentic," "carcinogenic," or "teratogen."
- Store according to the hazardous nature of the chemical.

Water-Reactive Chemicals
- Store in a cool, dry place.
- In case of fire, keep water away from these chemicals to avoid a reaction.

Large containers of chemicals should not be stored above eye level.

6.8.2 Chemical Inventory Review

The Health and Safety Program Manager will annually review the chemical inventory, inspect the chemical storage facilities and identify chemicals which are unfit for use by the **AGENCY NAME**.

Chemical found to be unfit for use will be disposed of using the procedure outlined in the Health and Safety Manual.

6.9 Transporting Chemicals

Bottle carriers will be used when transporting glass bottles of chemicals such as concentrated acids, flammable solvents, or other corrosives outside the laboratory or between the stockroom and the laboratory.

- Bottle carriers are not necessary if chemicals are in shatterproof containers.

Appropriate personal protective equipment will be worn when handling large quantities of corrosive or flammable liquids.

6.10 Employee Information and Training

Employees will be provided with the necessary information and training to comply with the requirements established within this manual.

- The Health and Safety Manual orientation will serve as the minimum training each employee will receive.
  - The orientation will be documented on the Health and Safety Manual orientation form.
- Employees will annually review the Health and Safety Manual.
  - The annual review will be documented on the Health and Safety Manual review form.
- Additional training will be provided as required.

Supervisors will provide training on unit specific safety practices and procedures.

All training records will be maintained in the employee's personnel file for the duration of employment.

6.11 Exposure/Injury Notification

All occupationally related injuries or exposures to hazardous or toxic substances will be reported immediately to the employee's supervisor.

The following conditions or symptoms should be reported to the Unit Chief/supervisor:

- Direct skin contact with a known hazardous substance
- Chemical or foreign substance in the eye
- Manifestation of health symptoms such as:
  - headache
  - nausea
  - dizziness
  - cough, tearing
  - irritation or redness of the eyes, nose, or throat
  - skin rash; or
  - loss of motor dexterity or judgment which resembles intoxication while or after working with chemicals

6.12 Medical Consultation and Follow-up

All employees who work with hazardous materials and have symptoms of exposure will be provided with an opportunity to receive medical attention, including follow-up examinations deemed necessary by the examining physician.

All medical examinations and consultations must be performed by, or under the direct supervision of, a licensed physician and will be provided at no cost to the employee, without loss of pay, and at a reasonable time and place.

When an exposure occurs, the following information shall be provided by the employee to the physician:

- The identity of the hazardous material(s) to which the employee may have been exposed and the MSDSs for those materials.
- A description of the conditions under which the exposure occurred.
- A description of the symptoms of exposure that the employee may manifest.

All medical consultations and examinations, including test results or written opinions, will be maintained in the employee's personnel file for the duration of employment plus 30 years.

Medical recordkeeping requirements will be kept, transferred, and made available in accordance with 29 CFR 1910.1020.

7 Hazardous Waste Disposal

7.1 Background

It is the goal of the hazardous waste program to minimize the impact of laboratory generated waste on the environment through pollution prevention, waste minimization, recycling, and reuse.

A hazardous waste is regulated as soon as it is "generated".

All employees who generate a hazardous waste are obligated to properly manage the hazardous waste in accordance with these regulations.

Hazardous wastes include:

- Spent solvents
- Unused reagents
- Reaction products
- Strong acid or alkaline solutions
- Reactive materials
- Flammable materials
- Heavy metals
- Photographic reagents
- Polychlorinated biphenyls (PCBs)
- Cleaning fluids
- Degreasers
- Batteries
- Printing inks
- Some aerosol containers

In addition, some ordinary office supplies that are unused and discarded, may be classified as hazardous waste.

7.2 Characterization of Hazardous Waste

40 CFR 261 and Appendix VIII will serve as the basis for the characterization and handling of hazardous waste.

Hazardous waste will be defined as any material (solid, semi-solid, liquid, or gas) that has been discarded or "abandoned" or sent for disposal by the generator.

The generator must determine if the waste is listed as a hazardous waste or if the waste possesses the "characteristics" of a hazardous waste.

- This determination may be based on either the generator's knowledge of the material and the process which generates the waste or through testing by a qualified laboratory.
- The basis for determining if a waste is hazardous or non-hazardous should be documented.

Hazardous waste characterization should be carried out conservatively and waste should be classified as nonhazardous only when supported by the applicable regulations and sufficient data about the material and the process is available to make a reliable decision.

Wastes are characterized as hazardous if listed by the EPA as a F-, K-, P-, and U-listed waste.

- F-listed wastes include spent solvents and plating and metal-finishing wastes.
- K-listed wastes are those wastes produced by specific industrial processes.
- P-listed ("acutely toxic") and U-listed wastes are unused chemical products, compounds or solutions.
- Listed wastes have been identified as such because they exhibit one of the characteristics of a hazardous waste or they contain a constituent that has been shown to be harmful to human health or the environment.

If a waste is not listed on one of the four lists, the generator must determine if the waste displays a "characteristic" that will cause it to be regulated. The four characteristics are:

IGNITABLE	Wastes with a flash point less than 60°C (140°F) and carry the EPA waste identification number D001.
CORROSIVE	Wastes with a pH <2 or >12.5 and carry the EPA waste identification number D002.
REACTIVE	Wastes that are unstable, react violently with water or other materials or form potentially explosive mixtures with water. Reactive wastes may generate toxic gases, vapors or fumes when mixed with water. Examples include sodium metal, Class A or B explosives, cyanide plating wastes, waste bleaches, and other waste oxidizers. Reactive characteristic wastes carry the EPA waste identification number D003.
TOXIC	The toxicity characteristic relates to the hazards of a waste leaching toxic substances through soils and into the ground water. The United States Environmental Protection Agency (EPA) has listed 39 substances for which maximum toxicity concentrations have been established. (See 40 CFR 261.24 Table 1.)

7.2.1 Hazardous Waste from Laboratories

The following list of laboratory generated hazardous waste that requires classification and disposal.

- F-listed spent halogenated and non-halogenated solvents from non-specific sources including solvent mixtures/blends used in cleaning, extraction, or other processes.
  - Halogenated solvents include tetrachloroethylene, methylene chloride, and carbon tetrachloride.
  - Non-halogenated solvents include xylene, pyridine, acetone, ethyl ether, methanol, and cyclohexanone.
- Commercial chemical products used in laboratories, including unused reagents that are no longer needed or are otherwise unusable.
  - These include U-listed products such as chloroform, phenol, benzene, acrylamide, methanol; and
  - P-listed compounds such carbon disulfide, sodium azide and most cyanide compounds.
- Concentrated known human carcinogens or reproductive toxins.
- Any substance identified as a known toxin or poison.
- Any compound or mixture having a flash point of less than 140°F (60°C) or which can undergo spontaneous combustion.
- Any oxidizer or oxidizing agent, defined as a compound that may cause or enhance the combustion of other materials.
  - Examples include chlorates, chromates, dichromates, nitric and sulfuric acid, peroxides; and permanganates.
- Any corrosive compound or aqueous solution having a pH < 2.0 or > 12.5.
- Any compound that reacts violently with air or water.
- Any explosive.
- Any liquid that is not water miscible.
- A solid or liquid waste containing any of the following metals:

Antimony	Arsenic	Barium	Beryllium	Cadmium	Chromium
Copper	Cobalt	Gallium	Germanium	Hafnium	Indium
Iridium	Lead	Manganese	Mercury	Nickel	Osmium
Platinum	Rhenium	Rhodium	Ruthenium	Selenium	Silver
Tellurium	Thallium	Tungsten	Zinc	Vanadium	

7.3 Handling and Disposal Procedures

Except as noted, the hazardous waste handling and disposal procedures described in this section are to be followed by all personnel.

It is the responsibility of the employee generating the waste to properly identify/characterize all waste materials intended for disposal.

Non-hazardous waste will not be combined with a characteristic or F-, K-, P-, or U-listed hazardous waste.

7.3.1 In-lab Treatment and Disposal of Hazardous Materials

Hazardous materials or waste will not be discharged into a sewer system.

The following situation may allow treated hazardous waste to be discharged into the sewer system.

- Wastes that are hazardous only on the basis of their corrosive characteristics (pH < 2 or > 12.5) may be neutralized by the addition of bases or acids, as appropriate, producing waste that is no longer hazardous.
  - Once neutralized, this waste may be discharged into the sewer system.
  - Flushing a corrosive waste down the laboratory drain does not constitute neutralization.
  - Note: If the waste is corrosive and contains a listed hazardous material, regardless of the concentration, it may not be discharged into the sewer system.
- Alcohol solutions may be discharged into the sewer system under the following conditions:
  - The solution is < 24% (v/v).
- Undiluted, flammable materials may never be discharged into the sewer system.
  - The solution does not contain any P- or U- listed material; and
  - The solution does not contain additional corrosive, reactive, or toxic components.

7.3.2 Liquid Hazardous Waste

Liquid hazardous wastes will be stored and disposed of as follows:

- Compatible container for storage and disposal will be utilized.
  - Empty containers that previously contained new chemicals may be rinsed and used for liquid hazardous waste disposal.
  - Containers which previously held P-listed materials may not be used for this purpose.
- Containers will be clearly labeled with:
  - The words "Hazardous Waste."
  - The content's chemical characteristics; or
  - EPA waste classification.
- Waste containers will be closed at all times, except when adding waste.
- Carcinogens and mutagens will be separated from other waste.
- Aqueous wastes will be separated from organic solvents.
- Halogenated solvents and wastes will be separated from non-halogenated solvents.
- Waste mercury and its compounds will be separated from all other waste.
- Store partially filled waste containers in a place where they will not be broken or contaminate the work area.
- Full waste containers will be stored in an area designated by the Health and Safety Program Manager until disposal can be arranged.

A record of the name and amount of each chemical added to the waste container will be maintained.

- Include the percentages of each chemical in the container and the date the container became full enough for disposal.
- The percent column must total 100%.
- A copy should accompany the waste container for disposal.

7.3.3 Solid Hazardous Waste

Solid chemicals will not be disposed of in laboratory waste bins or office waste baskets.

Solid hazardous wastes will be stored and disposed of as follows:

- Material in the original container with the manufacturer's label affixed:
  - Place a hazardous waste label on the container - do not cover the manufacturer's label.
  - Stored in an area designated by the Health and Safety Program Manager until disposal can be arranged.
- Material that is no longer in its original container:
  - Place a hazardous waste label on the container.
  - Document the contents.
  - Stored in an area designated by the Health and Safety Program Manager until disposal can be arranged.
- Used and unused rechargeable and nonrechargeable batteries are subject to the RCRA hazardous waste regulations.
  - Create a container for used batteries.
    - A separate container for each type of battery should be created.
  - Place a hazardous waste label on the container.
  - Document the contents.
  - Stored in an area designated by the Health and Safety Program Manager until disposal can be arranged.
- Do not produce any mixed wastes which consist of a Characteristic, F-, K-, U-, or P- Listed hazardous waste and a radioactive waste.

7.3.4 Highly Volatile and Peroxide-Forming Compounds

Highly volatile and peroxide forming hazardous wastes will be stored and disposed of as follows:

- Peroxide forming compounds listed in Section 6.3.1.6 of this manual will be disposed of using the following schedule:
  - 3 months after opening.
  - 12 months after receipt, if unopened.
- Material in the original container with the manufacturer's label affixed:
  - Place a hazardous waste label on the container - do not cover the manufacturer's label.
  - Stored in an area designated by the Health and Safety Program Manager until disposal can be arranged.
- Material that is no longer in its original container:
  - Place a hazardous waste label on the container.
  - Document the contents.
  - Stored in an area designated by the Health and Safety Program Manager until disposal can be arranged.

7.3.5 Unused/Surplus Hazardous Chemicals

All unused or surplus hazardous chemicals will be stored in an area designated by the Health and Safety Program Manager until disposal can be arranged.

Documentation of container contents is not required for, unopened, unused or surplus chemicals, provided that the materials are in their original container have the manufacturer's label affixed.

Surplus or unused material is defined as a hazardous material must also be clearly marked or labeled with the words "HAZARDOUS WASTE."

7.3.6 Disposal Procedure

The Generator will take a properly filled container of hazardous waste to the location designated for storage by the Health and Safety Program Manager and perform the following tasks.

- Complete a Waste Stream Information Sheet (WSIF).
- Assign the container a hazardous waste container number and make an entry in the Hazardous Waster Disposal Log.
- Label the container with:
  - Container #.
  - "HAZARDOUS WASTE" Label.
  - Hazard Information.
- Store the container of hazardous waste in the place designated by the Health and Safety Program Manager.
- File the in the place designated by the Health and Safety Program Manager.

The Health and Safety Program Manager Will:

- Contract with an authorized chemical waste disposal company to dispose of the **AGENCY NAME** hazardous waste.
  - Disposals will be conducted at regularly scheduled interval.
  - The contractor will lawfully dispose of the hazardous waste.
- Provide the chemical waste disposal contractor the information required to safely package and ship the **AGENCY NAME** hazardous waste.
- Will update the Hazardous Waste Disposal log with the date that a container was removed by the chemical waste disposal company.
- Will file the **AGENCY NAME** copy of the shipping manifest from the chemical disposal company the folder containing the associated WSIFs.

7.3.7 Documentation

All employees who generate hazardous waste for disposal MUST complete a "Waste Stream Information Form (WSIF)" for each container of hazardous waste generated.

Each container of hazardous waste stored for disposal will be assigned a unique container number using the following format HW-XX-YYY.

- **HW:** Hazardous Waste.
- **XX:** The last 2 digits of the year the waste was generated.
- **YYY:** A unique identification number for a given year. Numbering begins at 001 on 1 January.

The Health and Safety Program Manager will establish and maintain a log of filled hazardous waste containers that are store and disposed of (Hazardous Waste Disposal Log).

The Health and Safety Program Manager will establish and maintain a file that contains relevant hazardous waste disposal information, to include but not be limited to:

- Waste Stream Information Sheets
- Hazardous Waste Disposal Logs
- Shipping manifests from chemical waste disposal companies

If more than one container of the same waste is sent for disposal, only a single WSP form needs to be prepared for that waste stream.

The original copy of the WSP form should be kept on file in the unit and a copy affixed to the waste container by a single piece of tape across the top of the label in such a way that it can be later removed.

7.4 Disposal of Empty Containers

A container is "empty" when it is void of all material using the practices commonly employed to remove materials from that type of container.

Empty chemical containers, or container liners, (except for those containing P-listed materials) must be rinsed in the laboratory sink to remove all residual material.

- If the material is not water soluble, the open, empty container should be placed in a laboratory fume hood and the residue allowed to completely evaporate.

All labels should be defaced or removed from containers once emptied well rinsed or evaporated.

Plastic containers can then be thrown in the trash and glass bottles into glass disposal boxes.

The labels of larger containers should be defaced, labeled, the container labeled "EMPTY", and taken directly to the trash disposal area.

Rinsed empty containers, except those previously holding P-listed materials, may also be used for waste collection.

Empty containers, or container liners, which previously held P-listed, acute hazardous wastes must be triple rinsed using a solvent capable of removing the residue.

- The rinsed containers must be clearly labeled "TRIPLE RINSED" and the rinsed container disposed of directly in an appropriate trash container.

The solvent used to rinse the containers must be collected and disposed as a hazardous waste.

Containers which previously held compressed gasses, such as aerosol cans, must be handled as hazardous wastes.

7.5 Non-Hazardous Chemicals

Unused and surplus non-hazardous chemical waste will not be disposed of in local landfills and may not be disposed of in the regular trash.

Non-hazardous chemicals should be labeled "non-hazardous waste" and returned to area designated by the Health and Safety Program Manager until disposal can be arranged.

However, non-hazardous, liquid waste that do not contain a hazardous material or other recognized known or suspected carcinogen and which do not meet the definition of a hazardous waste as defined in Section 7.2, may be disposed of down the laboratory drain.

7.6 Regular Trash

Paper and cardboard boxes may be recycled if appropriate.

Broken glass and other sharps should be placed in boxes designated for glass or sharp disposal and should never be disposed of in regular trash cans.

- Boxes specifically for broken glass will be made available for this purpose.

Chemical or biological waste will not be placed into the regular office or laboratory waste baskets.

7.7 Radioactive Waste

Under Development

7.8 Biological Waste

Biological waste includes, but is not limited to:

- Human blood
- Blood products
- Body fluids, and urine
- Materials stained with blood or body fluids
- Human organs, tissues, and body parts, including autopsy specimens

All biohazard materials will be deposited in red, biohazard bags clearly marked with the biohazard symbol and/or the word "Biohazard".

- These bags should be kept closed except when adding waste.
- The closed bags should be placed in designated locations in each unit.

Biological waste, or material contaminated with this biological waste will not be placed into the regular trash cans.

Biological products that are toxic to humans will be considered hazardous and disposed of accordingly

As used in this section, "sharps" mean needles, syringes, scalpels, glass, or other materials capable of producing a puncture of the skin.

Sharps that are contaminated with human biological material must be placed in either metal or plastic sharps containers that are labeled with the biohazard symbol.

- Sharp objects of any type should never be placed in trash containers or waste baskets.

Contaminated sharps must be disposed of as a biohazard waste.

The Health and Safety Program Manager will:

- Designate a location for the storage of biohazard waste that is waiting for disposal.
- Contract with an authorized biohazard waste disposal company to dispose of the **AGENCY NAME** biohazard waste.
  - Disposals will be conducted at regularly scheduled interval.
  - The contractor will lawfully dispose of the biohazard waste.
- Provide the biohazard waste disposal contractor the information required to safely package and ship the **AGENCY NAME** hazardous waste.

7.9 Waste Minimization

The goals of waste minimization are to reduce the volume of hazardous waste generated, reduce the degree of hazard of the waste, and reduce the associated cost of disposal.

The following practices are intended to support compliance with the waste minimization requirements.

7.9.1 Waste Minimization through Purchasing

Employees are authorized to purchase any substance or material necessary to perform their assigned mission.

The following practices should be implemented to meet the goal of waste minimization:

- Less toxic materials should be substituted whenever technically feasible.
- Use of materials already in stock.
- Order only the minimum quantity required for a project.
  - A maximum of a 12 month supply of any material will be ordered.
  - Research project purchases will be limited the amount needed.
- Consider the cost requirements for disposal of unused material or its associated wastes when ordering.
  - Note: The disposal cost may be 10-20 times the original purchase price.
- Purchase compressed gas cylinders, including lecture bottles, only from vendors who will accept the return of empty cylinders.
- Use chemicals with the oldest received date first.

7.9.2 Procedures for Minimizing the Generation of Waste

The following practices should be implemented to meet the goal of waste minimization:

- Wherever possible, scale down laboratory procedures that produce hazardous waste.
- Determine if other units or operations may be able to use excess chemicals.
- Review procedures regularly (e.g., annually) to see if quantities of chemicals and/or chemical waste could be reduced.
- Consider the quantity and type of waste that may be generated when purchasing new equipment or implementing a new procedure.
- Examine the possibility of including detoxification and/or waste neutralization steps in the written laboratory procedures.

- Keep hazardous chemical waste separate from non-hazardous chemical waste.
  - Do not mix chemical waste with normal trash (paper, wood, etc.).
- Review the necessity to use highly toxic, reactive, carcinogenic or mutagenic materials.
  - Determine if safer alternatives are feasible.
- If possible, avoid-the use of reagents containing barium, arsenic, cadmium, chromium, lead, mercury, selenium, and silver, which, due to their toxicity, have been identified as hazardous by the EPA.
- Avoid procedures that produce wastes that contain both a radioactive and a hazardous chemical waste.
- Eliminate the use of uranium and thorium compounds (naturally -radioactive).
- Substitute red liquid (alcohol) thermometers (range up to 150° C) for mercury thermometers where possible.
- Use the least hazardous cleaning solutions and procedures for glassware.
- Eliminate the use of chromic acid.
- When necessary for cleaning purposes, use a spent solvent for initial cleaning and a fresh solvent for final cleaning.
- If possible, use detergent and hot water to clean parts instead of solvents.
- Precipitate silver out of solution. The resulting liquid must be tested prior to discharge into the sanitary sewer to confirm that the amount of any silver remaining in solution is below regulatory levels.
  - Records of such testing must be maintained. For those solutions where the silver cannot be effectively removed, the entire solution must be disposed of as hazardous waste.
- Keep halogenated solvent waste separate from non-halogenated solvent waste.
- Keep organic wastes separate from metal-containing or inorganic wastes.
- Keep highly toxic wastes (cyanides, etc) separated from all other wastes.
- Corrosive wastes (pH < 2 or > 12.5) that do not contain metals or other hazardous materials may be neutralized at the lab bench and disposed of down the laboratory drain.

8 Spill Control and Containment

8.1 Spill Control Policy

All employees are responsible for the safe and timely clean-up of spilled materials.

Facility maintenance, engineering, or custodial service personnel should not be called for assistance.

The **AGENCY NAME** will procure commercial spill kits and place them in areas where chemicals or other hazardous materials may be encountered.

8.2 Spill Control and Containment Guidelines

8.2.1 Liquid Spills

- Alert coworkers in the immediate area.
- If necessary, notify the unit safety representative.
- Assist contaminated persons to a safety shower or eyewash.
  - Administer first aid and summon help as needed.

- If necessary, evacuate nonessential personnel from the spill area.
- Avoid unnecessary contact or exposure to the spilled material.
- Assess the hazard.
  - Consult the Material Safety Data Sheet (MSDS).
- If the spilled material is flammable, eliminate ignition and heat sources within and near the spill area.
- Maintain or establish exhaust ventilation if it is safe to do so.
- Wear the recommended personal protective equipment (PPE) and clothing.
  - At minimum, wear gloves, lab coat, and safety goggles.
- Use absorbent materials from the spill control kit to confine or contain the spill to a small area.
  - Avoid letting it spread or spill into floor drains.
  - Spills involving hydrofluoric acid require specific absorbent material.
- Place spill cleanup residue and absorbent materials in yellow plastic hazardous material disposal bags, seal and label as hazardous waste.
  - These materials should be placed in durable, closable, polyurethane containers and labeled as hazardous waste. Containers are available in the hazardous waste storage room.
- Dispose of residue and cleanup materials as hazardous waste according to the guidelines given in the Hazardous Waste Disposal section.

8.2.2 Solid Spills

- Alert coworkers in the immediate area.
- If necessary, notify the unit safety representative.
- Assist contaminated persons to a safety shower or eyewash.
  - Administer first aid and summon help as needed.
- If necessary, evacuate nonessential personnel from the spill area.
- Avoid unnecessary contact or exposure to the spilled material.
- Wear the recommended PPE and clothing. At minimum, wear gloves, lab coat, and safety goggles.
- Assess the hazard (Consult the MSDS).
- Sweep spilled, non-carcinogenic solid materials of low toxicity into a dust pan and place in an appropriate container for disposal.
- Use a HEPA equipped vacuum cleaner for cleanup of spills of suspected or known, highly toxic and/or carcinogenic powders, flakes or granules.
- Dispose of the waste and cleanup materials as hazardous waste according to the guidelines given in the Hazardous Waste Disposal section.

8.2.3 Mercury Spills

Mercury is extremely toxic through inhalation, ingestion and skin contact: Mercury vapors have no odor or readily discernible warning properties. Because the permissible exposure limit (PEL) by inhalation is 0.05 mg/m^3, all spills of mercury, no matter how small, must be properly cleaned up. Units that use mercury, or equipment such as thermometers which contain mercury, should purchase mercury spill control kits. Report all mercury spills to supervisor.

- Follow steps a - f for Solid Spills.
- Follow the instructions in the spill kit and proceed with the spill cleanup.

- Residue from cleanup should be placed in a plastic bag, sealed to prevent vapor release, labeled and disposed of as hazardous waste (refer to the Hazardous Waste Disposal section).

8.2.4 Leaking Compressed Gas Cylinders

- If a leak is suspected, use a gas leak detector, soapy water or other suitable solution to detect the leak.
- If the leak cannot be stopped by tightening a valve, contact the supplier for instructions.
  - Supplier phone numbers can be obtained from the MSDS and canister labels.
- If the leak is of minimum size and does not pose a serious safety hazard or exposure of personnel, the cylinder may be moved through populated portions of the building if a plastic bag or similar device is placed over the top of the cylinder and taped to the cylinder to confine the leaking gas.
- For flammable or oxidizing gases, move the cylinder to an isolated area away from combustible materials and ignition sources.
  - Post signs that describe the hazards and state warnings. Contact the supplier.
- For toxic or corrosive gases, move the cylinder to an isolated and well ventilated area. Post signs that describe the hazards and state warnings. Contact the supplier.
- For large or uncontrollable leaks that pose a life-threatening hazard, emergency evacuation procedures, as described in the Occupant Emergency Plan - Fire or Emergency Evacuation Procedures section, should be followed.

8.2.5 Biohazard Spills (Potentially Infectious Materials)

- Close off the spill area to traffic.
- Wear the proper PPE.
  - At a minimum wear latex or nitrile gloves, lab coat, and safety glasses or goggles.
- Contain the spill with paper towels.
- Pour a freshly prepared 10% solution of chlorine bleach on the spill.
  - Let set for 15 minutes to allow for disinfection.
  - Repeat the process until the entire spill has been removed.
- Place cleanup materials in a color-coded biohazard bag and dispose of as infectious waste (refer to the Hazardous Waste Disposal section).

8.2.6 Radioactive Spills

- Notify the Radiation Safety Officer (RSO) or Assistant RSO.
- Monitor personal exposure before leaving the area to avoid contaminating other areas of the laboratory.
- Notify coworkers and close off spill area to traffic.
- Identify the extent of the spill using appropriate detecting equipment.
- Circle the affected areas using a marking pen or pencil.

- Spray the affected area with a high phosphate solution and absorb the spray and waste with absorbent material from a spill kit. Repeat this process until no significant radiation is detected.
- Place used absorbent materials in an appropriate container, and label accordingly.
- Dispose of all waste material as radioactive waste.

9 Laboratory Fume Hoods

9.1 Background

Fume hoods are designed to remove hazardous air contaminants, contain explosions and fires, and provide general ventilation for the laboratory.

All chemical analyses will be conducted in a fume hood when feasible.

Employees will correctly use and maintain fume hoods to ensure that maximum protection is afforded.

9.2 Laboratory Fume Hood Use Guidelines

Personnel who conduct procedures within a fume hood should follow the safe practices outlined below:

9.2.1 Fume Hood Operational Perameters

- Fume hoods should be evaluated before use to ensure adequate face velocities.
  - Tissue paper or strip of thin paper hung at the face of the hood may be used to provide a visible sign that air is flowing into the hood.
  - A vaneometer will be used to determine the face velocity of the air flow into the fume hood.
  - Fume hood malfunctions will be reported to the section supervisor.
  - If a fume hood is thought to be malfunctioning, relocate the procedure and any stored chemicals to another, properly operating fume hood.
    - A sign should be placed on the hood indicating that it is nonoperational.
- Hood face velocity should:
  - Average between 60–100 ft/min. when the sash is in the full open position.
  - The face velocity should be no greater than 125 ft/min. at any sash height opening.

9.2.2 Fume Hood Use

- Consult the Material Safety Data Sheet and other available references regarding the physical and chemical properties of the materials to be used.
- When performing a procedure in a fume hood, lower the sash to approximately 18 inches or to a level low enough to protect the face of the user.
- All work in a fume hood should be conducted at least six inches back from the hood face.
  - Large equipment should be supported one to two inches off the bench top with small blocks of wood.
  - This allows air to flow under the equipment.
- Laboratory equipment should be located as far back in the hood as practicable.

  - If the air slots are blocked, the air flow may be reduced and hazardous air contaminants may enter the work area creating a health hazard.
  - Air slots at the back of the hood should be cleaned as needed to remove dust and debris and maintain proper hood operation.
- Employees should not allow paper, disposable gloves, or other debris to be drawn into the slots at the rear of the hood.
- Employees will avoid placing your head inside the hood while chemicals are present in the hood.
- Employees will not place electrical receptacles or other spark sources in the hood when flammable or explosive materials are present.
- Fume hoods will not be used for disposal of waste chemicals by evaporation.

9.3 Storage in Fume Hoods

Employees will minimize chemical storage in fume hood to avoid impairing its effectiveness.

- Only the materials being used during the process should be stored in the hood.
- Containers of flammable liquids should not be stored in the fume hood.
- Solvent waste bottles may be stored in a fume hood while they are being filled.
- Full waste bottles should be promptly disposed of according to the procedures outlined in the Hazardous Waste Disposal section.

9.4 Ductless Fume Hoods

Ductless fume hoods may be used to provide personnel and the environment protection from contaminant fumes, vapors, odors, and particulates.

Ductless fume hood filter selection will depend on the type of contaminant to be removed.

Used ductless fume hood filters will be handled and disposed of as hazardous waste unless determined otherwise.

The manufacturer's recommendations will be used as a guide for appropriate operation and maintenance of ductless fume hoods.

9.5 Biological Safety Cabinets

The use of biological safety cabinets (BSCs) is authorized as effective primary containment devices in laboratories working with blood borne pathogens and potentially infectious materials.

Employees will utilize universal precautions, good laboratory techniques and properly maintained BSCs, to maximize the effective containment system for safe manipulation of potentially infectious materials.

BSCs will not be used with volatile or toxic chemicals and radionuclides.

Filters removed from BSCs will be handled and disposed of as infectious waste.

9.6 Glove Boxes

Glove boxes will be operated and maintained according to the manufacturer's instructions.

10 Ergonomics and Office Safety

10.1 Ergonomics

It's a **AGENCY NAME** goal to make the office setting as user-friendly as possible by offering common sense, practical solutions for changing work settings and work tasks to meet the comfort needs of workers.

The **AGENCY NAME** will strive to reduce or eliminate commonly reported occupational or ergonomic risk factors which include:

- Repetitive and sustained exertions
- Forceful exertions
- Awkward postures
- Mechanical stress concentrations
- Vibration, and
- Temperature extremes.

Recommendations provided in this section address each of the various risk factors that are commonly found in office or laboratory environments.

10.2 Laboratory Environment

Employees should attempt to reduce repeated and sustained exertions by:

- Organizing their work day to alternate between different types of activities.
- Performing stretching exercises.
- Pipetteing with both the left and right hand whenever possible.
- Using automatic pipettes.
- Using the computer mouse with both the left and right hand.
- Incorporate key commands with computer mouse usage, where possible.

Employees should attempt to reduce forceful exertions by:

- Using automatic pipettes.
- Using a tool to put on and snap off caps.
- Using the minimal amount of force necessary to use the mouse and to type.

Employees should attempt to reduce posture stresses by:

- Alternating work heights while working at the bench.
- Utilizing a test tube holder that brings the test tube up to eye level while extracting substances under the hood.

- Positioning the computer mouse close to edge of the keyboard when in use.
- Using an adjustable keyboard stand that can be positioned in front of the monitor to minimize posture stresses.
- Utilizing a document holder when appropriate to minimize forward bending of the neck.
- Alternating the position of the document holder and the mouse between your left and right.

Employees should attempt to reduce mechanical stress concentrations by:

- Utilizing a soft pad when resting your hands or elbows on a hard work bench surface.
- Utilizing a padded wrist rest so that your wrist and forearm are not resting on a hard surface.
- Choosing chair arm rests that have rounded edges and are adjustable.

10.3 Office Environment

Employees should attempt to reduce repeated and sustained exertions by:

- Taking short breaks or alternate activities other than keying every hour.
- Performing stretching exercises.
- Using the mouse with both the left and right hands.
- Incorporate key commands with computer mouse usage where possible.
- Organizing their work day to alternate between different types of activities.

Employees should attempt to reduce posture stresses by:

- Positioning the computer mouse close to the edge of the keyboard when in use.
- Using an adjustable keyboard stand that can be positioned in front of the monitor to minimize posture stresses.
- Utilizing a document holder when appropriate to minimize forward bending of the neck.
- Alternating the position of the document holder and the computer mouse between their left and right.

Employees should attempt to reduce mechanical stress concentrations by:

- Utilizing a padded wrist rest so that your wrist and forearm are not resting on a hard surface.
- Using a sit-stand chair if both standing and seated work are to be performed at the same work station.
    - If primarily seated work is to be completed at a workstation, then a traditional office chair is more desirable.

- Office chairs should have the following features:
  - Easily movable and on casters.
  - Easily adjustable seat height and angle (adjust while seated).
  - Adjustable backrest position and angle.
  - Adjustable height of backrest.
  - Arm rests should have rounded edges and should be adjustable.

10.4 Office Safety

General Considerations

Aisles should be less than 39 inches (1 meter) wide and exits should comply with fire codes.

Desks and equipment should be located in a manner which does not block exits and emergency equipment.

Desks, files, and other office equipment should be located so employees can work with them safely.

Video display terminals should be located in a manner that eliminates glare, provides enough light for reading and reduces fatigue.

Wires and cables should be properly anchored under desks, on walls, or in cable trays.

Wires and cables should be kept off the floor near walking areas and they should not be stretched between equipment.

- If cables must be located on floors, they should be covered with rubber trip guards.

Proper Lifting Techniques

Employees should utilize the following steps for safe and easy lifting:

- Face the object and get as close to it as you can.
- Balance yourself with your feet slightly apart.
- Squat down, bending your knees. Keep your back as straight and upright as possible.
- Grip the object firmly.
- Tighten your abdomen.
- Use your legs to bring to attain a standing position, keeping your back straight.
- Do not twist your body when lifting or setting an object down.

Tripping Hazards

- Walking areas should be kept free of loose rugs.
- Walking areas should be kept clear of trash, boxes, files, and any other materials that do not belong in the aisles.
- Tripping hazards that cannot be removed should be brightly marked to warn other employees.

Fall Hazards

- Ladders or step stools should be provided when access to overhead storage is required. Employees should never stand on chairs, desks, or other office equipment to gain access to overhead storage.
- Plastic floor pads should be provided for rolling chairs if office carpet makes moving chairs difficult.
- Broken chairs should be immediately removed from service.
- File cabinets and shelves that could tip over should be properly anchored to the wall or other cabinets.

Safe Work Practices

- Office personnel should never try to repair electrical equipment.
  - Malfunctioning equipment should be reported to the supervisor or the appropriate equipment vendor.
- To prevent accidental scalding, coffee makers should not be placed and operated on shelves.
  - Coffee makers should be turned off and unplugged at the end of each work day to prevent fires.
- Employees should not attempt to move objects that are too heavy for them to handle safely.

Document History

Rev. #	Issue Date	Description of Changes
01	01/01/2009	Original Document

End of Document

Appendix H

Name	Title

Sample Control Manual Orientation

Item	Trainee's Initials	Date Completed	Trainer's Initials	Date Reviewed
Property and Evidence Manual Issued				
Administrative Issues (Read/ Reviewed)				
Facilities (Read/Reviewed)				
Staffing Scheduling and Responsibilities (Read/ Reviewed)				
Packaging and Handling (Read/ Reviewed)				
Storage (Read/Reviewed)				
Evidence Control Procedures (Read/Reviewed)				
Disposition and Purging (Read/ Reviewed)				
Forms (Read/Reviewed)				

Orientation/Training Successfully Completed

Supervisor	Date
Quality Assurance Manager	**Date**

Date	**Examination Submission Form**	Record Number
# of Containers		Storage Location

Agency Name			Agency File Number
Type of Crime			Date of Occurrence
Investigator Name	ID number		Phone

Suspect ☐ Victim ☐	Last Name, First Name, MI	DOB	ID Number
Suspect ☐ Victim ☐	Last Name, First Name, MI	DOB	ID Number
Suspect ☐ Victim ☐	Last Name, First Name, MI	DOB	ID Number
Suspect ☐ Victim ☐	Last Name, First Name, MI	DOB	ID Number

Item #	Container #	Description	Exam Type

FROM	TO	TIME	Date	Purpose

Date	**Examination Submission Form (Continuation)**	Record Number
# of Containers		Storage Location
Agency Name		Agency File Number
Investigator Name	ID number	Phone

Item #	Container #	Description	Exam Requested

Page _____ of _____

Non-Examination Inventory Form

Date			**Record Number**
# of Containers			**Storage Location**
Agency Name			**Agency File Number**
Type of Crime			**Date of Occurrence**
Investigator Name		**ID number**	**Phone**

Submission Type	☐ Evidence	☐ Found Property	☐ Safekeeping

Personal Property [ ] YES [ ] NO

Name (Last, First, MI)	☐ OWNER ☐ SUSPECT ☐ FINDER

Item #	Container #	Description

FROM	TO	TIME	Date	Purpose

Date	**Non-Examination Inventory Form (Continuation)**	Record Number
# of Containers		Storage Location
Agency Name		Agency File Number
Investigator Name	ID number	Phone

Item #	Description

Page _____ of _____

Date	**Chain of Custody Continuation Form**	Record Number
# of Containers		Storage Location
Agency Name		Agency File Number
Investigator Name	ID number	Phone

FROM	TO	TIME	Date	Purpose

Page _____ of _____

Date		Case Number
	CURRENCY INVENTORY	Storage Location

Submission Type ☐ **Evidence** ☐ **Found Property** ☐ **Safekeeping**

Personal Property ☐ **YES** ☐ **NO**

Name (Last, First, MI)	☐ OWNER ☐ SUSPECT ☐ FINDER

Counterfeit ☐ **YES** ☐ **NO**

#	Currency Denomination	Value	#	Coin Denomination	Value
	100.00			**1.00**	
	50.00			**0.50**	
	20.00			**0.25**	
	10.00			**0.10**	
	5.00			**0.05**	
	1.00			**0.01**	
	Total Value			**Total Value**	

Comments

	Witness 1	Witness 2
Counted By		
Sealed By		

Date	**Firearm Inventory Form**	Record Number
		Storage Location

Agency Name		Agency File Number
Type of Crime		Date of Occurrence
Investigator Name	ID number	Phone

Submission Type	☐ Evidence	☐ Found Property	☐ Safekeeping

Personal Property ☐ **YES** ☐ **NO**

Name (Last, First, MI)	☐ OWNER ☐ SUSPECT ☐ FINDER

Item #	Manufacturer	Model
Storage Location	Caliber	Serial Number
Item #	Manufacturer	Model
Storage Location	Caliber	Serial Number
Item #	Manufacturer	Model
Storage Location	Caliber	Serial Number
Item #	Manufacturer	Model
Storage Location	Caliber	Serial Number
Item #	Manufacturer	Model
Storage Location	Caliber	Serial Number

Sample Control Database

RN	Agency Name	Agency File #	Date Submitted	Date Returned	Storage Location	Date to Lab	Examiner	Date From Lab	Examination Completed (YES/NO)	Exam Complete Notice Sent	Requires Destruction (YES/NO)	Date Destroyed

Date	**Sample Destruction/ Diversion Form**	Record Number
		Storage Location
Agency Name		Agency File Number
Type of Crime		Date of Occurrence
Investigator Name	ID number	Phone

Item #	Description	Destroyed/ Diverted	Destruction Method

Destruction Authorization Deputy Director

Property Custodian	Witness	TIME	Date

Notice of Examination Completion

DATE

Agency Name
Property and Evidence Section or Investigator's Name
Address
City Postal Code

Completion of RN XX-YYYY examination

The examination of the items submitted under AGENCY NAME record number XX-YYYYY has been completed. The items are available for your agency to retrieve at your earliest convenience.

The AGENCY NAME does not have the facilities to accommodate storage of evidentiary and non evidentiary items beyond the time required for their examination. Therefore, it is the policy of the AGENCY NAME to dispose of items thirty (30) days after the notice of examination completion of has been sent to the submitting agency.

Name, Chief
Property and Evidence Section

Storage Area Entry Log

Date	Time	Name	Escort	Reason

TEMPERATURE RECORD

Refrigerator Name:				Location:		
Date	**Morning Reading**	**Initials**	**Afternoon Reading**	**Initials**	**Evening Reading**	**Initials**

Sample Control Audit Form

Agency	Date
Location	Auditor

Summary

	Yes	No
Administrative		
Facilities		
Staffing		
Packaging and Handling		
Storage		
Evidence Control		
Disposition and Purging		
FORMS		
TOTALS		

1.0 ADMINISTRATIVE

Is the organizational placement of the Sample Control Section defined and documented?	☐ YES	☐ NO
Is the Sample Control Section chain of command designed to maintain organizational independence and integrity?	☐ YES	☐ NO
Does the Sample Control Section have a manual that service as to standardize the procedures for the collection, storage, security, release, and disposal of examination and non-examination items?	☐ YES	☐ NO
Does the Sample Control Section document all external transfers of examination and non-examination items?	☐ YES	☐ NO
Does the Sample Control Section document all internal transfers of examination and non-examination items?	☐ YES	☐ NO
Does each examination and non-examination submission have a unique identification number?	☐ YES	☐ NO
Does each examination and non-examination submission have a unique file?	☐ YES	☐ NO
Does the Sample Control Section utilize forms to document the transfer and storage of examintion and non-examination submission?	☐ YES	☐ NO
Do all forms utilized by the Sample Control Section contain space for the submission's unique identification number?	☐ YES	☐ NO
Does the Sample Control Section annually conduct a documented inventory of the contents of all storage facilities under its control?	☐ YES	☐ NO
Does the Sample Control Section conduct a documented annual audit to verify accounts and records for correctness?	☐ YES	☐ NO
Are all employees of the Sample Control Section provided documented training required to competently, safely and efficiently perform their assigned duties?	☐ YES	☐ NO
TOTAL		

1.1 ADMINISTRATIVE COMMENTS

2.0 FACILITIES

Is the Sample Control Section's storage area constructed of materials to secure the facility from unauthorized entry?	☐ YES	☐ NO
Are the Sample Control Section storage facilities located in a place that allows convenient access by personnel submitting examination and non-examination items for examination as well as the laboratory personnel responsible for its examination?	☐ YES	☐ NO
Do the Sample Control Section storage facilities provide office space outside the physical storage area to supply a work environment for Sample Control Section Personnel without compromising the items under its control?	☐ YES	☐ NO
Do the Sample Control Section storage facilities provide space outside the physical storage area to supply a work environment for personnel submitting or retrieving Sample Control without compromising the items under its control?	☐ YES	☐ NO
Do the Sample Control Section storage facilities provide office space outside the physical storage area to supply a work environment for laboratory personnel retrieving or returning evidence without compromising the items under its control?	☐ YES	☐ NO
Does the Sample Control Section take the precautions necessary to ensure security and integrity of the examination and non-examination items submitted to it?	☐ YES	☐ NO
Do only Sample Control Section personnel have unrestricted access to the Sample Control Section offices and storage facilities.	☐ YES	☐ NO
Are Sample Control Section personnel authorized access to the offices and storage facilities only during normal business hours?	☐ YES	☐ NO
Is access to the Sample Control Section offices and storage facilities by non Sample Control Section personnel done under escort only after the identity of the individual has been documented in the Storage Area Entry Log?	☐ YES	☐ NO
Does the Sample Control Section maintain a log of all individuals who enter any area of the Sample Control Section?	☐ YES	☐ NO
Do only Sample Control Section personnel possess keys to the Sample Control Section offices and storage facilities?	☐ YES	☐ NO
Does a security staff perform and document an hourly check on the security status of the Sample Control Section offices and storage facilities?	☐ YES	☐ NO

Does the Sample Control Section have intrusion alarms to ensure the security and integrity of the Sample Control stored in the offices and storage facilities?	☐ YES	☐ NO
Does the Sample Control Section have video surveillance cameras to ensure the security and integrity of the Sample Control stored in the offices and storage facilities?	☐ YES	☐ NO
Does the Sample Control Section have fire and smoke detection alarms to ensure the security and integrity of the Sample Control stored in the offices and storage facilities.	☐ YES	☐ NO
Does the Sample Control Section have duress alarms to ensure the safety of Sample Control Section personnel as well as the security and integrity of the Sample Control stored in offices and storage facilities?	☐ YES	☐ NO
Does the Sample Control Section have a policy or procedure to follow when a breach in security is identified?	☐ YES	☐ NO
TOTAL		

2.1 FACILITIES COMMENTS

3.0 STAFFING

Is the Sample Control Section staff with one (1) Section Chief and sufficient personnel to ensure a safe efficient operation?	☐ YES	☐ NO
Do all Sample Control Section employees meet the minimum qualifications for their respective positions?	☐ YES	☐ NO
Is the Sample Control Section office and storage facility staffed with a minimum of two (2) employees at all times?	☐ YES	☐ NO
Does the Sample Control Section have an established schedule for the receipt and return of examination and non-examination items?	☐ YES	☐ NO
TOTAL		

3.1 STAFFING COMMENTS

4.0 PACKAGING AND HANDLING

Are all Sample Control submitted to or handled by employees of the Sample Control Section required to be packaged and sealed in such a manner as to ensure the evidentiary quality of the individual and collective items?	☐ YES	☐ NO
Does the Sample Control Section have documented packaging guidelines?	☐ YES	☐ NO
Will the Sample Control Section refuse to accept improperly packaged evidentiary or non-evidentiary items?	☐ YES	☐ NO
Does the Sample Control Section have documented labeling guidelines?	☐ YES	☐ NO
Will the Sample Control Section refuse to accept improperly labeled evidentiary or non-evidentiary items?	☐ YES	☐ NO
Does the Sample Control Section have documented sealing guidelines?	☐ YES	☐ NO
Will the Sample Control Section refuse to accept improperly sealed evidentiary or non-evidentiary items?	☐ YES	☐ NO
Does the Sample Control Section have documented documentation guidelines?	☐ YES	☐ NO
Will the Sample Control Section refuse to accept improperly documented evidentiary or non-evidentiary items?	☐ YES	☐ NO
TOTAL		

4.1 PACKAGING AND HANDLING COMMENTS

5.0 STORAGE

Does the Sample Control Section provide storage for examination and non-examination items submitted for examination?	☐ YES	☐ NO
Does the Sample Control Section provide temporary storage for examination and non-examination items submitted for examination?	☐ YES	☐ NO
Does the Sample Control Section provide short term storage for examination and non-examination items submitted for examination?	☐ YES	☐ NO
Does the Sample Control Section provide long term storage for examination and non-examination items submitted for examination?	☐ YES	☐ NO
Is the shelving within the Sample Control Section designed to facilitate the efficient storage of Sample Control?	☐ YES	☐ NO
Is the shelving arranged in a manner that will not allow items to be stacked one upon another or one behind another?	☐ YES	☐ NO
Does the Sample Control Section have an area for packages that are to large for standard shelf dimensions?	☐ YES	☐ NO
Does the Sample Control Section storage facility have a separate safe or vault to store submission of currency and other valuables?	☐ YES	☐ NO
Does the Sample Control Section storage facility have a separate locked storage area to store submission of firearms?	☐ YES	☐ NO
Does the Sample Control Section storage facility have a separate locked storage area to store submission of contraband drugs?	☐ YES	☐ NO
Does the Sample Control Section storage facility have a separate storage area to store submission of biological evidence?	☐ YES	☐ NO
Does the Sample Control Section storage facility have a separate storage area to store submission of hazardous materials?	☐ YES	☐ NO
Does the Sample Control Section storage facility have a separate storage area for the short term storage of non-evidentiary property?	☐ YES	☐ NO
Does the Sample Control Section have a documented storage system?	☐ YES	☐ NO
Does each shelving unit in the Sample Control Section have a unique designation?	☐ YES	☐ NO
TOTAL		

5.1 STORAGE COMMENTS

6.0 EVIDENCE CONTROL

Does the Sample Control Section only accept examination and non-examination items during normal business hours?	☐ YES	☐ NO
Does the Sample Control Section have a documented procedure for receiving items for examination?	☐ YES	☐ NO
Does the Sample Control Section have a documented procedure for returning items after the examination has been completed?	☐ YES	☐ NO
Does the Sample Control Section have a documented policy for the transfer of items to the laboratory for examination purposes?	☐ YES	☐ NO
Is there a procedure to document the intra-laboratory exchange of items?	☐ YES	☐ NO
Does the Sample Control Section maintain a database of information concerning the status of items submitted for examination?	☐ YES	☐ NO
Is the information in the Sample Control Section database updated on a daily basis?	☐ YES	☐ NO
TOTAL		

6.1 EVIDENCE CONTROL COMMENTS

7.0 DISPOSITION AND PURGING

Does the Sample Control Section have documented criteria for the disposal and purging of examination and non-examination items?	☐ YES	☐ NO
Does the Sample Control Section have a documented procedure for the disposal and purging of examination and non-examination items?	☐ YES	☐ NO
Does the Sample Control Section have documented criteria for the destruction of examination and non-examination items?	☐ YES	☐ NO
Does the Sample Control Section have a documented procedure for the destruction of examination and non-examination items?	☐ YES	☐ NO
Does the Sample Control Section have documented criteria for the diversion of examination and non-examination items?	☐ YES	☐ NO
Does the Sample Control Section have a documented procedure for the diversion of examination and non-examination items?	☐ YES	☐ NO
TOTAL		

7.1 DISPOSITION AND PURGING COMMENTS

8.0 FORMS

Examination Submission Form	☐ YES	☐ NO
Examination Submission Form (Continuation Sheet)	☐ YES	☐ NO
Non-Examination Submission Form	☐ YES	☐ NO
Non-Examination Submission Form (Continuation Sheet)	☐ YES	☐ NO
Chain of Custody Continuation Form	☐ YES	☐ NO
Currency Inventory	☐ YES	☐ NO
Firearms Inventory Form	☐ YES	☐ NO
Notice of Examination Completion	☐ YES	☐ NO
Sample Destruction/Diversion Record Form	☐ YES	☐ NO
Security/Safety Breach Form	☐ YES	☐ NO
Storage Area Entry Log	☐ YES	☐ NO
Database Form	☐ YES	☐ NO
TOTAL		

8.1 FORMS COMMENTS

Security Breach/Safety Violation Report

Date	Time	Security Officer

Security Breach

Door	Location	☐ Open ☐ Unlocked
Window	Location	☐ Open ☐ Unlocked
Intrusion Alarms	Location	☐ Unarmed ☐ Activated
Fire/Smoke Alarms	Location	☐ Unarmed ☐ Activated
Unauthorized Entry	Location	Action Taken

Action Taken

Director Notified	☐ Yes ☐ No	Time
Section Chief Notified	☐ Yes ☐ No	Time
Police Notified	☐ Yes ☐ No	Time

Safety Violation

Violation	Action Taken

Sample Control Manual

Controlled Document Inventory

Doc. #	Rev. #	Description	Section	Status	Approval Date	Review Date
		POLICIES				

Doc. #	Rev. #	Description	Section	Status	Approval Date	Review Date
		FORMS				

Doc. #	Rev. #	Description	Section	Status	Approval Date	Review Date
		STATIC DOCUMENTS				

ADMINISTRATIVE ISSUES

Organizational Placement

1 PURPOSE

This document establishes the **AGENCY NAME** Sample Control Section organizational placement policy.

2 SCOPE

This policy applies to all factions of the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P001 will be used as a guide to define terms.

4 POLICY

The Sample Control Section shall be a centralized autonomous unit within the **AGENCY NAME**.

The Sample Control Section will organizationally be located within the **Division Name** of the **AGENCY NAME** to maintain organizational independence and integrity.

The Chief of the Sample Control Section will report to the Deputy Director of **Division Name** to maintain organizational independence and integrity.

All Sample Control Section supervisors will report to the Chief of the Sample Control Section to maintain organizational independence and integrity.

5 PROCEDURE

There are not procedures that directly apply to the implementation of this policy.

6 APPROVAL

The signatures below recognize that the above Property and Evidence Section Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

ADMINISTRATIVE ISSUES

Sample Control Manual

1 PURPOSE

This document establishes the **AGENCY NAME** Sample Control manual policy.

2 SCOPE

This policy applies to all factions of the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P001 will be used as a guide to define terms.

4 POLICY

The **AGENCY NAME** will establish and maintain a Sample Control Manual (SCM) that contains the procedures for the reception, storage, laboratory distribution, transportation and return of evidentiary and non-evidentiary items submitted to the **AGENCY NAME** for examination.

The SCM, in conjunction with the relevant policies and procedures outlined in the **AGENCY NAME's** Administrative Policy and Procedure Manual (APP) and Quality Assurance Manual (QAM) shall service as the standard procedures for the collection, storage, security, release, and disposal of evidentiary and non-evidentiary items submitted to the **AGENCY NAME**.

The SCM and supporting administrative and quality assurance documents establish the written procedures for all issues concerning the transfer and storage of evidentiary and non-evidentiary items within the **AGENCY NAME**.

The SCM directives will include but not be limited to:

- Requiring all evidentiary and non-evidentiary items to be placed under the control of the Sample Control Section prior to transfer to the laboratory section for examination.
- Providing guidelines for packaging and labeling of evidentiary and non-evidentiary items prior to storage.
- Establishing additional security measures for handling exceptional, valuable, or sensitive evidentiary and non-evidentiary items.
- Establishing procedures for the temporary storage, internal transfer and final release of evidentiary and non-evidentiary items from the control of the Property and Evidence Section.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

The signatures below recognize that the above Property and Evidence Section Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

ADMINISTRATIVE ISSUES

Documentation

1 PURPOSE

This document establishes the **AGENCY NAME's** sample control documentation policy.

2 SCOPE

This policy applies to all transactions involving evidentiary and non-evidentiary items submitted to the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P001 will be used as a guide to define terms.

4 POLICY

All transfers or exchanges of all evidentiary and non evidentiary items will be documented using approved forms.

- The documentation process commences upon the receipt of the items from the agency or individual requesting examination.
- The documentation process concludes upon return of items to the agency or individual requesting examination.

4.1 SUBMISSIONS

Evidentiary and non-evidentiary items will not be accepted into by the **AGENCY NAME** Sample Control Section without proper documentation.

Every submission of evidentiary and non-evidentiary items to the Sample Control Section will be using an approved form.

- The submission of evidentiary items will be documented using the **FORM NAME** and **FORM NAME** continuation form.
- The submission of non-evidentiary items will be documented using the **FORM NAME** and **FORM NAME** continuation form.

A documented inventory of all evidentiary and non-evidentiary items will be maintained on one or more approved forms.

The submission of valuables and firearms to the Sample Control Section requires additional documentation, which shall include:

- Currency Inventory Form for currency submissions in excess of $100.00.
- Firearms Inventory Form for firearms submissions.
- The serial number of any item with a value of in excess of $250.00 shall be recorded on the appropriate submission form prior to submission to the Sample Control Section.

4.2 INTERIM EXCHANGES

Every evidentiary and non-evidentiary item exchange will be documented using an approved form.

4.3 DESTRUCTION AND DIVERSION

The destruction, diversion or disposal of evidentiary and non-evidentiary items will be documented on one or more approved forms.

4.4 TRANSACTION RECEIPT

A copy of **FORM NAME** shall be furnished as a receipt to any person, regardless of status, anytime property is taken from that person irrespective of the classification of that property.

4.5 CASE FILE

The Sample Control Section will establish and maintain a file for every submission of evidentiary and non-evidentiary item(s).

The case file will contain all original documents related to the inventory, exchange, transfer, destruction and diversion of the submitted item(s).

Each case file will be retained and filed by the Sample Control Section in accordance with the **AGENCY NAME** document retention policy.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

The signatures below recognize that the above Sample Control Section Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

ADMINISTRATIVE ISSUES

Forms

1 PURPOSE

This document establishes the **AGENCY NAME's** Sample Control Section forms policy.

2 SCOPE

This policy applies to all forms utilized by the Sample Control Section of the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P001 will be used as a guide to define terms.

4 POLICY

The Sample Control Section will develop and maintain standardized forms to be used for all Sample Control submissions.

The Sample Control Section will modify each form as necessary.

4.1 GENERAL INFORMATION

Documentation concerning the submission of evidentiary and non-evidentiary item(s) will contain sufficient information to identify the status of the item(s) at any time while under the control of the **AGENCY NAME**.

Sample Control Section forms will contain some or all of the following information:

- Submitting Officer Information
- Record Number
- Control Number
- Bar Code Number
- Item Number(s)
- Description line for each item
- Owner, Victim, Suspect box
- Address of party involved
- Phone number of party involved
- Type of Crime
- Date/time item was submitted
- Receiving Property Officer Information
- Removed from locker by
- Date/time received
- Location stored
- Location within the evidence room

- Chain of custody information
- Signature of person providing items
- Signature of person receiving the items
- Date and time the exchange takes place
- Reason for the exchange
- Detective/Investigator responsible for case
- Approval signature to release, destroy, divert
- Description of items to be released/destroyed (items numbers, etc.)
- Documentation when the card or letter was sent
- Property Room History – Released or Destroyed
- Name of person property is to be released to
- Address of person property is to be
- Drivers license or other government ID of person
- Release by
- Date of release
- Destroyed by
- Date of destruction

Each form will contain sufficient information to allow it to be associated with other forms used to monitor the status and location of the item(s) submitted to the Sample Control Section under a specific Record Number (RN).

All submissions will be assigned a unique Record Number (RN) that will be placed on all individual forms.

4.2 INDIVIDUAL FORMS

The following forms are to be used to monitor the location of items that enter the Sample Control Section.

4.2.1 Submission and Transfer Forms

The Sample Control Section will establish and maintain forms for the submission of evidentiary and non-evidentiary items submitted to the Sample Control Section for examination or storage.

Submission and transfer forms include:

- SCM-F001: Chain of Custody Continuation Form
- SCM-F004: Evidence Submission Form
- SCM-F005: Evidence Submission Form Continuation
- SCM-F008: Non-evidence Submission Form
- SCM-F009: Non-evidence Submission Form Continuation

4.2.2 Inventory Forms

The Sample Control Section will establish and maintain forms for the inventory of specific evidentiary and non-evidentiary items submitted to the Sample Control Section for examination or storage.

Inventory forms include:

- SCM-F001: Currency Inventory Form
- SCM-F007: Firearms Inventory Form

4.2.3 Disposal Forms

The Sample Control Section will establish and maintain forms document the disposal of evidentiary and non-evidentiary items submitted to the Sample Control Section for examination or storage. Disposal forms include:

- SCM-F006: Exam Completion Notice
- SCM-F003: Property Destruction Form

4.2.4 Additional Forms

The Sample Control Section will establish and maintain additional forms as required to evaluate the effectiveness of the Sample Control Section.
Additional forms include:

- SCM-F003: Database Form
- SCM-F011: Storage Area Entry Log
- SCM-F012: Sample Control Orientation Checklist
- SCM-F013: Sample Control Audit Packet

5 PROCEDURE

There are no procedures or forms that directly apply to the implementation of this policy.

6 APPROVAL

The signatures below recognize that the above Sample Control Section Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

ADMINISTRATIVE ISSUES

Inventories

1 PURPOSE

This document establishes the **AGENCY NAME** Sample Control Section inventory policy.

2 SCOPE

This policy applies to the Sample Control Section of the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P001 will be used as a guide to define terms.

4 POLICY

The Sample Control Section shall annually conduct an inventory of the contents of all storage facilities under its control.

- Additional random inventories of all or a portion of the Sample Control storage facilities may be conducted at the discretion of the Chief of the Sample Control Section.

The inventory will document the type and location of all packages within the Sample Control Section storage facility and will:

- Compare the list of items within the Sample Control Section storage facility to the database of samples logged into the storage facility.
- Include:
  - Record Number (RN)
  - Number of packages
  - Location of packages

The Chief of the Sample Control Section will submit a report to the Director of the **AGENCY NAME** detailing the results of the inventory.

All inventory reports will be filed in accordance with **AGENCY NAME** document retention policy.

5 PROCEDURE

Inventory methods:

- Shelf to Property Sheet: (Recommended)
  - List items on a specific shelf or location and compare with the submission forms or database log.
- Property Sheet to Shelf:
  - Select Property Sheets and locate items on the shelf.
  - The major disadvantage with this system is that it doesn't document items on the shelf where the identifying numbers have been detached or are misfiled.

6 APPROVAL

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John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

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ADMINISTRATIVE ISSUES

Audits

1 PURPOSE

This document defines **AGENCY NAME's** Sample Control Section audit policy.

2 SCOPE

This policy applies to the Sample Control Section of the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P001 will be used as a guide to define terms.

4 POLICY

The Sample Control Section will conduct an annual audit to verify accounts and records for correctness as well as compliance with established quality systems.

The Chief of the Sample Control Section may conduct internal audits as required.

4.1 AUDIT SCOPE

A review of the Sample Control Section's policies, procedures, and actions will be conducted annually to determine whether they meet recognized standards and comply with the agency's own policies.

The audit will evaluate one or more of the following issues:

- Determine if legal requirements are being met. (Basic audit)
- Evaluate the use of resources. This also includes attention to procedures and management policies. (Procedural audit)
- Evaluate the **AGENCY NAME's** structure and encompasses plans, policies, and systems. (An organizational audit)

4.2 AUDITORS

All audits will be conducted by an impartial party outside the direct chain of command of the Chief of the Sample Control Section.

The auditor may be:

- An employee of the **AGENCY NAME**, or
- Qualified government official, or
- Qualified private consultant

4.3 DOCUMENTATION

Internal auditors will utilize checklists authorized by the Quality Assurance Manager to document their findings.

External auditors document their findings utilizing the checklists and forms prescribed by their auditing body.

The Quality Assurance Manager will establish and maintain a file for every sample control audit. Each file will contain:

- A summary report of the auditor's findings.
- Copies of all deficiency reports that are generated as a result of the audit.
- Copies of all risk assessment/issue resolution reports that are generated as a result of the audit.
- Copies of relevant checklists used during the auditing process.

5 PROCEDURE

One or more of the following methods can be used to conduct an audit of the Sample Control Section:

- ***Selection and review of one case file***: The file is traced through the entire system to the current location. This method provides verification of the file and accuracy of all related forms.
- ***Random selection of an item of property off the shelf***: The auditor traces it back through the case file again verifying the file and associated documentation.
- ***Selection of an inactive case file***: The auditor traces the file through the system to the property, or if purged, verifying that all documentation is correct. A physical inspection of the last storage place prior to disposal is recommended to insure validity.

The audit team will submit a report to the Director of the **AGENCY NAME** with copies sent to the Chief of the Sample Control Section and the Quality Assurance Manager detailing the results of the audit within 30 days of completion of the audit.

6 APPROVAL

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John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

FACILITIES

Evidence Storage Facility Requirements

1 PURPOSE

This document establishes the **AGENCY NAME** sample storage facility requirements.

2 SCOPE

This policy applies to all sample storage facilities of the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P001 will be used as a guide to define terms.

4 POLICY

The **AGENCY NAME** will establish and maintain facilities for the safe and secure storage of evidentiary and non-evidentiary items submitted to the **AGENCY NAME**.

4.1 GENERAL REQUIREMENTS

General storage facilities will have controlled access entry points which are only accessible by Sample Control Section personnel.

The shelving within the Sample Control section general storage facilities will be designed in such a manner as to facilitate the safe and efficient storage of Sample Control submitted to the Sample Control Section.

- Total Height: 190 cm (72 inches)
- Depth: 46 cm (18 inches)
- Between Shelves: 35 cm (14 inches)

An area will be established for the storage of packages that are to large for standard shelf dimensions.

Shelving will be arranged in a manner that will not allow items to be stacked one upon another or one behind another.

Each shelving unit shall have a unique number designation.

Each shelf will be labeled with its unique row and shelf designation.

The storage facility will have a separate safe or vault to store submissions of currency and other valuables.

The storage facility will have a separate locked storage area to store submission of firearms.

The storage facility will have a separate storage area for the short term storage of non-evidentiary property.

4.2 CURRENCY

The Sample Control Section will store all currency submissions in excess of $100.00 in a separate vault dedicated to the secure storage of money and other valuable items.

The vault will have a combination lock, whose combination is only known by Sample Control Section personnel.

The combination on the vault will be changed as require to maintain the vault's security.

4.3 FIREARMS

The Sample Control Section storage facility will contain a separate locked area for the secure storage of firearms separate from locations where items of general evidence are located.

The firearm storage area will be constructed in a manner that would prevent unwarranted entry.

The door to the firearms storage area will:

- Be installed in such a manner that cannot be unbolted at the hinges or the locking panel.
- Contain a locking mechanism that is secured with a dead bolt latch.

The shelving inside the firearm storage area will be:

- Designed for the efficient storage of both long guns and handguns.
- Adjustable to optimize the available space.
- Have a space to store exceptional sized weapons.

Each long gun storage location will be labeled with its unique designation.

The storage position of firearms will be marked in such a manner to prompt the property custodians to look for a firearm that has not been returned in a timely manner.

Non-evidentiary firearms may be stored in the firearms and toolmark section using similar storage requirements.

4.4 CONTRABAND DRUGS

Evidentiary submission containing small amounts of contraband drugs may be commingled with any other evidence types.

The Sample Control Section will not accept contraband drug submission in excess of one (1) kilogram total weight.

- Property Custodians will refer individuals with submissions in excess of the established limit to the **AGENCY NAME** laboratory for assistance in obtaining representative samples.
- The Chief of the Sample Control Section may authorize the temporary short term storage of large seizures of contraband drugs.

The Chief of the Sample Control Section will identify and establish an area of heightened security for the short term storage of large seizures of contraband drugs.

4.5 BIOLOGICAL EVIDENCE

Evidentiary submissions containing properly dried and packaged biological stains may be commingled with any other property types using the storage guidelines.

The Chief of the Sample Control Section will establish two distinct refrigerated storage areas for samples of liquid blood and urine.

- One storage area will be reserved for sample waiting for examination.
- One storage area will be reserved for samples that have been examined.

Analytical sections responsible for the analysis of liquid blood or urine will establish a refrigerated sample storage area to store samples during the examination process.

The temperature of all refrigerated units will be monitored continually and the temperature inside each unit will be documented 3 times daily.

4.6 HAZARDOUS MATERIALS

The Chief of the Sample Control Section will designate an area for the safe storage of hazardous materials samples.

The storage area will be ventilated to prevent the accumulation of explosive, flammable, corrosive or otherwise toxic fumes.

The storage area ventilation will be designed in such a manner as to not contaminate the building's Heating/Ventilating/Air Conditioning (HVAC) system.

The storage of hazardous materials in a secured ventilated area outside of the regular storage facility is acceptable.

Hazardous material samples will NOT be stored in the laboratory's chemical storage facilities or otherwise commingled with the AGENCY NAME materials and supplies.

5 PROCEDURE

Each shelving unit shall have a unique designation.

Each shelf of a shelving unit will be labeled with its unique row and shelf designation.

Each submitting agency will be assigned a specific location in which all of their submissions will be stored.

Each assigned section will be labeled with the name of the agency whose submissions are store there.

Submission from agencies and individuals with fewer than 100 submissions per year will all be placed in a section labeled "Other Agencies".

All submissions will be sorted and stored in the following manner:

- Submissions will be sorted and stored by packaging type.
- Similar packaging types will be stored on the same shelves.

- Packages on a shelf will be arranged numerically by, laboratory record number (RN), increasing in value from left to right.
- Packages will not be stacked on top of another.
- Packages will not be placed on a shelf one in front of another.
- Currency submissions in excess of $100.00 will be stored in the Property vault.
- Jewelry and other property with a value in excess of $250.00 will be stored in the vault.
- Firearms will be stored in a locked storage area within the storage facility.

6 APPROVAL

The signatures below recognize the above Administrative Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

EVIDENCE CONTROL

Regional Evidence Collection Facilities

1 PURPOSE

This document establishes the **AGENCY NAME's** regional sample collection facility policy.

2 SCOPE

This policy applies to all regional evidence collection facilities of the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P001 will be used as a guide to define terms.

4 POLICY

The **AGENCY NAME** will establish and maintain regional facilities for the collection and secure storage of evidentiary and non-evidentiary items submitted to the **AGENCY NAME**.

- The Director of the **AGENCY NAME** will establish the number and location of the regional facilities used to collect and store evidentiary and non-evidentiary items submitted to the **AGENCY NAME**.

The **AGENCY NAME** will establish and maintain procedures for the reception, storage, transportation and return of evidentiary and non-evidentiary items submitted to the regional sample collection center(s) for examination.

5 PROCEDURE

There are currently no procedures directly apply to the implementation of this policy.

6 APPROVAL

The signatures below recognize the above Administrative Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

FACILITY ISSUES

Construction

1 PURPOSE

This document establishes the **AGENCY NAME** Sample Collection Section construction policy.

2 SCOPE

This policy applies to all Sample Collection Section facilities of the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P001 will be used as a guide to define terms.

4 POLICY

The Sample Collection Section's storage area shall be constructed of materials to secure the facility from unauthorized entry.

Windows and exterior entrances will be minimized.

Exterior windows will:

- Have security bars installed
- Be covered in such a way as to prohibit view from the outside
- Have intrusion alarms, if possible

Exterior doors will:

- NOT have door handles exposed to the outside
- Key only access to exterior surface
- Have intrusion alarms when possible

Interior walls will extend from floor to ceiling and be constructed of a material that will not be penetrated easily and deter intrusion.

Interior windows will:

- Be minimized
- Be covered in such a way as to prohibit view from the outside
- Have intrusion alarms, if possible

Interior doors will:

- Be minimized
- Have intrusion alarms when possible

Additional storage facility requirements:

- An operational fire suppression system
- An operational fire alarm
- An operational intrusion alarm
- An area for the secure storage of firearms
- An area for the secure storage of currency and other valuables
- An area for the safe storage of biological evidence
- An area for the safe storage of hazardous materials

5 PROCEDURE

There are currently no procedures that directly apply to the implementation of this policy.

6 APPROVAL

The signatures below recognize that the above Sample Collection Section Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

FACILITY ISSUES

Design

1 PURPOSE

This document establishes the **AGENCY NAME** Sample Control Section facility design policy.

2 SCOPE

This policy applies to all Sample Control Section facilities of the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P001 will be used as a guide to define terms.

4 POLICY

The Sample Control Section storage facilities shall be located in a place that allows convenient access by personnel submitting evidentiary and non-evidentiary items for examination as well as the laboratory personnel responsible for its examination.

The Sample Control Section storage facilities will provide office space outside the physical storage area to supply a work environment for Sample Control Section Personnel without compromising the security of the items under its control.

The Sample Control Section storage facilities will provide space outside the physical storage area to supply a work environment for personnel submitting or retrieving samples without compromising the security of the samples under its control.

The Sample Control Section storage facilities will provide office space outside the physical storage area to supply a work environment for laboratory personnel retrieving or returning evidence without compromising the security of the items under its control.

5 PROCEDURE

There are currently no procedures that directly apply to the implementation of this policy.

6 APPROVAL

The signatures below recognize that the above Sample Control Section Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

FACILITY ISSUES

Security – Access

1 PURPOSE

This document establishes the **AGENCY NAME** Sample Control Section security access policy.

2 SCOPE

This policy applies to all Sample Control Section facilities of the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P001 will be used as a guide to define terms.

4 POLICY

4.1 General

The Sample Control Section will take the precautions necessary to ensure security and integrity of the evidentiary and non-evidentiary items submitted to it.

Evidentiary and non-evidentiary items submitted to the **AGENCY NAME** will remain in the sole care and custody of the Sample Control Section.

The Sample Control Section is authorized to transfer the care and custody of evidentiary and non-evidentiary items under its control to:

- Laboratory personnel for authorized examinations
- Authorized law enforcement personnel for investigative purposes
- Authorized officers of the court for adjudication purposes
- Agents of the submitting Agency for transportation purposes
- Owner of personal property not involved in a criminal investigation

4.2 Access

Only Sample Control Section personnel will have unrestricted access to Sample Control Section offices and storage facilities.

Sample Control Section personnel are authorized access to the offices and storage facilities only during normal business hours.

Sample Control Section personnel are authorized access to the offices and storage facilities outside of normal business hours when there is evidence of a breach of security.

Access to the Sample Control Section offices and storage facilities by non Sample Control Section personnel will be done under escort only after the identity of the individual has been documented in the Storage Area Entry Log.

4.3 Entry Log

The Chief of the Sample Control Section shall establish and maintain a log of all individuals who enter any storage area of the Sample Control Section.

A log of Sample Control Section personnel entry is not required, except for entries outside normal duty hours.

All unauthorized personnel who enter the storage area of the Sample Control Section shall sign the Storage Area Entry Log (PEM-F011). The information on the property storage entry log shall include, but not be limited too:

- Individual's name
- Date
- Time
- Escort's name
- Reason for entry

5 PROCEDURE

There are currently no procedures that directly apply to the implementation of this policy.

6 APPROVAL

The signatures below recognize that the above Sample Control Section Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

FACILITY ISSUES

Security – Key Control

1 PURPOSE

This document establishes the **AGENCY NAME** Sample Control Section key control policy.

2 SCOPE

This policy applies to all Sample Control Section facilities of the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P001 will be used as a guide to define terms.

4 POLICY

Only Sample Control Section personnel will possess keys to the Sample Control Section offices and storage facilities.

The following areas will each be keyed individually:

- Sample Control Section office space
- Main storage facility
- Auxiliary storage facilities
- Currency and valuable storage vault
- Firearms storage vault

Key control is outlined in **AGENCY NAME** security policy.

5 PROCEDURE

There are currently no procedures that directly apply to the implementation of this policy.

6 APPROVAL

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John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

FACILITY ISSUES

Security – Intrusion Security

1 PURPOSE

This document establishes the **AGENCY NAME** Sample Control Section intrusion security policy.

2 SCOPE

This policy applies to all Sample Control Section facilities of the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P001 will be used as a guide to define terms.

4 POLICY

4.1 Alarms

The Sample Control Section shall be secured during vacant hours by means of electronic alarms or by security personnel.

The Director of the **AGENCY NAME** will determine the number of alarm systems required to ensure the security and integrity of the Sample Control Section facilities.

Alarm systems shall include but not limited to:

- Intrusion alarms
- Fire and smoke detection alarms
- Duress alarms
- Video surveillance cameras

4.2 Security Personnel

The Director of the **AGENCY NAME** will determine the number of security personnel required to augment electronic alarms used to ensure the security and integrity of the Sample Control Section facilities.

AGENCY NAME security staff will perform and document an hourly check on the security status of the Sample Control Section offices and storage facilities.

- During business hours the security status check may consist solely of telephone communication with Sample Control Section personnel.
- After hours security status check will involve the physical evaluation of the Sample Control Section's doors and windows.

The security staff will operate and maintain the alarm and electronic security systems installed in **AGENCY NAME** facilities.

4.3 Security Breach

Security personnel they will notify the Director of the **AGENCY NAME** and the Chief of the Sample Control Section upon the detection of a security breach of the Sample Control Section offices or storage facility.

The Director of the **AGENCY NAME** and the Chief of the Sample Control Section will confer to determine the nature of the security breach.

If criminal in nature:

- Law enforcement will be notified.
- A criminal investigation will ensue.
- The Sample Control Section offices and storage facilities involved will be treated as a crime scene.
- A complete inventory of all Sample Control stored in the area of the security breach will be conducted.

If Non-criminal in nature:

- The Chief of the Sample Control Section will:
- Identify the cause of the security breach.
- Implement changes necessary to ensure the security breach does not reoccur.
- Authorize an inventory of all Sample Control stored in the area of the security breach, if necessary.

4.4 Documentation

Security personnel will document all detected security breaches in the security log and on a Detection of Breach of Security Form, which will be forwarded to the Chief of the Sample Control Section with a copy sent to the Director of the **AGENCY NAME**.

5 PROCEDURE

There are currently no procedures that directly apply to the implementation of this policy

6 APPROVAL

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John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

STAFFING, SCHEDULING AND RESPONSIBILITIES

Staffing

1 PURPOSE

This document establishes the **AGENCY NAME** Sample Control Section staffing policy.

2 SCOPE

This policy applies to all Sample Control Section personnel of the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P001 will be used as a guide to define terms.

4 POLICY

The Sample Control Section will be staff with one (1) Section Chief and sufficient personnel to ensure a safe efficient operation.

The number of authorized personnel will be established by the Director of the **AGENCY NAME** and documented in the **AGENCY NAME** official organizational chart.

4.1 MINIMUM QUALIFICATIONS AND SELECTION

The minimum qualifications for employees of the Sample Control Section are established in the **AGENCY NAME** personnel selection requirements.

The following position descriptions outline the minimum requirements and duties of Sample Control Section personnel:

- APP-PD04: Section Chief
- APP-PD14: Clerk Typist
- APP-PD15: Office Assistant
- APP-PD16: Senior Property Custodian
- APP-PD17: Property Custodian
- APP-PD18: Property Courier

Sample Control Section personnel statement of qualifications will be maintained in accordance with the **AGENCY NAME** administrative policies.

Sample Control Section personnel are selected using the guidelines found in the **AGENCY NAME** administrative policies.

5 PROCEDURE

There are currently no procedures that directly apply to the implementation of this policy

6 APPROVAL

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Mary Doe, Quality Assurance Manager	Date

End of Document

STAFFING, SCHEDULING AND RESPONSIBILITIES

Training

1 PURPOSE

This document establishes the **AGENCY NAME** Sample Control Section training policy.

2 SCOPE

This policy applies to all employees of the **AGENCY NAME** Sample Control Section.

3 DEFINITIONS

The current revision of document APP-P001 will be used as a guide to define terms.

4 POLICY

All employees of the Sample Control Section will be provided the training required to competently, safely and efficiently perform their assigned duties.

The Sample Control Section training should include the following topics:

- Sample Control Section policies and procedures
- Safety training to include:
  - Hazardous materials
  - Biohazards
  - Blood borne pathogens
  - Basic firearm orientation and how to safely handle weapons

All employees of the Sample Control Section will be provided in-service training as required to maintain or increase their job performance.

Training records of Sample Control Section employees shall be maintained in accordance with **AGENCY NAME** training policy.

5 PROCEDURE

There are currently no procedures that are directly applicable to the implementation of this policy.

6 APPROVAL

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Mary Doe, Quality Assurance Manager	Date

End of Document

STAFFING, SCHEDULING AND RESPONSIBILITIES

Scheduling

1 PURPOSE

This document establishes the **AGENCY NAME** Sample Control Section scheduling policy.

2 SCOPE

This policy applies to all **AGENCY NAME** Sample Control Section facilities.

3 DEFINITIONS

The current revision of document APP-P001 will be used as a guide to define terms.

4 POLICY

The Chief of the Sample Control Section is responsible for scheduling staff members to operate the Sample Control Section.

The Sample Control Section office and storage facility will be staffed with a minimum of two (2) employees at all times.

The Sample Control Section will be open to receive and return Sample Control during the **AGENCY NAME** normal business hours.

The Sample Control Section will be staffed one (1) hour prior to and one (1) hour after the **AGENCY NAME** normal business hours.

5 PROCEDURE

There are currently no procedures that directly apply to the implementation of this policy.

6 APPROVAL

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STAFFING, SCHEDULING AND RESPONSIBILITIES

Responsibilities

1 PURPOSE

This document establishes the **AGENCY NAME** Sample Control Section responsibilities policy.

2 SCOPE

This policy applies to all **AGENCY NAME** Sample Control Section employees.

3 DEFINITIONS

The current revision of document APP-P001 will be used as a guide to define terms.

4 POLICY

The Sample Control Section will be responsible for the secure storage and inventory of evidentiary and non-evidentiary items submitted to the **AGENCY NAME** for examination or storage.

The Sample Control Section will be responsible for assigning a unique record number (RN) to each submission of evidentiary and non-evidentiary items.

The responsibilities of Sample Control Section employees are outlined in the "Duties" section of the respective Position Description.

- APP-PD04: Section Chief
- APP-PD14: Clerk Typist
- APP-PD15: Office Assistant
- APP-PD16: Senior Property Custodian
- APP-PD17: Property Custodian
- APP-PD18: Property Courier

5 PROCEDURE

There are currently no procedures that directly apply to the implementation of this policy.

6 APPROVAL

The signatures below recognize that the above Sample Control Section Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

PACKAGING AND HANDLING

General Policy

1 PURPOSE

This document establishes the **AGENCY NAME** Sample Control Section general policy concerning the packaging and handling of items submitted to the **AGENCY NAME** for examination or storage.

2 SCOPE

This policy applies to all items submitted to the **AGENCY NAME** for examination or storage.

3 DEFINITIONS

The current revision of document APP-P001 will be used as a guide to define terms.

4 POLICY

All evidentiary and non-evidentiary items submitted to or handled by employees of the **AGENCY NAME** will be packaged and sealed in such a manner as to ensure the evidentiary quality of the individual and collective items.

General Sample Control packaging guidelines include:

- Individual exhibits will be packaged in separately prior to submission to the Sample Control Section.
  - The physical properties of the individual exhibit will determine the type of packaging used.
- The packaging of individual exhibits will be properly sealed prior to placing into the container that is submitted or returned to the Sample Control Section.
- Multiple individual exhibits from a single submission may be sealed into one or more authorized containers prior to submission to the Sample Control Section under a single record number.
- The Sample Control Section will not accept containers that have exhibits from more than one case.
- The Sample Control Section will not accept containers that are not properly sealed.

5 PROCEDURE

There are currently no procedures that directly apply to the implementation of this policy.

6 APPROVAL

The signatures below recognize that the above Sample Control Section Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
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End of Document

PACKAGING AND HANDLING

Individual Item Packaging

1 PURPOSE

This document establishes the **AGENCY NAME** Sample Control Section policy concerning the packaging and handling of individual exhibits submitted to the **AGENCY NAME** for examination or storage.

2 SCOPE

This policy applies to individual items submitted to the **AGENCY NAME** for examination or storage.

3 DEFINITIONS

The current revision of document APP-P001 will be used as a guide to define terms.

4 POLICY

4.1 GENERAL

The exhibit's size and physical characteristics will determine the type of packaging material used.

Acceptable packaging materials for individual exhibits include, but are not limited to:

- Paper envelopes
- Paper bags
- Plastic bags
- Cardboard boxes
- Glass jars and bottles
- Plastic jars and bottles
- Pasteboard pill boxes
- Metal specimen containers
- Metal paint cans

All containers should be unused.

- Used containers may be used if the container has been thoroughly cleaned, dried and decontaminated prior to use.

4.2 SMALL ITEMS

Paper bags and envelopes are not suitable for small pieces of evidence (e.g., hairs, fibers, charred materials such as ashtray contents, blood scrapings, powders, glass, soil, paint chips) if the corners and seams leak.

- Seams should be taped to prevent loss.

Plastic bags or paper folded using druggist folds that are subsequently placed into an envelope is suitable packaging for these types of submissions.

Large evidence containing trace evidence should be submitted in a brown paper bag to contain potential loss.

Pasteboard pill boxes and metal specimen containers may be used.

Properly packaged small items may be packaged in standard evidence envelopes.

4.3 LARGE ITEMS

Paper bags or wrapping can be used to package large items, garments and other non-sharp or non-fragile evidence.

Large items will be packaged in such a way as to isolate and protect the area to be examined.

Card board boxes are acceptable, if the item is secured inside the container.

4.4 FRAGILE ITEMS

Exhibits that are delicate and subject to breakage should be placed into rigid containers.

Exhibits that are delicate and subject to breakage should be packaged in such a manner as to prevent damage or alteration.

4.5 SHARP ITEMS

Exhibits with sharp or pointed edges must be placed into a ridged puncture-proof container.

4.6 LIQUID BODY FLUID SAMPLES:

Liquid blood and urine should be collected in sealed rigid leak proof containers.

The sealed container should be placed into a leak proof that will hold any liquid should the primary container break.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

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PACKAGING AND HANDLING

Case Packaging Policy

1 PURPOSE

This document establishes the **AGENCY NAME** Sample Control Section policy concerning the packaging and handling of groups of exhibits (cases) submitted to the **AGENCY NAME** for examination or storage.

2 SCOPE

This policy applies to all cases submitted to the **AGENCY NAME** for examination or storage.

3 DEFINITIONS

The current revision of document APP-P001 will be used as a guide to define terms.

4 POLICY

All of a case's individual exhibits will be packaged and sealed into one or more approved containers prior to submission to the Sample Control Section.

- The standardized container size is used maximize the Sample Control Section's storage area.

Sample Control Section will not accept case submissions that are not packaged and sealed in an approved container.

Approved containers include:

- Envelopes with the following dimensions:
  - 28# Brown Kraft, or
  - 9" (22.8 cm) × 12" (30.5 cm)
- Corrugated Boxes with one of the following dimensions:
  - 16" (40.65 cm) (l) × 12" (30.5 cm) (w) × 4" (10 cm) (h)
  - 16" (40.65 cm) (l) × 12" (30.5 cm) (w) × 6" (15.25 cm) (h)
  - 16" (40.65 cm) (l) × 12" (30.5 cm) (w) × 12" (30.5 cm) (h)
  - Larger sizes as required

Other containers will be considered on a case by case basis

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

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John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

PACKAGING AND HANDLING

Package Labeling Policy

1 PURPOSE

This document establishes the **AGENCY NAME** Sample Control Section policy concerning the packaging and handling of groups of exhibits (cases) submitted to the **AGENCY NAME** for examination or storage.

2 SCOPE

This policy applies to all cases submitted to the **AGENCY NAME** for examination or storage.

3 DEFINITIONS

The current revision of document APP-P001 will be used as a guide to define terms.

4 POLICY

Every container submitted to the Sample Control Section will be labeled with the following information:

- The Agency Name
- The agency reference number
- The exhibit number or numbers
- A brief description of the exhibit
- The initials of the person collecting the evidence or sealing the container
- The container number and number of containers associated with the submission
  - Example 1 of 2

The Property Custodian will label each container received by the Sample Control Section with the **AGENCY NAME** Record Number (RN), if it has not been labeled prior to acceptance.

The Property Custodian will write the RN on every surface of the package prior to storage in the Sample Control Section's storage facility.

Biohazard evidence should be marked with the international BIOHAZARD symbol when it is suspected or known that the material comes from any of the following:

- Liquid or dried blood
- Other body fluids (semen, saliva, urine, vaginal fluid, fecal material, and hypodermic needles in contact with body fluids)
- Body packed contraband (note on evidence exam form if the evidence was recovered from a body cavity)

Fragile evidence that is delicate, such as light bulbs and windows, require FRAGILE warnings on the outermost packaging.

Sharp evidence such as broken glass and bent metal; require SHARP warnings on the outer most packaging.

Evidence that has been chemically processed prior to submission requires CHEMICALLY TREATED warnings on the outermost packaging.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

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John Smith, Laboratory Director	Date
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End of Document

PACKAGING AND HANDLING

Package Sealing Policy

1 PURPOSE

This document establishes the **AGENCY NAME** Sample Control Section policy concerning the sealing of packages submitted to or examined by the **AGENCY NAME**.

2 SCOPE

This policy applies to all packages submitted to or processed by the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P001 will be used as a guide to define terms.

4 POLICY

Every package opening or potential opening will be properly sealed prior submission and acceptance by the Sample Control Section.

A proper seal is one where the evidence cannot escape, be contaminated or altered without apparent damage to the seal or packaging.

Examples of a proper seal are:

- Tamper evident tape.
- Heat seals.
- Other tamper evident seals should be used, and the responsible individual must initial/sign the seal.
- Cellophane tape, regular plastic tape, etc. are acceptable sealing materials if:
  - The individual sealing the package will write his initials and the date the seal was applied on the seal.
  - The writing will be administered in such a manner as to cover both the container and the sealing material.
  - The use of an official seal may be used in addition to the examiner's initials.
- Manufacturer seals, such as the bottom flap of envelopes, must be initialed or taped and initialed, to show that the seal integrity was checked.
- The evidence must be accessible by opening in the packaging, while still maintaining any seals that are already in place.
  - Outer packaging material should NEVER be folded numerous times around the evidence before sealing.
- Stapled packages are NEVER considered sealed.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

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End of Document

PACKAGING AND HANDLING

Special Circumstances (Currency)

1 PURPOSE

This document establishes the **AGENCY NAME** Sample Control Section policy concerning the packaging and handling of currency.

2 SCOPE

This policy applies to all packages submitted to or processed by the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P001 will be used as a guide to define terms.

4 POLICY

The Sample Control Section will provide enhanced levels of security and documentation regarding the handling and ultimate disposition of currency submissions.

All currency will be sealed in a separate approved packaging container upon completion of the itemization.

All currency submissions in excess of $100.00 logged into the Sample Control Section will be itemized by denomination and quantity using the Currency Inventory Form (PEM-F002).

All currency submissions greater than $100.00 in total value shall be stored in the valuables vault located in the Sample Control Section's storage area.

Currency submissions less than $100.00 may be stored in properly sealed containers with the balance of the exhibits submitted by the agency.

Counterfeit currency will be treats in the same manner as genuine currency.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

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John Smith, Laboratory Director	Date
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End of Document

PACKAGING AND HANDLING

Special Circumstances (Firearms)

1 PURPOSE

This document establishes the **AGENCY NAME** Sample Control Section policy concerning the packaging and handling of firearms.

2 SCOPE

This policy applies to all packages submitted to or processed by the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P001 will be used as a guide to define terms.

4 POLICY

The Sample Control Section will provide enhanced levels of security and documentation regarding their handling and ultimate disposition of firearms submissions.

All firearms submissions will be documented using a Firearms Submission Form.

All firearms should be unloaded prior to packaging and submission to the Sample Control section.

Firearms should be packaged in a manner that permits efficient storage.

Individual handguns should be packaged in boxes in such a way as to keep the firearm secured from moving within the box when transported.

Individual long guns/rifles should be placed in long gun boxes in such a way as to keep the firearm secured from moving within the box when transported, or wrapped and sealed in paper.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

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John Smith, Laboratory Director	Date
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End of Document

PACKAGING AND HANDLING

Special Circumstances (Contraband Drugs)

1 PURPOSE

This document establishes the **AGENCY NAME** Sample Control Section policy concerning the packaging and handling of contraband drugs.

2 SCOPE

This policy applies to all packages submitted to or processed by the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P001 will be used as a guide to define terms.

4 POLICY

The Sample Control Section will only accept representative core samples taken from large seizures of contraband drugs.

- The Director of the **AGENCY NAME** may authorize deviations from this policy as required.

The packaging of contraband drugs will be accomplished in accordance with the applicable Sample Control Manual Policies.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

The signatures below recognize that the above Sample Control Section Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

PACKAGING AND HANDLING

Special Circumstances (Biological Evidence)

1 PURPOSE

This document establishes the **AGENCY NAME** Sample Control Section policy concerning the packaging and handling of biological evidence by.

2 SCOPE

This policy applies to all packages submitted to or processed by the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P001 will be used as a guide to define terms.

4 POLICY

The Sample Control Section will only accept biological evidence that has been properly packaged and sealed.

- Biological evidence refers to bodily fluids in dried or liquid form that possess evidentiary value. These fluids include blood semen, saliva, urine, vaginal fluid and fecal material.

All biological evidence stains will be air dried prior to packaging.

All air dried biological stains will be packaged in a paper or cardboard container.

Liquid biological fluids will be collected, packaged and sealed in rigid leak proof containers. The sealed container should then be placed into a separate container that will hold any liquid should the primary container break.

Biological evidence should be marked with the international BIOHAZARD symbol.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

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John Smith, Laboratory Director	Date
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End of Document

PACKAGING AND HANDLING

Special Circumstances (Hazardous Material)

1 PURPOSE

This document establishes the **AGENCY NAME** Sample Control Section policy concerning the packaging and handling of hazardous materials.

2 SCOPE

This policy applies to all packages submitted to or processed by the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P001 will be used as a guide to define terms.

4 POLICY

The Sample Control Section will only accept representative samples, taken from bulk quantities of hazardous materials.

- Representative samples of bulk quantities of hazardous material will not exceed 60 ml (2 fl. oz.).

The Sample Control Section will NOT accept compressed gas containers.

Hazardous material samples will be collected, packaged and sealed into a leak proof primary container designed to hold the type of hazardous material to be packaged.

- The primary container will be packaged and sealed into a ridged secondary container.

Multiple hazardous material samples may be segregated and packed together according to their chemical properties, reactivity and incompatibility.

- Sample Control Section personnel should consult with laboratory forensic chemistry section personnel to resolve issues of chemical reactivity and compatibility.

Hazardous material samples should be marked with the international symbol denoting the classification of the sample. Classifications include:

- Class 1: Explosive
- Class 2: Gases: Flammable and Nonflammable
- Class 3: Flammable: Liquid
- Class 4: Flammable: Solid

- Class 5: Oxidizer or Organic Peroxide
- Class 6: Toxic materials and infectious substances
- Class 7: Radioactive materials
- Class 8: Corrosive materials
- Class 9: Miscellaneous dangerous goods

The Director of the **AGENCY NAME** may authorize deviations from this policy, as required.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

The signatures below recognize that the above Sample Control Section Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

PACKAGING AND HANDLING

Special Circumstances (Non-Evidentiary Items)

1 PURPOSE

This document establishes the **AGENCY NAME** Sample Control Section policy concerning the storage of non-evidentiary items.

2 SCOPE

This policy applies to all packages submitted to or processed by the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P001 will be used as a guide to define terms.

4 POLICY

The short or long term storage of non-evidentiary items is not the function of the Sample Control Section.

The **AGENCY NAME** Director may authorize deviations from this policy as required.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

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John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

PACKAGING AND HANDLING

Special Circumstances (Found Property)

1 PURPOSE

This document establishes the **AGENCY NAME** Sample Control Section policy concerning the packaging and handling of non-evidentiary items.

2 SCOPE

This policy applies to all packages submitted to or processed by the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P001 will be used as a guide to define terms.

4 POLICY

The Sample Control Section will not accept found items for short or long term storage.

- Found property is any item of no evidentiary value whose rightful owner may, or may not, be known to the finder.

Property Custodians will refer individuals who desire to submit found property to local the law enforcement agency.

- The **AGENCY NAME** Director may authorize deviations from this policy as required.

If found property acceptance is approved:

- The packaging requirements of found items will be the same as those of evidentiary items with the same physical characteristics, if short term storage were authorized.
- The submission of found items should be documented through the use of a Non-Evidence Submission Form.
- The Chief of the Sample Control Section will designate an area for the storage of found items, if acceptance is authorized.
- Unclaimed found items will be purged from the Sample Control Section system thirty (30) days after their submission.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

The signatures below recognize that the above Sample Control Section Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

PACKAGING AND HANDLING

Special Circumstances (Safe Keeping)

1 PURPOSE

This document establishes the **AGENCY NAME** Sample Control Section policy concerning the packaging and handling of safe keeping items.

2 SCOPE

This policy applies to all packages submitted to or processed by the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P001 will be used as a guide to define terms.

4 POLICY

The Sample Control Section will not accept items from non law enforcement entities or individuals for the purpose of safe keeping.

- Safe keeping items are non-evidentiary items surrendered for temporary custody with the understanding that the person surrendering the item has the legal right to do so, and that the item will be returned to the rightful owner(s) unless disposition by the **AGENCY NAME**, is requested by the owner(s).

The Sample Control Section may accept non-evidentiary items from law enforcement entities for the purpose of safe keeping if the items are acquired as a result of a law enforcement action and the storage of the items in question is for a term not to exceed thirty (30) days.

The packaging requirements of safe keeping items will be the same as those of evidentiary items with the same physical characteristics.

The submission of safe keeping items should be documented through the use of a Non-Evidence Submission Form.

The Chief of the Sample Control Section will designate an area for the storage of safe keeping items.

Safe keeping items will be returned to their legal owner or submitting law enforcement authority within thirty (30) days of submission.

- The **AGENCY NAME** Director may authorize deviations from this policy as required.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

The signatures below recognize that the above Sample Control Section Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

STORAGE

Temporary Storage

1 PURPOSE

This document establishes the **AGENCY NAME** Sample Control Section policy concerning the temporary storage of items.

2 SCOPE

This policy applies to all packages submitted to or processed by the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P001 will be used as a guide to define terms.

4 POLICY

The Sample Control Section will NOT provide temporary storage of evidentiary or non-evidentiary items.

- Temporary Storage refers to the gap between the time the employee who seized the evidence leaves it at the station, and the time that it is actually received by a property room employee. During this time, which could vary from a few hours to a few days, the property has left the hands of one person, but has not yet been received by another.
- This gap in the chain of custody is unacceptable.
- The **AGENCY NAME** Director may authorize deviations from this policy as required.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

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John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

STORAGE

Short Term Storage

1 PURPOSE

This document establishes the **AGENCY NAME** Sample Control Section policy concerning the temporary storage of items.

2 SCOPE

This policy applies to all packages submitted to or processed by the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P001 will be used as a guide to define terms.

4 POLICY

The Sample Control Section will provide short term storage for items submitted to the **AGENCY NAME** for examination.

- Short term storage includes the time prior to examination and up to thirty (30) days after the completion of the final requested examination.

The laboratory examiner is responsible for the secure storage of the evidentiary and non-evidentiary items in their custody during the examination process.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

The signatures below recognize that the above Sample Control Section Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

STORAGE

Long Term Storage

1 PURPOSE

This document establishes the **AGENCY NAME** Sample Control Section policy concerning the long term storage of items.

2 SCOPE

This policy applies to all packages submitted to or processed by the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P001 will be used as a guide to define terms.

4 POLICY

The Sample Control Section will not provide long term storage for evidentiary and non-evidentiary items.

- Long term storage is considered storage of an item beyond the thirty first day after the last examination has been completed.

The Chief of the Sample Control Section may grant long term storage privileges on a case by case basis.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

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John Smith, Laboratory Director	Date
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End of Document

STORAGE

Storage Areas (General)

1 PURPOSE

This document establishes the **AGENCY NAME** Sample Control Section policy concerning the general storage areas.

2 SCOPE

This policy applies to all Sample Control Section storage areas of the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P001 will be used as a guide to define terms.

4 POLICY

The Sample Control Section will provide will provide storage for evidentiary and non-evidentiary items submitted to the **AGENCY NAME** for examination.

The shelving within the general storage area will be designed to facilitate the efficient storage of Sample Control submitted to the Sample Control Section.

The approximate dimensions of the shelving in the general storage will be:

- Total Height: 190 cm (72 inches)
- Depth: 46 cm (18 inches)
- Between Shelves: 35 cm (14 inches)

An area for packages will be established for packages that are to large for standard shelf dimensions.

Shelving will be arranged in a manner that will not allow items to be stacked one upon another or one behind another.

The Sample Control Section storage facility will have a separate safe or vault to store submission of currency and other valuables.

The Sample Control Section storage facility will have a separate storage area to store submission of biological samples that require refrigeration.

The Sample Control Section storage facility will have a separate locked storage area to store submission of firearms.

The Sample Control Section storage facility will have a separate storage area for the short term storage of non-evidentiary property.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

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John Smith, Laboratory Director	Date
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End of Document

STORAGE

Storage Areas (Currency)

1 PURPOSE

This document establishes the **AGENCY NAME** Sample Control Section policy concerning the currency storage areas.

2 SCOPE

This policy applies to all Sample Control Section storage areas of the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P001 will be used as a guide to define terms.

4 POLICY

The Sample Control Section will store all currency submissions in excess of $100.00 in a separate vault dedicated to the secure storage of money and other valuable items.

The vault will have a combination lock, whose combination is only known by Sample Control Section personnel.

The combination on the vault will be changed as require to maintain the vault's security.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

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John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

STORAGE

Storage Areas (Biological Evidence)

1 PURPOSE

This document establishes the **AGENCY NAME** Sample Control Section policy concerning the biological evidence storage areas.

2 SCOPE

This policy applies to all Sample Control Section storage areas of the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P001 will be used as a guide to define terms.

4 POLICY

Evidentiary submission containing properly dried and packaged biological stains may be commingled with any other property types using the storage guidelines.

The Chief of the Sample Control Section will establish two distinct refrigerated storage areas for samples of liquid blood and urine.

- One storage area will be reserved for sample waiting for examination.
- The other storage area will be reserved for samples that have been examined.

Analytical sections responsible for the analysis of liquid blood or urine will establish a refrigerated sample storage area to store samples during the examination process.

The temperature of all refrigerated units will be monitored continually.

- The temperature inside each unit will be documented 3 times daily.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

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John Smith, Laboratory Director	Date
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End of Document

STORAGE

Storage Areas (Hazardous Materials)

1 PURPOSE

This document establishes the **AGENCY NAME** Sample Control Section policy concerning the hazardous materials storage areas.

2 SCOPE

This policy applies to all Sample Control Section storage areas of the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P001 will be used as a guide to define terms.

4 POLICY

The Chief of the Sample Control Section will designate an area for the safe storage of hazardous materials samples.

The storage area will be ventilated to prevent the accumulation of explosive, flammable, corrosive or otherwise toxic fumes.

The storage area ventilation will be designed in such a manner as to not contaminate the building's Heating/Ventilating/Air Conditioning (HVAC) system.

The storage of hazardous materials in a secured ventilated area outside of the Sample Control section's regular storage facility is acceptable.

Hazardous material samples will NOT be stored in the laboratory's chemical storage facilities or otherwise commingled with **AGENCY NAME** materials and supplies.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

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John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

STORAGE

Storage System

1 PURPOSE

This document establishes the **AGENCY NAME** Sample Control Section storage system policy.

2 SCOPE

This policy applies to all Sample Control Section storage areas of the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P001 will be used as a guide to define terms.

4 POLICY

Each shelving unit shall have a unique designation.

Each shelf of a shelving unit will be labeled with its unique row and shelf designation.

Each submitting agency will be assigned a specific location in which all of their submissions will be stored.

Each assigned section will be labeled with the name of the agency whose submissions are store there.

Submission from agencies and individuals with fewer than 100 submissions per year will all be placed in a section labeled "Other Agencies".

5 PROCEDURE

All submissions will be sorted and stored in the following manner:

- Submissions will be sorted and stored by packaging type.
- Similar packaging types will be stored on the same shelves.
- Packages on a shelf will be arranged numerically by, laboratory record number, increasing in value from left to right.
- Packages will not be stacked on top of another.
- Packages will not be placed on a shelf one in front of another.
- Currency submissions in excess of $100.00 will be stored in the Sample Control Section vault.
- Jewelry and other property with a value in excess of $250.00 will be stored in the Sample Control Section vault.
- Firearms will be stored in a locked storage area within the Sample Control Section storage facility.

6 APPROVAL

The signatures below recognize that the above Sample Control Section Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

SAMPLE CONTROL
Database

1 PURPOSE

This document establishes the **AGENCY NAME** Property and Evidence Section database policy.

2 SCOPE

This policy applies to all Property and Evidence Section information.

3 DEFINITIONS

The current revision of document APP-P001 will be used as a guide to define terms.

4 POLICY

The Property and Evidence Section will maintain a database of information concerning the status of items submitted to the **AGENCY NAME**.

The information in the database will be updated daily.

Each submission to the Property and Evidence Section will have a unique database record for each submission, which will contain the following information:

- **AGENCY NAME** Record Number
- Name of the submitting agency
- Submitting agency's file number
- Date submitted by the agency
- Date returned to the agency
- Storage location within the Property and Evidence Section's storage location
- Date transferred to the laboratory
- Examiner item was transferred to
- Date returned to the Property and Evidence Section
- Examination Complete (YES or NO)
- Date the Notice of Examination Completion form was sent
- Requires Destruction (YES or NO)
- Evidence Destroyed (YES or NO)

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

The signatures below recognize that the above Property and Evidence Section Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

SAMPLE CONTROL

Submission Policy

1 PURPOSE

This document establishes the **AGENCY NAME** Sample Control Section submission policy.

2 SCOPE

This policy applies to all evidentiary and non-evidentiary items submitted to Sample Control Section.

3 DEFINITIONS

The current revision of document APP-P001 will be used as a guide to define terms.

4 POLICY

All evidentiary and non-evidentiary items will only be received by the **AGENCY NAME** through the direct documented exchange of items between the Sample Control Section and the individual submitting the items.

Sample Control Section personnel will only accept items that are properly packaged, sealed and labeled.

Sample Control Section personnel will only accept items that are accompanied by the appropriate documentation.

5 PROCEDURE

There are currently no procedures that directly affect the implementation of this policy.

6 APPROVAL

The signatures below recognize that the above Sample Control Section Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

SAMPLE CONTROL

Return Policy

1 PURPOSE

This document establishes the **AGENCY NAME** Sample Control Section return policy.

2 SCOPE

This policy applies to all evidentiary and non-evidentiary items submitted to Sample Control Section.

3 DEFINITIONS

The current revision of document APP-P001 will be used as a guide to define terms.

4 POLICY

The **AGENCY NAME** will establish a procedure to document the return of items submitted to the Sample Control Section.

The Sample Control Section will only return evidentiary and non-evidentiary items during normal business hours.

- The Chief of the Sample Control Section may authorize a deviation from this policy.

5 PROCEDURE

The Sample Control Section will return evidentiary and non-evidentiary items to the submitting agency using the following sequence:

- The Sample Control Section will be notified that all laboratory examinations have been completed.
- The Sample Control Section will notify the submitting agency, in writing using a **FORM NAME**, that laboratory examination have been completed and the submitted items should be retrieved within thirty (30) days.
  - A copy of the form will be attached to the original **FORM NAME**.
- A representative of the submitting agency will present the **FORM NAME** to the Sample Control Section.
- Property Custodian will retrieve the original **FORM NAME** from the Sample Control Section's files.
- Property Custodian will retrieve the items from its storage location.

- Property Custodian will sign and date the "FROM" portion of the "Chain of Custody" on the **FORM NAME**.
- The submitting individual will sign the "TO" portion of the "Chain of Custody" on the **FORM NAME**.
- Property Custodian will provide the retrieving individual a copy of the signed **FORM NAME** as a receipt.
- Property Custodian will log the submission into the Sample Control Section property database within 24 hours of return.
- Property Custodian will file and maintain the original **FORM NAME** in the Sample Control Sections files.

6 APPROVAL

The signatures below recognize that the above Sample Control Section Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

SAMPLE CONTROL

Laboratory Distribution

1 PURPOSE

This document establishes the **AGENCY NAME** Sample Control Section laboratory distribution policy.

2 SCOPE

This policy applies to all evidentiary and non-evidentiary items submitted to Sample Control Section.

3 DEFINITIONS

The current revision of document APP-P001 will be used as a guide to define terms.

4 POLICY

The **AGENCY NAME** will establish a procedure to document the laboratory distribution and return of items submitted to the Sample Control Section.

The Sample Control Section will only distribute and return evidentiary and non-evidentiary items to laboratory personnel during normal business hours.

- The Chief of the Sample Control Section may authorize a deviation from this policy.

5 PROCEDURE

5.1 Distribution

The Sample Control Section will distribute evidentiary and non-evidentiary items to laboratory examiners using the following sequence:

- The examiner will present the Sample Control Section a copy of the ESM or NSF associated with the item(s) he is desires.
- Property Custodian will retrieve the original submission form from the Sample Control Section's files.
- Property Custodian will retrieve the items from its storage location.
- Property Custodian will sign and date the "FROM" portion of the "Chain of Custody" on the both copies of the submission form.
- The examiner will sign the "TO" portion of the "Chain of Custody" on both copies of the **FORM NAME**.

- Property Custodian will log the information into the Sample Control Section property database within 24 hours of laboratory distribution.
- Property Custodian will file and maintain the originals **FORM NAME** in the Sample Control Sections files.

5.2 Return

The Sample Control Section will only receive evidentiary and non-evidentiary items from laboratory examiners during normal business hours.

The Sample Control Section will receive evidentiary and non-evidentiary items after laboratory examination using the following sequence:

- The examiner will present the package containing the examined items and the associated **FORM NAME** to the Property Custodian.
- Property Custodian will ensure the submission is packaged properly.
  - Items will not be accepted if they are not properly packaged, sealed and labeled.
- Property Custodian will retrieve the original **FORM NAME** from the Sample Control Section's files.
- The examiner will sign both copies of the "FROM" portion of the "Chain of Custody" section on the ESM or NSF.
- Property Custodian will sign and date both copies of the "TO" portion of the "Chain of Custody" section on the **FORM NAME**.
- Property Custodian will place the submitted item in the holding area of the evidence storage facility until it can be placed in the appropriate storage location.
- Property Custodian will return the package to the storage location on the **FORM NAME**.
- Property Custodian will update the information in the Sample Control Section property database within 24 hours of the transaction.
- Property Custodian will send a Notice of Examination Completion Form to the submitting agency within five (5) days of completion of the final examination.
  - A copy of the Notice of Examination Completion Form will be attached to and filed with the original **FORM NAME**.

6 APPROVAL

The signatures below recognize that the above Sample Control Section Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

SAMPLE CONTROL

Intra Laboratory Exchange

1 PURPOSE

This document establishes the **AGENCY NAME** Sample Control Section intra laboratory exchange policy.

2 SCOPE

This policy applies to all evidentiary and non-evidentiary items submitted to Sample Control Section.

3 DEFINITIONS

The current revision of document APP-P001 will be used as a guide to define terms.

4 POLICY

The AGENCY NAME will establish a procedure to document the intra laboratory exchange of items submitted to the Sample Control Section.

The control and custody of evidentiary and non-evidentiary items between examiners for the purpose of authorized laboratory examination is permissible.

Every exchange of control and evidentiary and non-evidentiary items between laboratory examiners will be documented on the "Chain of Custody" section of examiner's copy of the **FORM NAME**.

5 PROCEDURE

The documentation of the exchange between laboratory examiners will be accomplished using the following sequence:

- The examiner will properly package, label and seal the item(s) prior to any exchange of control.
- The receiving examiner will ensure the items to be exchanged are properly packaged, labeled and sealed.
- Original examiner will sign and date the "FROM" portion of the "Chain of Custody" on the **FORM NAME**.
- The receiving examiner will sign the "TO" portion of the "Chain of Custody" on the **FORM NAME**.
- A copy of the signed form will be made.
  - The original examiner will retain the copy.
  - The receiving examiner will retain the copy with the original signatures.

- The receiving examiner will return the items to the Sample Control Section at the completion of his examination(s).
- This exchange process will be repeated if additional examinations by another examiner are required.

6 APPROVAL

The signatures below recognize that the above Sample Control Section Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

SAMPLE CONTROL

Regional Facility Transfer Procedure

1 PURPOSE

This document establishes the **AGENCY NAME** Sample Control Section regional facility transfer procedure.

2 SCOPE

This policy applies to headquarters and regional evidence collection facilities of the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P001 will be used as a guide to define terms.

4 POLICY

The AGENCY NAME will establish and maintain procedures for the exchange of evidentiary and non-evidentiary items between the headquarters and regional evidence collection and storage facilities.

Transfers of evidentiary and non-evidentiary items will only occur during normal business hours.

- The Chief of the Sample Control Section may authorize a deviation from this policy.

5 PROCEDURE

The following methods describe the procedures used by the **AGENCY NAME** to transfer evidentiary and non-evidentiary items between evidence collection facilities.

5.1 REGIONAL CENTER TO HEADQUARTERS TRANSFERS

5.1.1 Regional Center to Courier

Prior to the Property Courier's arrival the Property Custodian will:

- Place all items scheduled for transfer in a secure holding area.
- Retrieve all of the associated **FORM NAME** and place them with the appropriate items.

The Property Custodian and the Property Courier will conduct the following sequence for each submission transferred from the custody of the regional evidence collection facility to the Property Courier.

- The Property Custodian will present the submission and its associated **FORM NAME** to the Property Courier.
- The Property Custodian will sign and date the "FROM" portion of the **FORM NAME**.
  - Purpose: TRANSFER.
- The Property Courier will compare the package(s) markings and seals on to the associated **FORM NAME**.
  - The Property Courier will not accept package(s) for transfer if the RN on the package(s) does not correspond to the RN number on the associated **FORM NAME**.
  - The Property Courier will not accept packages for transfer if the package(s) are improperly sealed.
- The Property Courier will sign and date the "TO" portion of the **FORM NAME**.
- Property Custodian will provide the Property Courier a copy of each signed **FORM NAME** as a receipt.
- Property Courier will place the submitted item in a secure portion of the transportation vehicle and continue on his route.
- Property Custodian will update the regional evidence collection facility property database within 24 hours of the transfer.
- Property Custodian will file and maintain the original **FORM NAME** in the regional evidence collection facility's files.

5.1.2 Courier to Headquarters

The Property Custodian and the Property Courier will conduct the following sequence for each submission transferred from the custody of the Property Courier to Headquarters Evidence Facility.

- The Property Courier will present the package(s) and the associated FORM NAME to Property Custodian.
- The Property Custodian will compare the package(s) markings and seals on to the associated **FORM NAME**.
  - The Property Custodian will not accept package(s) for transfer if the RN on the package(s) does not correspond to the RN number on the associated **FORM NAME**.
  - The Property Custodian will not accept packages for transfer if the package(s) are improperly sealed.
- The Property Courier will sign the "FROM" portion of the "Chain of Custody" on the **FORM NAME**.
- Property Custodian will sign and date the "TO" portion of the "Chain of Custody" on the **FORM NAME**.
  - Purpose: STORAGE.
- Property Custodian will place the submitted item in the holding area of the evidence storage facility until it can be placed in the appropriate storage location.
- Property Custodian will document the submission's storage location on the **FORM NAME**.
  - A single line will be place through the all previous storage locations documented on the **FORM NAME**.
  - The new storage location will be place directly under the last documented storage location.

- Property Custodian will log the submission into the Sample Control Section property database.
- Property Custodian will send a copy of the **FORM NAME** to the Deputy Director for case assignment and distribution.
- Property Custodian will file and maintain the original copy of the **FORM NAME** in the Sample Control Sections files.

5.2 HEADQUARTERS TO REGIONAL CENTER TRANSFERS

5.2.1 Headquarters to Courier

Prior to the Property Courier's arrival the Property Custodian will:

- Place all items scheduled for transfer in a secure holding area.
- Retrieve all of the associated **FORM NAME** and place them with the appropriate items.

The Property Custodian and the Property Courier will conduct the following sequence for each submission transferred from the custody of the regional evidence collection facility to the Property Courier.

- The Property Custodian will present the submission and its associated **FORM NAME** to the Property Courier.
- The Property Custodian will sign and date the "FROM" portion of the **FORM NAME**.
  - Purpose: TRANSFER.
- The Property Courier will compare the package(s) markings and seals on to the associated **FORM NAME**.
  - The Property Courier will not accept package(s) for transfer if the RN on the package(s) does not correspond to the RN number on the associated **FORM NAME**.
  - The Property Courier will not accept packages for transfer if the package(s) are improperly sealed.
- The Property Courier will sign and date the "TO" portion of the **FORM NAME**.
- Property Custodian will provide the Property Courier a copy of each signed **FORM NAME** as a receipt.
- Property Courier will place the submitted item in a secure portion of the transportation vehicle and continue on his route.
- Property Custodian will update the Headquarters Sample Control Section database within 24 hours of the transfer.
- Property Custodian will file and maintain the original copy of the FORM NAME in the Sample Control Section's files.

5.2.2 Courier to Headquarters

The Property Custodian and the Property Courier will conduct the following sequence for each submission transferred from the custody of the Property Courier to regional evidence collection facility.

- The Property Courier will present the package(s) and the associated **FORM NAME** to Property Custodian.
- The Property Custodian will compare the package(s) markings and seals on to the associated **FORM NAME**.
  - The Property Custodian will not accept package(s) for transfer if the RN on the package(s) does not correspond to the RN number on the associated **FORM NAME**.
  - The Property Custodian will not accept packages for transfer if the package(s) are improperly sealed.
- The Property Courier will sign the "FROM" portion of the "Chain of Custody" on the **FORM NAME**.
- Property Custodian will sign and date the "TO" portion of the "Chain of Custody" on the **FORM NAME**.
  - Purpose: STORAGE.
- Property Custodian will place the submitted item in the holding area of the evidence storage facility until it can be placed in the appropriate storage location.
- Property Custodian will document the submission's storage location on the **FORM NAME**.
  - A single line will be place through the all previous storage locations documented on the **FORM NAME**.
  - The new storage location will be place directly under the last documented storage location.
- Property Custodian will log the submission into the regional evidence collection facility's database.
- Property Custodian will file and maintain the original copy of the **FORM NAME** in the regional evidence collection facility's files.

6 APPROVAL

The signatures below recognize the above Sample Control Section Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

DISPOSITION AND PURGING

Purging

1 PURPOSE

This document establishes Sample Control Section purging procedure.

2 SCOPE

This policy applies to headquarters and regional evidence collection facilities of the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P001 will be used as a guide to define terms.

4 POLICY

The Sample Control Section will store evidentiary and non-evidentiary items no longer than necessary.

Evidentiary and non-evidentiary items will be returned to the submitting agency and purged from the system within thirty (30) days of notice of examination completion has been sent.

- The Chief of the Sample Control Section may authorize a deviation from this policy.

5 PROCEDURE

Evidentiary and non-evidentiary items are purged from the Sample Control Section system when:

- A documented transfer of an evidentiary or non-evidentiary item(s) to the originating agency has been performed.
- A documented transfer of an evidentiary or non-evidentiary item(s) to a laboratory section for use as an exemplar has been performed.
- A documented destruction of the evidentiary and non-evidentiary items has been performed.
- A documented return of an non-evidentiary item to the owner of record.

All documents related to the submission, transfer and disposal of evidentiary and non-evidentiary items submitted the Sample Control Section will be filed and maintained in accordance with the **AGENCY NAME** document retention policy.

Evidentiary and non-evidentiary item purging process:

- The laboratory section notifies the Sample Control Section that all requested examinations have been completed.
- Property custodian enters the notice of the completion of examinations of evidentiary and non-evidentiary items into the Sample Control Section database as they become available.
- The Property Custodian attaches the laboratory's notice of completion to the original **FORM NAME**.
- Property custodian will review the Sample Control Section database and identify which evidentiary and non-evidentiary items require collection on the last Monday of the month.
- Notice of Examination Completion (NEC) forms are sent to agencies with evidentiary and non-evidentiary items that require collection on the last Monday of the month.
- Property Custodian will review the Sample Control Section database and identify the evidentiary and non-evidentiary items that have not been retrieved within the thirty (30) day time frame, on the last Monday of the month.
- Evidentiary and non-evidentiary items that have not been retrieved by the agency of origin within thirty (30) days of transmission of the NEC form are subject to purging and disposal.
- Property Custodian will notify the submitting agency of the pending disposal of the evidentiary or non-evidentiary items that have not been retrieved.
    - The Property Custodian will make a notation of this contact on the file copy of the NEC form attached to the original **FORM NAME**.

- Sample Control Section will schedule the disposal of all evidentiary and non-evidentiary items that meet the disposal criteria.

6 APPROVAL

The signatures below recognize the above Sample Control Section Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

DISPOSITION AND PURGING

Destruction

1 PURPOSE

This document establishes Property and Evidence Section destruction policy.

2 SCOPE

This policy applies to headquarters and regional evidence collection facilities of the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P001 will be used as a guide to define terms.

4 POLICY

All evidentiary and non-evidentiary items in the Property and Evidence Section that meet the destruction criteria will be destroyed on the schedule outlined in this section.

An independent witness will verify the destruction of all evidentiary and non-evidentiary items.

The destruction of all evidentiary and non-evidentiary items will be documented on a **FORM NAME**. This form will be attached to and filed with the original **FORM NAME**.

A sufficient number of armed officers will be present to security during the destruction of contraband drugs. The number of armed officers will be determined by the volume of contraband drugs to be destroyed and the location of the destruction site.

4.1 Destruction Criteria

The criteria for the destruction evidentiary and non-evidentiary items include:

- Evidentiary and non-evidentiary items of criminal cases in which the adjudication has been completed.
- Evidentiary and non-evidentiary items of criminal cases in which the examination has been completed and the submitting agency has not retrieved the items within the designated time frame.
- Evidentiary or non-evidentiary items that the **AGENCY NAME** laboratory does not request to be placed into their reference collection.
- Non-evidentiary items which the owner of record cannot be located or has not retrieved the item within thirty (30) days of notification of pending destruction.
- Other situations authorized by the Director.

4.2 Destruction Methods

Destruction methods of evidentiary and non-evidentiary items include:

- Incineration or smelting.
- Shredding.
- Saw cutting, torching, crushing or other method which would render the item useless.
  - The removal of usable parts from firearms may be permissible if authorized by the Director.
- Disposal into a sanitary landfill if the items do not possess an environmental hazard.
- Auction.
- Other means authorized by the Director.
- Disposal of in the ocean, lake or other body of water is unacceptable.

4.3 Destruction Schedule

The destruction schedule will be:

- First Wednesday of the month: **Firearms**
- Second Wednesday of the month: **Contraband Drugs**
- Third Wednesday of the month: **Biological Evidence**
- Fourth Wednesday of the month: **Hazardous Materials and General Disposal**

5 PROCEDURE

Destruction procedure:

- A Property Custodian will prepare a **FORM NAME**.
- A Property Custodian submits a completed **FORM NAME** form to the Director for approval.
- The Director approves the destruction by signing in the designated location on the **FORM NAME** form and returns the form to the Property and Evidence Section for action.
- A Property Custodian retrieves the original **FORM NAME** from the file.
- A Property Custodian retrieves the property from the assigned storage location.
- In the presence of one or more individuals the Property Custodian destroys the items utilizing one or more authorized methods.
- Each Property Custodian and witness will sign and date **FORM NAME** form.
  - An independent witness will verify the serial numbers and destruction of all firearms.
- A Property Custodian will file the original **FORM NAME** and its associated PDDR form using guidelines established in the **AGENCY NAME** document retention policy.
- A Property Custodian will document the destruction of the property in the property and evidence database.

6 APPROVAL

The signatures below recognize the above Sample Control Section Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

DISPOSITION AND PURGING

Diversion

1 PURPOSE

This document establishes Sample Control Section diversion policy.

2 SCOPE

This policy applies to headquarters and regional evidence collection facilities of the **AGENCY NAME**.

3 DEFINITIONS

The current revision of document APP-P001 will be used as a guide to define terms.

4 POLICY

The Director may authorize the diversion of evidentiary and non-evidentiary items scheduled for destruction, for official use.

5 PROCEDURE

The following is the procedure for diverting items scheduled for destruction, for official use.

- An official letter will be submitted to the **AGENCY NAME** Director requesting the diversion of evidentiary and non-evidentiary items.
  - The letter will contain a description of the evidentiary or non-evidentiary items.
  - The purpose the diversion.
- The Director will write or stamp the word "Approved" or "Denied" with his signature on the request for diversion letter.
- The letter will be submitted to the Sample Control Section for disposition.
- The letter will be attached to and filed with the original **FORM NAME**.
- The diversion of all evidentiary and non-evidentiary items will be documented on a **FORM NAME** form. This form will be attached to and filed with the original **FORM NAME**.

6 APPROVAL

The signatures below recognize that the above Sample Control Section Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

Appendix I

Sample Control Manual

(Revision XX)

This document represents the sample control policies of the **AGENCY NAME**. All additions, deletions and modifications to this document are done in accordance with the policy preparation policy. This document is the property of the **AGENCY NAME** and cannot be reproduced without authorization.

Official revisions are incorporated annually. Interim modifications will be documented and implemented in accordance to the document modification policy. A copy of the interim modification will be distributed and inserted into the appropriate portion of each printed section of this manual.

The signatures below recognize the total volume as the official sample control policy of the **AGENCY NAME** effective **DATE**.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

CONTENTS

1 Administrative Issues

1.1 Organizational Placement

The Sample Control Section shall be a centralized autonomous unit within the **AGENCY NAME**.

The Sample Control Section will organizationally be located within the **Section Name** of the **AGENCY NAME** to maintain organizational independence and integrity.

The Chief of the Sample Control Section will report to the Deputy Director of the **Section Name** to maintain organizational independence and integrity.

All Sample Control Section employees will report to the Chief of the Sample Control Section to maintain organizational independence and integrity.

1.2 Policy Manual

The Sample Control Manual (SCM), in conjunction with the relevant policies and procedures outlined in the **AGENCY NAME's** Administrative Policy and Procedure Manual (APP) and Quality Assurance Manual (QAM) shall service as the standardize the procedures for the collection, storage, security, release, and disposal of evidentiary and non-evidentiary items submitted to the **AGENCY NAME**.

The SCM and supporting administrative and quality assurance documents establish the written procedures for receiving all evidentiary and non-evidentiary items into the **AGENCY NAME**.

The SCM directives will include but not be limited to:

- Requiring all evidentiary and non-evidentiary items to be placed under the control of the Sample Control Section prior to transfer to the laboratory section for examination.
- Providing guidelines for packaging and labeling of evidentiary and non-evidentiary items prior to storage.
- Establishing additional security measures for handling exceptional, valuable, or sensitive evidentiary and non-evidentiary items.
- Establishing procedures for the temporary and final release of evidentiary and non-evidentiary items from the control of the Sample Control Section.

1.3 Documentation

NO evidentiary and non-evidentiary items will be accepted into the **AGENCY NAME** Sample Control Section without proper documentation.

Every evidentiary and non-evidentiary item exchange will be documented using the appropriate form.

The **AGENCY NAME** will develop and maintain standardized forms to be used for all Sample Control submissions.

The **AGENCY NAME** will modify each form as necessary.

Documentation concerning the submission of evidentiary and non-evidentiary item(s) will contain sufficient information to identify the status of the item(s) at any time while under the control of the **AGENCY NAME.**

Sample Control Section forms will contain some or all of the following information:

- Submitting Officer Information
- Case Number
- Control Number
- Bar Code Number
- Item Number(s)
- Description line for each item
- Owner, Victim, Suspect box
- Address of party involved
- Phone number of party involved
- Type of crime
- Date/time item was submitted
- Receiving Property Officer Information
- Removed from locker by
- Date/time received
- Location stored
- Location within the evidence room
- Chain of custody information
- Signature of person providing items
- Signature of person receiving the items
- Date and time the exchange takes place
- Reason for the exchange
- Minimum of eight (8) lines
- Detective/Investigator responsible for case
- Approval signature to release, destroy, divert
- Description of items to be released/destroyed (items numbers, etc.)
- Documentation when the card or letter was sent
- Property Room History – Released or Destroyed
- Name of person property is to be released to
- Address of person property is to be
- Drivers license or other government ID of person
- Release by
- Date of release
- Destroyed by
- Date of destruction

Each separate form will contain sufficient information to allow it to be associated with other forms used to monitor the status and location of the item(s) originally submitted to the Sample Control Section under a specific Record Number (RN).

1.3.1 Forms

The following forms are to be used to monitor the location of items that enter the Sample Control Section.

All submissions will be assigned a unique Record Number (RN) that will be placed on all individual forms.

Continuation sheets will be used in situations, which the first page of the submission form does not contain sufficient space to document all items that will be submitted to the Sample Control section.

All forms associated with a specific submission will contain a space for the submission's unique record number.

The Sample Control Section Forms include:

- **ESF:** Evidence Submission Form, for evidentiary item submissions to the **AGENCY NAME**
- **ESFc:** Continuation sheet for form ESF
- **NSF:** Non-evidence Submission Form for non-evidentiary item submissions to the **AGENCY NAME**
- **NSFc:** Continuation sheet for form NSF
- **PDDF:** Property Destruction/Diversion Form to document an item(s) destruction or diversion to use as a reference standard
- **SAEL:** Storage Area Entry Log
- **CIF:** Currency Inventory Form
- **FIF:** Firearms Inventory Form
- Other forms as required by the Chief of the Sample Control Section and approved by Director of the **AGENCY NAME**

1.3.2 Valuables and Firearms

The submission of valuables and firearms to the Sample Control Section requires additional documentation, which shall include:

- All currency shall be inventoried and documented prior to submission to the Sample Control Section.
  - Currency submissions in excess of $100.00 shall be documented using the (CIF).
  - Currency submissions in excess of $100.00 shall be counted, itemized and documented in the presence of two or more individuals prior to being received by the Sample Control Section.
  - Each individual will initial the CIF.
  - The CIF will be attached to the corresponding ASF or OASF and become part of the permanent record.
  - Currency submissions less than $100.00 will be documented on the ASF or the OASF.

The submission of all firearms will be documented on an ESM and a FIF with the following descriptive information:

- The manufacturer's name
- Model name or number
- Caliber
- Serial number

The serial number of any item with a value of in excess of $250.00 shall be recorded on the ESF or NSF prior to submission to the Sample Control Section.

1.4 Inventories

The Sample Control Section shall annually conduct an inventory of the contents of all storage facilities under its control.

Additional random inventories of all or a portion of the Sample Control storage facilities will be conducted at the discretion of the Chief of the Sample Control Section.

The inventory will document the type and location of all packages within the Sample Control Section storage facility and will:

- Compare the list of items within the Sample Control Section storage facility to the database of Sample Control logged into the storage facility
- Include:
  - Record Number (RN)
  - Number of packages
  - Location of packages

Inventory methods:

- ***Shelf to Property Sheet:*** List items on a specific shelf or location and compare with the ESF, NSF or database log. (Recommended.)
- ***Property Sheet to Shelf:*** Select Property Sheets and locate items on the shelf. The major disadvantage with this system is that it doesn't document items on the shelf where the identifying numbers have been detached or are misfiled.

The Chief of the Sample Control Section will submit a report to the Director of the **AGENCY NAME** detailing the results of the inventory.

All inventory reports will be filed in accordance with **AGENCY NAME** document retention policy.

1.5 Audits

The Sample Control Section will conduct an annual audit to verify accounts and records for correctness.

A review of the Sample Control Section's policies, procedures, and actions of an operation will be conducted annually to determine whether or not they meet the recognized standards and the agency's own policies.

The audit will evaluate one or more of the following issues:

- Determine if legal requirements are being met (basic audit).
- Evaluate the use of resources. This also includes attention to procedures and management policies (procedural audit).
- Evaluate the **AGENCY NAME's** structure and encompasses plans, policies, and systems (an organizational audit).

All audits will be conducted by an impartial party outside the direct chain of command of the Chief of the Sample Control Section.

- The auditor may be an employee of the **AGENCY NAME** or other qualified government official. Qualified private consultants may also be contracted to conduct the audit.

The Chief of the Sample Control Section may conduct internal audits as required.

One or more of the following methods can be used to conduct an audit of the Sample Control Section:

- ***Selection and review of one case file:*** The file is traced through the entire system to the current location. This method provides verification of the file and accuracy of all related forms.
- ***Random selection of an item of property off the shelf:*** The auditor traces it back through the case file again verifying the file and associated documentation.
- ***Selection of an inactive case file:*** The auditor traces the file through the system to the property, or if purged, verifying that all documentation is correct. A physical inspection of the last storage place prior to disposal is recommended to insure validity.

The auditor(s) will submit a report to the Director of the **AGENCY NAME** with a copy sent to the Chief of the Sample Control Section detailing the results of the audit.

All audit reports will be filed in accordance with **AGENCY NAME** document retention policy.

1.6 Training

All employees of the Sample Control Section will be provided the training required to competently, safely and efficiently perform their assigned duties. The training should include the following topics:

- Sample Control Section policies and procedures
- Safety training to include:
  - Hazardous materials
  - Biohazards
  - Blood borne pathogens
- Basic firearm orientation and how to safely handle weapons

All employees of the Sample Control Section will be provided in-service training as required to maintain or increase their job performance.

Training records of Sample Control Section employees shall be maintained in accordance with **AGENCY NAME** training policy.

All employees of the Sample Control Section are encouraged to join and participate in professional associations that focus on issues related to management and warehousing of Sample Control.

2 Facilities

2.1 Construction

The Sample Control Section's storage area shall be constructed of materials to secure the facility from unauthorized entry.

Exterior walls will be of masonry or similar construction.

Windows and exterior entrances will be minimized.

Exterior windows will:

- Have security bars installed
- Be covered in such a way as to prohibit view from the outside
- Have intrusion alarms, if possible

Exterior doors will:

- NOT have door handles exposed to the outside
- Key only access to exterior surface
- Have intrusion alarms when possible

Interior walls will extend from floor to ceiling and be constructed of a material that will not be penetrated easily and deter intrusion.

Interior windows will:

- Be minimized
- Be covered in such a way as to prohibit view from the outside
- Have intrusion alarms, if possible

Interior doors will:

- Be minimized
- Have intrusion alarms when possible

Additional storage facility requirements:

- An operational fire suppression system
- An operational fire alarm
- An operational intrusion alarm
- An area for the secure storage of firearms will be established
- An area for the secure storage of currency and other valuables will be established
- An area for the safe storage of biological evidence will be established
- An area for the safe storage of hazardous materials will be established

2.2 Layout

The Sample Control Section storage facilities shall be located in a place that allows convenient access by personnel submitting evidentiary and non-evidentiary items for examination as well as the laboratory personnel responsible for its examination.

The Sample Control Section storage facilities will provide office space outside the physical storage area to supply a work environment for Sample Control Section Personnel without compromising the items under its control.

The Sample Control Section storage facilities will provide space outside the physical storage area to supply a work environment for personnel submitting or retrieving Sample Control without compromising the items under its control.

The Sample Control Section storage facilities will provide office space outside the physical storage area to supply a work environment for laboratory personnel retrieving or returning evidence without compromising the items under its control.

2.3 Security

2.3.1 General

The Sample Control Section will take the precautions necessary to ensure security and integrity of the evidentiary and non-evidentiary items submitted to it.

Evidentiary and non-evidentiary items submitted to the **AGENCY NAME** will remain in the sole care and custody of the Sample Control Section.

The Sample Control Section is authorized to transfer the care and custody of evidentiary and non-evidentiary items under its control to:

- Laboratory personnel for authorized examinations
- Authorized law enforcement personnel for investigative purposes
- Authorized officers of the court for adjudication purposes
- Agents of the submitting Agency for transportation purposes
- Owner of personal property not involved in a criminal investigation

2.3.2 Access

Only Sample Control Section personnel will have unrestricted access to the Sample Control Section offices and storage facilities.

Sample Control Section personnel are authorized access to the offices and storage facilities only during normal business hours.

Sample Control Section personnel are authorized access to the offices and storage facilities outside of normal business hours when there is evidence of a breach of security.

Access to the Sample Control Section offices and storage facilities by non Sample Control Section personnel will be done under escort only after the identity of the individual has been documented in the Storage Area Entry Log.

2.3.2.1 Entry Log The Chief of the Sample Control Section shall maintain a log of all individuals who enter any area of the Sample Control Section.

A log of Sample Control Section personnel entry is not required, except for entries outside normal duty hours.

All unauthorized personnel who enter the storage area of the Sample Control Section shall sign the Storage Area Entry Log (SAEL). The information on the property storage entry log shall include, but not be limited too:

- Individuals name
- Date
- Time
- Escort's name
- Reason for Entry

2.3.3 Key Control

Only Sample Control Section personnel will have possess keys to the Sample Control Section offices and storage facilities.

The following areas will each be keyed individually:

- Sample Control Section office space
- Main storage facility
- Auxiliary storage facilities
- Currency and valuable storage vault
- Firearms storage vault

Key control is outlined in **AGENCY NAME** security policy.

2.3.4 Intrusion Security

AGENCY NAME security staff will perform and document an hourly check on the security status of the Sample Control Section offices and storage facilities.

- During business hours the security status check may consist solely of telephone communication with Sample Control Section personnel.
- After hours security status check will involve the physical evaluation of the Sample Control Section's doors and windows.

The Director of the **AGENCY NAME** will determine the number of intrusion alarms required to ensure the security and integrity of the Sample Control stored in the Sample Control Section offices and storage facilities.

AGENCY NAME security staff will monitor the intrusion alarms twenty-four (24) hours a day, seven (7) days a week basis, when required.

AGENCY NAME security staff will test and document the functionality of intrusion alarms the first week of every month, if required.

The Director of the **AGENCY NAME** will determine the number of video surveillance cameras required to ensure the security and integrity of the Sample Control stored in the Sample Control Section offices and storage facilities.

AGENCY NAME security staff will monitor the video surveillance cameras on twenty-four (24) hours a day, seven (7) days a week basis, when required.

AGENCY NAME security staff will test and document the functionality of the video surveillance cameras the first week of every month, if required.

The Director of the **AGENCY NAME** will determine the number of fire and smoke detection alarms required to ensure the security and integrity of the Sample Control stored in the Sample Control Section offices and storage facilities.

AGENCY NAME security staff will monitor the fire and smoke detection alarms on twenty-four (24) hours a day, seven (7) days a week basis, when required.

AGENCY NAME security staff will test and document the functionality of the fire and smoke detection alarms the first week of every month, if required.

The Director of the **AGENCY NAME** will determine the number of duress alarms required to ensure the safety of Sample Control Section personnel as well as the security and integrity of the Sample Control stored in the Sample Control Section offices and storage facilities.

AGENCY NAME security staff will monitor the duress alarms on twenty-four (24) hours a day, seven (7) days a week basis, when required.

AGENCY NAME security staff will test and document the functionality of the duress alarms the first week of every month, if required.

2.3.5 Security Breach

Security personnel they will notify the Director of the **AGENCY NAME** and the Chief of the Sample Control Section upon the detection of a security breach of the Sample Control Section offices or storage facility.

The Director of the **AGENCY NAME** and the Chief of the Sample Control Section will confer to determine the nature of the security breach.

If criminal in nature:

- Law enforcement will be notified.
- A criminal investigation will ensue.
- The Sample Control Section offices and storage facilities involved will be treated as a crime scene.
- A complete inventory of all Sample Control stored in the area of the security breach will be conducted.

If non-criminal in nature:

- The Chief of the Sample Control Section will:
  - Identify the cause of the security breach.
  - Implement changes necessary to ensure the security breach does not reoccur.
  - Authorize an inventory of all Sample Control stored in the area of the security breach, if necessary.

Security personnel will document all detected security breaches in the security log and on a Detection of Breach of Security Form, which will be forwarded to the Chief of the Sample Control Section with a copy sent to the Director of the **AGENCY NAME**.

3 Staffing Scheduling and Responsibilities

3.1 Staffing

3.1.1 Staffing Levels

The Sample Control Section will be staff with one (1) Section Chief and sufficient personnel to ensure a safe efficient operation.

The number of authorized personnel will be established by the Director of the **AGENCY NAME** and documented in the **AGENCY NAME** official organizational chart.

3.1.2 Minimum Qualifications and Selection

The minimum qualifications for employees of the Sample Control Section are established in the **AGENCY NAME's** personnel selection requirements.

Sample Control Section personnel statement of qualifications will be maintained in accordance with the **AGENCY NAME** administrative policies.

Sample Control Section personnel are selected using the guidelines found in the **AGENCY NAME** administrative policies.

3.2 Scheduling

The Chief of the Sample Control Section is responsible for scheduling staff members to operate the Sample Control Section.

The Sample Control Section office and storage facility will be staffed with a minimum of two (2) employees at all times.

The Sample Control Section will be open to receive and return Sample Control during the **AGENCY NAME's** normal business hours.

The Sample Control Section will be staffed one (1) hour prior to and one (1) hour after the **AGENCY NAME's** normal business hours.

3.3 Responsibilities

The responsibilities of Sample Control Section personnel (Property Custodians) include, but are not limited to:

- Preserve all incoming property from contamination, theft, or loss.
  - Property Custodians will not accept property or evidence that does not meet the packaging guidelines listed in the Sample Control Manual.
  - When necessary, Property Custodians will provide the appropriate packaging material and assist in items repackaging.
- Maintain and update property documentation with tracking information, commonly referred to as the "chain of custody."
  - Property Custodians will not accept property or evidence that is not accompanied with a completed Evidence Submission Form (ESF).
  - When necessary, Property Custodians will provide the appropriate ESF and assist in its completion.

- Ensure that all releases and dispositions of evidentiary and non-evidentiary items are legal and properly documented.
  - Property Custodians will not release evidentiary or non-evidentiary items with out documentation authorizing its release.
- Arrange and document interim releases and returns of evidentiary and non-evidentiary items for court, crime lab analysis, or investigative use.
- Maintain manual and computerized databases as required.
- Prepare and forward property-related forms to the appropriate entities.
- Serve as liaison between the **AGENCY NAME** and the agencies or entities that utilize the Sample Control Section.
- Maintain current knowledge of laws related to Sample Control management.
- Provide for maintenance of the storage facility.
- Inventory evidentiary and non-evidentiary items based on the Sample Control Manual.
- Ensure that all efforts are taken to make the Sample Control Section's storage facility as safe as possible for employees as well as property.

4 Packaging and Handling

4.1 General Circumstances

All Sample Control submitted to or handled by employees of the **AGENCY NAME** will be packaged and sealed in such a manner as to ensure the evidentiary quality of the individual and collective items.

General Sample Control packaging guidelines include:

- Individual exhibits will be packaged in separately prior to submission to the Sample Control Section.
- The physical properties of the individual exhibit will determine the type of packaging used.
- The packaging of individual exhibits will be properly sealed prior to placing into the container that is submitted or returned to the Sample Control Section.
- Multiple individual exhibits from a single submission may be sealed into one or more authorized containers prior to submission to the Sample Control Section under a single record number.
- The Sample Control Section will not accept containers that have exhibits from more than one case.
- The Sample Control Section will not accept containers that are not properly sealed.

4.1.1 Individual Items

The item's size and physical characteristics will determine the type of packaging material used.

Acceptable packaging materials for individual items include, but are not limited to:

- Paper envelopes
- Paper bags
- Plastic bags
- Cardboard boxes
- Glass jars and bottles

- Plastic jars and bottles
- Pasteboard pill boxes
- Metal specimen containers
- Metal paint cans

All containers should be unused.

Used containers may be used if the container has been thoroughly cleaned, dried and decontaminated prior to use.

The following is a guide for the packaging of generic types of evidence.

Small evidence:

- Paper bags and envelopes leak at the corners and seams and as such, are not suitable for small pieces of evidence (e.g., hairs, fibers, charred materials such as ashtray contents, blood scrapings, powders, glass, soil, paint chips).
- Plastic bags or paper folded using druggist folds that are subsequently placed into an envelope is suitable packaging for these types of submissions.
- Large evidence submitted in a brown paper bag may shed miscellaneous smaller debris, soil, hair, etc.
    - Tape the seams to prevent.
- Pasteboard pill boxes and metal specimen containers may also be used.

Large evidence:

- Paper bags or wrapping can be used for large items, garments and other non-sharp or non-fragile evidence.
- It is preferable to isolate and protect the area to be examined, rather than wrap an entire object (e.g., tape white paper over an area of suspected latent prints with tamper evident tape).
- Card board boxes are acceptable, if the item is secured inside the container.

Fragile evidence:

- Evidence that is delicate and subject to breakage should be placed into rigid containers.

Sharp evidence:

- Knives and hypodermic needles/syringes must be placed into a rigid plastic “sharps” tube.
- Larger sharp items must be placed into a puncture-proof container.
- Broken glass or sharp metal objects should be wrapped in paper then place them into a cardboard box.

Liquid body fluid samples:

- Liquid blood and urine should be collected in sealed rigid leak proof containers.
- The sealed container should be placed into a leak proof that will hold any liquid should the primary container break.

4.1.2 Case Submissions

All individual exhibits will be packaged and sealed into an approved container prior to submission to the Sample Control Section.

- The standardized container size is used maximize the Sample Control Section's storage area.

Sample Control Section will not accept case submissions that are not packaged and sealed in an approved container.

Approved containers include:

- Envelopes with the following dimensions:
  - 28# Brown Kraft or
  - 9″ (22.8 cm) # 12″ (30.5 cm)
- Corrugated Boxes with one of the following dimensions:
  - 16″ (40.65 cm) (l) × 12″ (30.5 cm) (w) × 4″ (10 cm) (h)
  - 16″ (40.65 cm) (l) × 12″ (30.5 cm) (w) × 6″ (15.25 cm) (h)
  - 16″ (40.65 cm) (l) × 12″ (30.5 cm) (w) × 12″ (30.5 cm) (h)
  - Larger sizes as required

4.1.3 Package Labeling

Every container submitted to the Sample Control Section will be labeled with the following information:

- The Agency Name
- The agency reference number
- The exhibit number or numbers
- The initials of the person collecting the evidence or sealing the container
- The container number and number of containers associated with the submission
  - Example 1 of 2

The Property Custodian will label each container received by the Sample Control Section with the **AGENCY NAME** Record Number (RN), if it has not been labeled prior to acceptance.

The Property Custodian will write the RN on every surface of the package prior to storage in the Sample Control Section's storage facility.

Biohazard evidence should be marked with the international BIOHAZARD symbol when it is suspected or known that the material comes from any of the following:

- Liquid or dried blood
- Other body fluids (semen, saliva, urine, vaginal fluid, fecal material, and hypodermic needles in contact with body fluids)
- Body packed contraband (note on evidence exam form if the evidence was recovered from a body cavity)

Fragile evidence that is delicate, such as light bulbs and windows, require FRAGILE warnings on the outermost packaging.

Sharp evidence such as broken glass and bent metal; require SHARP warnings on the outer most packaging.

Evidence that has been chemically processed prior to submission requires CHEMICALLY TREATED warnings on the outermost packaging.

4.1.4 Package Seals

Every package opening or potential opening will be properly sealed prior submission and acceptance by the Sample Control Section.

- A proper seal is one where the evidence cannot escape, be contaminated or altered without apparent damage to the seal or packaging.

Examples of a proper seal are:

- Tamper evident tape.
- Heat seals.
- Other tamper evident seals should be used, and the responsible individual must initial/sign the seal.
- Cellophane tape, regular plastic tape, etc. are acceptable sealing materials if:
  - The individual sealing the package will write his initials and the date the seal was applied on the seal.
  - The writing will be administered in such a manner as to cover both the container and the sealing material.
  - The use of an official seal may be used in addition to the examiner's initials.
- Manufacturer seals, such as the bottom flap of envelopes, must be initialed or taped and initialed, to show that the seal integrity was checked.
- The evidence must be accessible by opening in the packaging, while still maintaining any seals that are already in place.
  - Outer packaging material should NEVER be folded numerous times around the evidence before sealing.
- Stapled packages are NEVER considered sealed.

4.1.5 Package Documentation

All evidentiary and non-evidentiary items that are taken into custody and retained by the Sample Control Section must be documented using an approved form.

Each submission will be assigned a unique record number in accordance with the **AGENCY NAME** evidence submission policy.

A copy of form ESF or NSM shall be furnished as a receipt to any person, regardless of status, anytime property is taken from that person irrespective of the classification of that property.

The original copy of form ESF or NSM will be retained and filed by the Sample Control Section in accordance with the **AGENCY NAME** document retention policy.

A property custodian shall enter the information concerning each submission into the Sample Control Section database within twenty-four (24) hours of receipt.

4.2 Special Circumstances

4.2.1 Currency

The Sample Control Section will provide enhanced levels of security and documentation regarding the handling and ultimate disposition of currency submissions.

All currency will be sealed in a separate approved packaging container upon completion of the itemization.

All currency submissions in excess of $100.00 logged into the Sample Control Section will be itemized by denomination and quantity using the SCM Currency Inventory Form (CIF).

All currency submissions greater than $100.00 in total value shall be stored in the valuables vault located in the Sample Control Section's storage area.

Currency submissions less than $100.00 may be stored in properly sealed containers with the balance of the exhibits submitted by the agency.

Counterfeit currency will be treats in the same manner as genuine currency.

4.2.2 Firearms

The Sample Control Section will provide enhanced levels of security and documentation regarding their handling and ultimate disposition of firearms submissions.

All firearms submissions will be documented using a firearms submission form.

All firearms should be unloaded prior to packaging and submission to the Sample Control section.

Firearms should be packaged in a manner that permits efficient storage.

Individual handguns should be packaged in boxes in such a way as to keep the firearm secured from moving within the box when transported.

Individual long guns/rifles should be placed in long gun boxes in such a way as to keep the firearm secured from moving within the box when transported, or wrapped and sealed in paper.

4.2.3 Contraband Drugs

The Sample Control Section will only accept representative core samples taken from large seizures of contraband drugs.

The Director of the **AGENCY NAME** may authorize deviations from this policy as required.

The packaging of contraband drugs will be accomplished in accordance with Sample Control Manual.

4.2.4 Biological Evidence

The Sample Control Section will only accept biological evidence that has been properly packaged and sealed.

- Biological evidence refers to bodily fluids in dried or liquid form that possess evidentiary value. These fluids include blood semen, saliva, urine, vaginal fluid, and fecal material.

All biological evidence stains will be air dried prior to packaging.

All air dried biological stains will be packaged in a paper or cardboard container.

Liquid biological fluids will be collected, packaged and sealed in rigid leak proof containers. The sealed container should then be placed into a separate container that will hold any liquid should the primary container break.

Biological evidence should be marked with the international BIOHAZARD symbol.

4.2.5 Hazardous Material

The Sample Control Section will only accept representative samples, taken from bulk quantities of hazardous materials.

- Representative samples of bulk quantities of hazardous material will not exceed 60 ml (2 fl. oz.).

The Sample Control Section will NOT accept compressed gas containers.

The Director of the **AGENCY NAME** may authorize deviations from this policy as required.

Hazardous material samples will be collected, packaged and sealed into a leak proof primary container designed to hold the type of hazardous material to be packaged. The primary container will be packaged and sealed into a ridged secondary container.

Multiple hazardous material samples may be segregated and packed together according to their chemical properties, reactivity and incompatibility.

Sample Control Section personnel should consult with personnel from the laboratory forensic chemistry section to resolve issues of chemical reactivity and compatibility.

Hazardous material samples should be marked with the international symbol denoting the classification of the sample. Classifications include:

- Class 1: Explosive
- Class 2: Gases; Flammable and Nonflammable
- Class 3: Flammable: Liquid
- Class 4: Flammable: Solid
- Class 5: Oxidizer or Organic Peroxide
- Class 6: Toxic materials and infectious substances
- Class 7: Radioactive materials
- Class 8: Corrosive materials
- Class 9: Miscellaneous dangerous goods

4.2.6 Non-Evidentiary Items

The short or long term storage of non-evidentiary items is not the function of the Sample Control Section.

The **AGENCY NAME** Director may authorize deviations from this policy as required.

4.2.6.1 Found Property The Sample Control Section will not accept found items for short or long term storage.

- Found property is any item of no evidentiary value whose rightful owner may, or may not, be known to the finder.

The Director of the **AGENCY NAME** may authorize deviations from this policy as required.

Property Custodians will refer individuals who desire to submit found property to the authorities to local the law enforcement agency.

The packaging requirements of found items will be the same as those of evidentiary items with the same physical characteristics, if short term storage were authorized.

The submission of found items should be documented through the use of a Non-Evidence Submission Form (NSF).

The Chief of the Sample Control Section will designate an area for the storage of found items, if acceptance is authorized.

Unclaimed found items will be purged from the Sample Control Section system thirty (30) days after their submission.

4.2.6.2 Safe Keeping The Sample Control Section will not accept items from non law enforcement entities or individuals for the purpose of safe keeping.

- Safe keeping items are non-evidentiary items surrendered for temporary custody with the understanding that the person surrendering the item has the legal right to do so, and that the item will be returned to the rightful owner(s) unless disposition by the **AGENCY NAME**, is requested by the owner(s).

The Sample Control Section may accept non-evidentiary items from law enforcement entities for the purpose of safe keeping if the items are acquired as a result of a law enforcement action and the storage of the items in question is for a term not to exceed thirty (30) days.

The packaging requirements of safe keeping items will be the same as those of evidentiary items with the same physical characteristics.

The submission of safe keeping items should be documented through the use of a Non Evidence Submission Form (NES).

The Chief of the Sample Control Section will designate an area for the storage of safe keeping items.

Safe keeping items will be returned to their legal owner or submitting law enforcement authority within thirty (30) days of submission.

The Director of the **AGENCY NAME** may authorize deviations from this policy as required.

5 Storage

The Sample Control Section will provide will provide storage for evidentiary and non-evidentiary items submitted to the **AGENCY NAME** for examination.

5.1 Temporary Storage

The Sample Control Section will NOT provide temporary storage of evidentiary or non-evidentiary items.

- Temporary Storage refers to the gap between the time the employee who seized the evidence leaves it at the station, and the time that it is actually received by a property room employee. During this time, which could vary from a few hours to a few days, the property has left the hands of one person, but has not yet been received by another.

This gap in the chain of custody is unacceptable.

5.2 Short Term

The Sample Control Section will provide short term storage for items submitted to the **AGENCY NAME** for examination.

- Short term storage includes the time prior to examination and up to thirty (30) days after the completion of the final requested examination.
- The laboratory examiner in custody of the evidentiary and non-evidentiary items is responsible for the secure storage of the items in their custody during the examination process.

5.3 Long Term Storage

The Sample Control Section will not provide long term storage for evidentiary and non-evidentiary items.

- Long term storage is considered storage of an item beyond the thirty first day after the last examination has been completed.

The Chief of the Sample Control Section may grant long term storage privileges on a case by case basis.

5.4 Storage Areas

The shelving within the Sample Control section will be designed in such a manner as to facilitate the efficient storage of Sample Control submitted to the Sample Control Section.

Total Height:	190 cm (72 inches)
Depth:	46 cm (18 inches)
Between Shelves:	35 cm (14 inches)

An area for packages will be established for packages that are to large for standard shelf dimensions.

Shelving will be arranged in a manner that will not allow items to be stacked one upon another or one behind another.

The Sample Control Section storage facility will have a separate safe or vault to store submission of currency and other valuables.

The Sample Control Section storage facility will have a separate locked storage area to store submission of firearms.

The Sample Control Section storage facility will have a separate storage area for the short term storage of non-evidentiary property.

5.4.1 Currency

The Sample Control Section will store all currency submissions in excess of $100.00 in a separate vault dedicated to the secure storage of money and other valuable items.

The vault will have a combination lock, whose combination is only known by Sample Control Section personnel.

The combination on the vault will be changed as require to maintain the vault's security.

5.4.2 Firearms

The Sample Control Section storage facility will contain a separate locked area for the secure storage of firearms separate from locations where items of general evidence are located.

The firearm storage area will:

- Be constructed in a manner that would prevent unwarranted entry.

The door will:

- Be of sold construction with a locking mechanism that is secured with a dead bolt latch; or
- Be made of security screening that cannot be unbolted at the hinges or the locking panel.

The shelving will be designed for the efficient storage of both long guns and handguns.

The shelves will be adjustable to optimize the available space.

Wall racks or a hanging bag area will be available to store exceptional sized weapons.

Each storage location shall have a row and shelf number designation

Each shelf will be labeled with its unique row and shelf designation.

Each long gun storage location will be labeled with its unique designation.

The storage position of firearms that are in the possession of laboratory personnel will be marked in such a manner to prompt the property custodians to look for a firearm that has not been returned in a timely manner.

Non-evidentiary firearms may be stored in the firearms and toolmark section using similar storage requirements.

5.4.3 Contraband Drugs

Evidentiary submission containing small amounts of contraband drugs may be commingled with any other property types.

The Chief of the Sample Control Section may authorize the temporary short term storage of large seizures of contraband drugs.

The Chief of the Sample Control Section will identify and establish an area of heightened security for the short term storage of large seizures of contraband drugs.

5.4.4 Biological Evidence

Evidentiary submission containing properly dried and packaged biological stains may be commingled with any other property types using the storage guidelines.

The Chief of the Sample Control Section will establish two distinct refrigerated storage areas for samples of liquid blood and urine. One storage area will be reserved for sample waiting for examination. The other storage area will be reserved for samples that have been examined.

Analytical sections responsible for the analysis of liquid blood or urine will establish a refrigerated sample storage area to store samples during the examination process.

The temperature of all refrigerated units will be monitored continually and the temperature inside each unit will be documented 3 times daily.

5.4.5 Hazardous Materials

The Chief of the Sample Control Section will designate an area for the safe storage of hazardous materials samples.

The storage area will be ventilated to prevent the accumulation of explosive, flammable, corrosive or otherwise toxic fumes.

The storage area ventilation will be designed in such a manner as to not contaminate the building's Heating/Ventilating/Air Conditioning (HVAC) system.

The storage of hazardous materials in a secured ventilated area outside of the Sample Control section's regular storage facility is acceptable.

Hazardous material samples will NOT be stored in the laboratory's chemical storage facilities or otherwise commingled with the **AGENCY NAME's** materials and supplies.

5.5 Storage System

Each shelving unit shall have a unique designation.

Each shelf of a shelving unit will be labeled with its unique row and shelf designation.

Each submitting agency will be assigned a specific location in which all of their submissions will be stored.

Each assigned section will be labeled with the name of the agency whose submissions are store there.

Submission from agencies and individuals with fewer than 100 submissions per year will all be placed in a section labeled "Other Agencies".

All submissions will be sorted and stored in the following manner:

- Submissions will be sorted and stored by packaging type.
- Similar packaging types will be stored on the same shelves.
- Packages on a shelf will be arranged numerically by, laboratory record number, increasing in value from left to right.
- Packages will not be stacked on top of another.
- Packages will not be placed on a shelf one in front of another.
- Currency submissions in excess of $100.00 will be stored in the Sample Control Section vault.
- Jewelry and other property with a value in excess of $250.00 will be stored in the Sample Control Section vault.
- Firearms will be stored in a locked storage area within the Sample Control Section storage facility.

6 Evidence Control Procedures

All evidentiary and non-evidentiary items will only be received by the **AGENCY NAME** through the direct documented exchange of items between the Sample Control Section and the individual submitting the items.

Sample Control Section personnel will only accept items that are properly packaged, sealed and labeled.

Sample Control Section personnel will only accept items that are accompanied by a completed ESM or NSF.

6.1 Submission Procedures

6.1.1 Intake

The Sample Control Section will only accept evidentiary and non-evidentiary items during normal business hours.

- The Chief of the Sample Control Section may authorize a deviation from this policy.

The Sample Control Section will accept evidentiary and non-evidentiary items using the following sequence:

- The agency or individual will present the package containing the items to be submitted to the **AGENCY NAME** and the associated ESM or NSF to Property Custodian.
- Property Custodian will ensure the submission is packaged properly.
  - Property Custodian will assist in the proper packaging of items prior to submission as required.
  - Sample Control Section will provide proper packaging materials as required.
- Property Custodian will ensure the submission form is completed properly.
  - Property Custodian will assist in the preparation of the appropriate forms prior to submission as required.
- Property Custodian assign the submission a Record Number (RN).
  - The RN assigned to a submission will be the next number in the sequence.
- Property Custodian will write the submission's assigned RN in the designated place on the ESM or NSF.
- Property Custodian will write the RN on every surface of the package prior to storage in its designated location.
- The submitting individual will sign the "FROM" portion of the "Chain of Custody" on the ESM or NSF.
- Property Custodian will sign and date the "TO" portion of the "Chain of Custody" on the ESM or NSF.
- Property Custodian will provide the individual submitting a copy of the signed ESM or NSF as a receipt.
- Property Custodian will place the submitted item in the holding area of the evidence storage facility until it can be placed in the appropriate storage location.
- Property Custodian will document the submission's storage location on the ESM or NSF.
- Property Custodian will log the submission into the Sample Control Section property database.
- Property Custodian will send a copy of the ESM or NSF to the Deputy Director for case assignment and distribution.
- Property Custodian will file and maintain the original ESM or NSF in the Sample Control Sections files.

6.1.2 Return

The Sample Control Section will only return evidentiary and non-evidentiary items during normal business hours.

The Sample Control Section will return evidentiary and non-evidentiary items to the submitting agency using the following sequence:

- The Sample Control Section will be notified that all laboratory examinations have been completed.
- The Sample Control Section will notify the submitting agency, in writing using a Notice of Examination Completion (NEC) form, that laboratory examination have been completed and the submitted items should be retrieved within thirty (30) days.
  - A copy of the form will be attached to the originals ESM or NSF.
- A representative of the submitting agency will present the NEC form to the Sample Control Section.
- Property Custodian will retrieve the original ESM or NSF from the Sample Control Section's files.
- Property Custodian will retrieve the items from its storage location.
- Property Custodian will sign and date the "FROM" portion of the "Chain of Custody" on the ESM or NSF.
- The submitting individual will sign the "TO" portion of the "Chain of Custody" on the ESM or NSF.
- Property Custodian will provide the retrieving individual a copy of the signed ESM or NSF as a receipt.
- Property Custodian will log the submission into the Sample Control Section property database within 24 hours of return.
- Property Custodian will file and maintain the original ESM or NSF in the Sample Control Sections files.

6.2 Laboratory Distribution Procedures

6.2.1 Distribution

The Sample Control Section will only distribute evidentiary and non-evidentiary items to laboratory examiners during normal business hours.

The Sample Control Section will distribute evidentiary and non-evidentiary items to laboratory examiners using the following sequence:

- The examiner will present the Sample Control Section a copy of the ESM or NSF associated with the item(s) he is desires.
- Property Custodian will retrieve the original submission form from the Sample Control Section's files.
- Property Custodian will retrieve the items from its storage location.
- Property Custodian will sign and date the "FROM" portion of the "Chain of Custody" on the both copies of the submission form.
- The examiner will sign the "TO" portion of the "Chain of Custody" on both copies of the ESM or NSF.
- Property Custodian will log the information into the Sample Control Section property database within 24 hours of laboratory distribution.
- Property Custodian will file and maintain the original s ESM or NSF in the Sample Control Sections files.

6.2.2 Return

The Sample Control Section will only receive evidentiary and non-evidentiary items from laboratory examiners during normal business hours.

The Sample Control Section will receive evidentiary and non-evidentiary items after laboratory examination using the following sequence:

- The examiner will present the package containing the examined items and the associated ESM or NSF to the Property Custodian.
- Property Custodian will ensure the submission is packaged properly.
  - Items will not be accepted if they are not properly packaged, sealed and labeled.
- Property Custodian will retrieve the original ESM or NSF from the Sample Control Section's files.
- The examiner will sign both copies of the "FROM" portion of the "Chain of Custody" section on the ESM or NSF.
- Property Custodian will sign and date both copies of the "TO" portion of the "Chain of Custody" section on the ESM or NSF.
- Property Custodian will place the submitted item in the holding area of the evidence storage facility until it can be placed in the appropriate storage location.
- Property Custodian will return the package to the storage location on the ESM or NSF.
- Property Custodian will update the information in the Sample Control Section property database within 24 hours of the transaction.
- Property Custodian will send a Notice of Examination Completion Form to the submitting agency within five (5) days of completion of the final examination.
  - A copy of the Notice of Examination Completion Form will be attached to and filed with the original ESM or NSF.

6.3 Intra Laboratory Exchange Procedures

The control and custody of evidentiary and non-evidentiary items between examiners for the purpose of authorized laboratory examination is permissible.

Every exchange of control and evidentiary and non-evidentiary items between laboratory examiners will be documented on the "Chain of Custody" section of examiner's copy of the ESM or NSF.

The documentation of the exchange between laboratory examiners will be accomplished using the following sequence:

- The examiner will properly package, label and seal the item(s) prior to any exchange of control.
- The receiving examiner will ensure the items to be exchanged are properly packaged, labeled and sealed.
- Original examiner will sign and date the "FROM" portion of the "Chain of Custody" on the ESM or NSF.
- The receiving examiner will sign the "TO" portion of the "Chain of Custody" on the ESM or NSF.
- A copy of the signed form will be made.
  - The original examiner will retain the copy.
  - The receiving examiner will retain the copy with the original signatures.

- The receiving examiner will return the items to the Sample Control Section at the completion of his examination(s).
- This exchange process will be repeated if additional examinations by another examiner are required.

6.4 Database Information

The Sample Control Section will maintain a database of information concerning the status of items submitted to the **AGENCY NAME** for examination.

The information in the database will be updated daily.

Each submission to the Sample Control Section will have a unique database record for each submission, which will contain the following information:

- **AGENCY NAME** Record Number
- Name of the submitting agency
- Submitting agency's file number
- Date submitted by the agency
- Date returned to the agency
- Storage location within the Sample Control Section's storage location
- Date transferred to the laboratory
- Examiner item was transferred to
- Date returned to the Sample Control Section
- Examination Complete (YES or NO)
- Date the Notice of Examination Completion form was sent
- Requires Destruction (YES or NO)
- Evidence Destroyed (YES or NO)

7 Disposition and Purging

7.1 Purging

The Sample Control Section will store evidentiary and non-evidentiary items no longer than necessary.

Evidentiary and non-evidentiary items will be returned to the submitting agency and purged from the system within thirty (30) days of notice of examination completion has been sent.

Evidentiary and non-evidentiary items are purged from the Sample Control Section system when:

- A documented transfer of an evidentiary or non-evidentiary item(s) to the originating agency has been performed.
- A documented transfer of an evidentiary or non-evidentiary item(s) to a laboratory section for use as an exemplar has been performed.
- A documented destruction of the evidentiary and non-evidentiary items has been performed.
- A documented return of an non-evidentiary item to the owner of record.

All documents related to the submission, transfer and disposal of evidentiary and non-evidentiary items submitted the Sample Control Section will be filed and maintained in accordance with the **AGENCY NAME** document retention policy.

Evidentiary and non-evidentiary item purging process:

- The laboratory section notifies the Sample Control Section that all requested examinations have been completed.
- Property custodian enters the notice of the completion of examinations of evidentiary and non-evidentiary items into the Sample Control Section database as they become available.
- The Property Custodian attaches the laboratory's notice of completion to the original ESF.
- Property custodian will review the Sample Control Section database and identify which evidentiary and non-evidentiary items require collection on the last Monday of the month.
- Notice of Examination Completion (NEC) forms are sent to agencies with evidentiary and non-evidentiary items that require collection on the last Monday of the month.
- Property Custodian will review the Sample Control Section database and identify the evidentiary and non-evidentiary items that have not been retrieved within the thirty (30) day time frame, on the last Monday of the month.
- Evidentiary and non-evidentiary items that have not been retrieved by the agency of origin within thirty (30) days of transmission of the NEC form are subject to purging and disposal.
- Property Custodian will notify the submitting agency of the pending disposal of the evidentiary or non-evidentiary items that have not been retrieved.
    - The Property Custodian will make a notation of this contact on the file copy of the NEC form attached to the original ESF.
- Sample Control Section will schedule the disposal of all evidentiary and non-evidentiary items that meet the disposal criteria.

7.2 Destruction

All evidentiary and non-evidentiary items in the Sample Control Section that meet the destruction criteria will be destroyed on the schedule outlined in this section.

Destruction criteria:

- Evidentiary and non-evidentiary items of criminal cases in which the adjudication has been completed.
- Evidentiary and non-evidentiary items of criminal cases in which the examination has been completed and the submitting agency has not retrieved the items within the designated time frame.
- Evidentiary or non-evidentiary items that the **AGENCY NAME** laboratory does not request the to be placed into their reference collection.
- Non-evidentiary items which the owner of record cannot be located or has not retrieved the item within thirty (30) days of notification of pending destruction.

An independent witness will verify the destruction of all evidentiary and non-evidentiary items.

The destruction of all evidentiary and non-evidentiary items will be documented on a Property Destruction/Diversion Record Form (PDDR). This form will be attached to and filed with the original ESF or NSF.

A sufficient number of armed officers will be present to security during the destruction of contraband drugs. The number of armed officers will be determined by the volume of contraband drugs to be destroyed and the location of the destruction site.

Destruction methods of evidentiary and non-evidentiary items include:

- Incineration or smelting.
- Shredding.
- Saw cutting, torching, crushing or other method which would render the item useless.
  - The removal of usable parts from firearms may be permissible if authorized by the Director of the **AGENCY NAME**.
- Disposal into a sanitary landfill if the items do not possess an environmental hazard.
- Auction.
- Other means authorized by the Director of the **AGENCY NAME**.
- Disposal of in the ocean, lake or other body of water is acceptable.

Destruction procedure:

- A Property Custodian will prepare a Property Destruction/Diversion Record form (PDDR).
- A Property Custodian submits a completed PDDR form to the Director of the **AGENCY NAME** for approval.
- The Director of the **AGENCY NAME** approves the destruction by signing in the designated location on the PDDR form and returns the form to the Sample Control Section for action.
- A Property Custodian retrieves the original ESF or NSF from the file.
- A Property Custodian retrieves the property from the assigned storage location.
- In the presence of one or more individuals the Property Custodian destroys the items utilizing one or more authorized methods.
- Each Property Custodian and witness will sign and date PDDR form,
  - An independent witness will verify the serial numbers and destruction of all firearms.
- A Property Custodian will file the original ESF or NSF and its associated PDDR form using guidelines established in the **AGENCY NAME** document retention policy.
- A Property Custodian will document the destruction of the property in the Sample Control database.

The destruction schedule will be:

- First Wednesday of the month: **Firearms**
- Second Wednesday of the month: **Contraband Drugs**
- Third Wednesday of the month: **Biological Evidence**
- Fourth Wednesday of the month: **Hazardous Materials and general disposal**

7.3 Diversion

The Director of the **AGENCY NAME** may authorize the diversion of evidentiary and non-evidentiary items scheduled for destruction, for official use.

Diversion Process

- An official letter will be submitted to the Director of the **AGENCY NAME** requesting the diversion of evidentiary and non-evidentiary items.
  - The letter will contain a description of the evidentiary or non-evidentiary items.
  - The purpose the diversion.
- The Director of the **AGENCY NAME** will write or stamp the word "Approved" or "Denied" with his signature on the request for diversion letter.
- The letter will be submitted to the Sample Control Section for disposition.
- The letter will be attached to and filed with the original ESF or NSF.
- The diversion of all evidentiary and non-evidentiary items will be documented on a PDDR form. This form will be attached to and filed with the original ESF or NSF.

End of Document

Appendix J

TECHNICAL METHODS MANUAL

Outline

- Training Manual
  - Background
  - Training program mechanics
  - Individual training modules
    - Objectives
    - Required Reading
    - Suggested Reading
    - Study and Discussion Exercises
    - Practical Exercises
  - Written quiz
  - Written final exam
  - Practical final
  - Moot court
  - Supervised casework
  - Unsupervised casework
- Analytical Procedures Manual
  - Sampling Scheme
  - Reagent Preparation
  - Examination Protocol
    - Descriptive information
    - Document identification information
    - Purpose statement
    - Scope statement
    - Related procedure list
    - Safety considerations
    - Instrumentation
    - Standards and controls
    - Analytical procedure
    - Report writing
    - References
    - Approval

- Quality Assurance Manual
- Documentation Requirements
  - Forms and Worksheets
  - Examination Notes
  - Examination Reports
- Inventories
  - Chemical inventories
    - Bulk chemicals
    - Bulk prepared reagent solutions
  - Equipment inventories
    - Analytical instruments
    - Spare parts
    - Maintenance and calibration logs
  - Reference inventories
    - Reference standards
    - Reference material
    - Reference literature to include books and technical journals
    - Calibration standards

CATEGORY

Descriptive Title

1 PURPOSE

A statement concerning why this policy exists.

2 SCOPE

A statement concerning who and what is affected by the policy.

3 RELATED PROCEDURES

A list of the policies, procedures or analytical methods that are related to this procedure or analytical method:

- XXX P00a
- YYY M00a

4 SAFETY CONSIDERATIONS

Statements concerning the hazards involved with the procedure and the precautions taken to abate them.

5 INSTRUMENTATION

A list of the instrumentation required.

6 STANDARDS AND CONTROLS

A list of the reference standards and procedural controls required for a successful analysis.

7 PROCEDURE OR ANALYSIS

Statements that describe the sequence of events required to properly conduct the analysis.

8 REPORT WORDING

Suggest or approved verbiage used to describe analytic results in reports issued by the laboratory.

9 REFERNCES

List of literature citations used to validate the procedure.

10 APPROVAL

The signatures of the approving authority defined in the document approval policy.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

CATEGORY

Descriptive Title

1 PURPOSE

A statement concerning why this policy exists.

2 OBJECTIVES

List the learning objectives of the training module.

- At the completion of this training module the student will be able to:
  - …
  - …

3 REQUIRED READING

List the titles of the treaties that the student must read as part of the training module.

- The text of the treaties may or may not be included as part of the manual.

4 SUGGESTED READING

List the titles of the treaties that would be beneficial for the student to read as part of the training module.

- The text of the treaties may or may not be included as part of the manual.

5 STUDY AND DISCUSSION EXERCISES

Include a detailed outline of the discussion exercises that are part of the training module.

6 PRACTICAL EXERCISES

Include a detailed outline of the practical exercises that are part of the training module.

7 APPROVAL

The signatures of the approving authority defined in the document approval policy.

John Smith, Laboratory Director	Date
Mary Doe, Quality Assurance Manager	Date

End of Document

Appendix K

ISO 17025:2005 Criteria File
(Rev. 01/01/2005)

Underlined Text = hyperlink directly to file or book-marked area of file

No.	Requirement	Policy # Hyperlinks
4.0	**MANAGEMENT REQUIREMENTS**	
4.1	**Organization**	
4.1.1	The laboratory or the organization of which it is part shall be an entity that can be held legally responsible.	APP-P102: Legal Authority
4.1.2	It is the responsibility of the laboratory to carry out its testing and calibration activities in such a way as to meet the requirements of this International Standard and to satisfy the needs of the customer, the regulatory authorities or organizations providing recognition.	QAM-P106: Accreditation QAM-P107: Commitment to Quality
4.1.3	The laboratory management system shall cover work carried out in the laboratory's permanent facilities, at sites away from its permanent facilities, or in associated temporary or mobile facilities.	APP-P110: Organizational Structure APP-P112: Delegation of Authority APP-P113: Supervision
4.1.4	If the laboratory is part of an organization performing activities other than testing and/or calibration, the responsibilities of key personnel in the organization that have an involvement or influence on the testing and/or calibration activities of the laboratory shall be defined in order to identify potential conflicts of interest.	APP-P110: Organizational Structure APP-P112: Delegation of Authority APP-P113: Supervision

No.	Requirement	Policy # Hyperlinks
	Note 1: Where a laboratory is part of a larger organization, the organizational arrangements should be such that departments having conflicting interests, such as production, commercial marketing or financing do not adversely influence the laboratory's compliance with the requirements of this International Standard. ***Note 2:*** If the laboratory wishes to be recognized as a third-party laboratory, it should be able to demonstrate that it is impartial and that it and its personnel are free from any undue commercial, financial and other pressures which might influence their technical judgment. The third-party testing or calibration laboratory should not engage in any activities that may endanger the trust in its independence of judgment and integrity in relation to its testing or calibration activities.	
4.1.5	The laboratory shall:	
a)	Have managerial and technical personnel with the authority and resources needed to carry out their duties and to identify the occurrence of departures from the quality system or from the procedures for performing tests and/or calibrations, and to initiate actions to prevent or minimize such departures (see also 5.2).	APP-P106: Budget APP-P112: Delegation of Authority APP-P113: Supervision QAM-P105: Quality Manager QAM-P512: Technical Leaders QAM-P513: Peer Groups
b)	Have arrangements to ensure that its management and personnel are free from any undue internal and external commercial, financial and other pressures and influences that may adversely affect the quality of their work.	APP-P318: Outside Work Permits QAM-P514: Conflict of Interest

No.	Requirement	Policy # Hyperlinks
c)	Have policies and procedures to ensure the protection of its customers' confidential information and proprietary rights, including procedures for protecting the electronic storage and transmission of results.	APP-P508: Report Dissemination APP-P510: Freedom of Information Act APP-P513: File Removal APP-P514: Electronic File Security QAM-P312: Notes Dissemination QAM-P317: Examination Report Storage
d)	Have policies and procedures to avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgment or operational integrity.	APP-P304: Code of Conduct APP-P318: Outside Work Permits QAM-P514: Conflict of Interest
e)	Define the organization and management structure of the laboratory, its place in any parent organization, and the relationships between quality management, technical operations and support services.	APP-P102: Legal Authority APP-P110: Organizational Structure QAM-P104: Quality Program Definition QAM-P105: Quality Manager
f)	Specify the responsibility, authority and interrelationships of all personnel who manage, perform and verify work affecting the quality of the tests and/or calibrations.	APP-P110: Organizational Structure APP-P113: Supervision APP-P301: Position Description APP-PDxx: All Position Descriptions QAM-P105: Quality Manager QAM-P302: Operational Document Development QAM-P305: Technical Document Development QAM-P314: Examination Report Review
g)	Provide adequate supervision of testing and calibration staff, including trainees, by persons familiar with methods and procedures, purpose of each test and/or calibration, and with the assessment of the test or calibration results.	APP-P113: Supervision QAM-P314: Examination Report Review

No.	Requirement	Policy # Hyperlinks
h)	Have technical management which has overall responsibility for the technical operations and the provision of the resources needed to ensure the required quality of laboratory operations.	QAM-P503: Proficiency Test Review QAM-P505: Testimony Review QAM-P512: Technical Leaders QAM-P513: Peer Groups
i)	Appoint a member of staff as quality manager (however named) who, irrespective of other duties and responsibilities, shall have defined responsibility and authority for ensuring that the quality system is implemented and followed at all times; the quality manager shall have direct access to the highest level of management at which decisions are made on laboratory policy or resources.	QAM-P105: Quality Manager
j)	Appoint deputies for key managerial personnel.	APP-P110: Organizational Structure APP-P113: Supervision APP-P301: Position Description APP-PDxx: Management Position Descriptions
	Note: Individuals may have more than one function and it may be impractical to appoint deputies for every function.	
k)	Ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the objectives of the management system.	APP-P108: Policy and Procedure Understanding
4.1.6	Top management shall ensure that appropriate communication processes are established within the laboratory and that communication takes place regarding the effectiveness of the management system.	APP-P114: Communication

No.	Requirement	Policy # Hyperlinks
4.2	**Quality System**	
4.2.1	The laboratory shall establish, implement and maintain a quality system appropriate to the scope of its activities. The laboratory shall document its policies, systems, programs, procedures and instructions to the extent necessary to assure the quality of the test and/or calibration results. The system's documentation shall be communicated to, understood by, available to, and implemented by the appropriate personnel.	Administrative Policy and Procedure Manual: In total. APP-P107: Policy and Procedure Development and Distribution APP-P108: Policy and Procedure review and Understanding APP-P509: Manual Dissemination Quality Assurance Manual: In total QAM-P103: Quality Program Objectives QAM-P104: Quality Program Definition QAM-P301: Manuals QAM-P303: Operational Policy Dissemination QAM-P306: Technical Manual Dissemination
4.2.2	The laboratory's quality system policies and objectives shall be defined in a quality manual (however named). The overall objectives shall be documented in a quality policy statement. The quality policy statement shall be issued under the authority of the chief executive. It shall include at least the following:	APP-P115: Quality Assurance Program QAM-P103: Quality Program Objectives QAM-P106: Accreditation QAM-P107: Commitment to Quality
a)	the laboratory management's commitment to good professional practice and to the quality of its testing and calibration in servicing its customers	QAM-P102: Quality Program Mission Statement QAM-P103: Quality Program Objectives QAM-P106: Accreditation QAM-P107: Commitment to Quality
b)	the management's statement of the laboratory's standard of service	QAM-P102: Quality Program Mission Statement QAM-P107: Commitment to Quality
c)	the purpose of the management system related to quality	QAM-P102: Quality Program Mission Statement QAM-P103: Quality Program Objectives QAM-P107: Commitment to Quality

No.	Requirement	Policy # Hyperlinks
d)	a requirement that all personnel concerned with testing and calibration activities within the laboratory familiarize themselves with the quality documentation and implement the policies and procedures in their work	QAM-P107: Commitment to Quality
e)	the laboratory management's commitment to comply with this International Standard and to continually improve the effectiveness of the management system	QAM-P107: Commitment to Quality
	Note: The quality policy statement should be concise and may include the requirement that tests and/or calibrations shall always be carried out in accordance with stated methods and customers' requirements. When the test and/or calibration laboratory is pat of a larger organization, some quality policy elements may be in other documents.	
4.2.3	Top management shall provide evidence of commitment to the development and implementation of the management system and to continually improving its effectiveness.	QAM-P102: Quality Program Mission Statement QAM-P103: Quality Program Objectives QAM-P107: Commitment to Quality
4.2.4	Top management shall communicate to the organization the importance of meeting customer requirements as well as statutory and regulatory requirements.	APP-P114: Communication
4.2.5.	The quality manual shall include or make reference to the supporting procedures including technical procedures. It shall outline the structure of the documentation used in the quality system.	QAM-P301: Manuals
4.2.6.	The roles and responsibilities of technical management and the quality manager, including their responsibility for ensuring compliance with this International Standard, shall be defined in the quality manual.	QAM-P105: Quality Manager QAM-P512: Technical Leaders QAM-P517: Quality Roles of Personnel
4.2.7.	Top management shall ensure that the integrity of the management system is maintained when changes to the management system are planned and implemented.	QAM-P108: Change Management

No.	Requirement	Policy # Hyperlinks
4.3	**Document Control**	
4.3.1	General	
	The laboratory shall establish and maintain procedures to control all documents that form part of its quality system (internally generated or from external sources), such as regulations, standards, other normative documents, test and/or calibration methods, as well as drawings, software, specifications, instructions and manuals.	APP-P501: Document Retention APP-P502: Document Disposal APP-P503 Document Inventory APP-P504: Document Approval APP-P505: Document Format APP-P506: Document Numbering APP-P507: Document Filing APP-P508: Report Dissemination APP-P509: Manual Dissemination APP-P510: FIA Requests APP-P511: Document Retirement APP-P512: Document Review APP-P513: File Removal APP-P514: Electronic File Security QAM-P302: Operational Policy Development QAM-P303: Operational Policy Dissemination QAM-P304: Operational Policy Retirement QAM-P305: Technical Policy Development QAM-P306: Technical Policy Dissemination QAM-P307: Technical Policy Retirement QAM-P308: Controlled Document Review QAM-P309: Examination Documentation QAM-P310: Examination Notes QAM-P311: Examination Note Corrections QAM-P312: Examination Notes Dissemination

No.	Requirement	Policy # Hyperlinks
		QAM-P313: Examination Reports QAM-P314: Examination Report Review QAM-P315: Examination Report Corrections QAM-P316: Examination Report Dissemination QAM-P317: Examination Report Storage QAM-P318: Technical Procedure Acceptance
	Note 1: In this context "document" could be policy statements, procedures, specifications, calibration tables, charts, text books, posters, notices, memoranda, software, drawings, plans, etc. These may be on various media, whether hard copy or electronic, and they may be digital, analog, photographic or written. ***Note 2:*** The control of data related to testing and calibration is covered in 5.4.7. The control of records is covered in 4.13.	
4.3.2	Document Approval and Issue	APP-P504: Document Approval APP-P508: Report Dissemination APP-P509: Manual Dissemination APP-P510: FIA Requests APP-P511: Document Retirement APP-P512: Document Review QAM-P302: Operational Policy Development QAM-P303: Operational Policy Dissemination QAM-P304: Operational Policy Retirement QAM-P305: Technical Policy Development QAM-P306: Technical Policy Dissemination QAM-P308: Controlled Document Review QAM-P311: Examination Note Corrections QAM-P312: Examination Notes Dissemination

No.	Requirement	Policy # Hyperlinks
		QAM-P313: Examination Reports QAM-P314: Examination Report Review QAM-P315: Examination Report Corrections QAM-P316: Examination Report Dissemination QAM-P318: Technical Procedure Acceptance
4.3.2.1	All documents issued to personnel in the laboratory as part of the quality system shall be reviewed and approved for use by authorized personnel prior to issue. A master list or an equivalent document control procedure identifying the current revision status and distribution of documents in the quality system shall be established and be readily available to preclude the use of invalid and/or obsolete documents.	APP-P503 Document Inventory APP-P504: Document Approval APP-P509: Manual Dissemination APP-P512: Document Review QAM-P302: Operational Policy Development QAM-P305: Technical Policy Development QAM-P308: Controlled Document Review QAM-P318: Technical Procedure Acceptance
4.3.2.2	The procedure(s) adopted shall ensure that:	
a)	authorized editions of the appropriate documents are available at all locations where operations essential to the effective functioning of the laboratory are performed	APP-P504: Manual Dissemination QAM-P301: Manuals
b)	documents are periodically reviewed and, where necessary, revised to ensure continuing suitability and compliance with applicable requirements	APP-P511: Document Retirement APP-P512: Document Review QAM-P308: Controlled Document Review

No.	Requirement	Policy # Hyperlinks
c)	invalid or obsolete documents are promptly removed from all points of issue or use, or otherwise assured against unintended use	APP-P501: Document Retention APP-P503: Document Inventory APP-P511: Document Retirement QAM-P303: Operational Policy Dissemination QAM-P304: Operational Policy Retirement QAM-P306: Technical Procedure Dissemination QAM-P307: Technical Procedure Retirement QAM-P315: Examination Report Corrections
d)	obsolete documents retained for either legal or knowledge preservation purposes are suitably marked	APP-P503: Document Inventory APP-P511: Document Retirement QAM-P304: Operational Policy Retirement QAM-P307: Technical Procedure Retirement QAM-P315: Examination Report Corrections
4.3.2.3	Management system documents generated by the laboratory shall be uniquely identified. Such identification shall include the date of issue and/or revision identification, page numbering, the total number of pages or a mark to signify the end of the document, and the issuing authority(ies).	APP-P505: Document Formatting APP-P506: Document Numbering
4.3.3	Document Change	
4.3.3.1	Changes to documents shall be reviewed and approved by the same function that performed the original review unless specifically designated otherwise. The designated personnel shall have access to pertinent background information upon which to base their review and approval.	APP-P504: Document Approval QAM-P302: Operational Policy Development QAM-P305: Technical Policy Development
4.3.3.2	Where practicable, the altered or new test shall be identified in the document or the appropriate attachments.	QAM-P303: Operational Policy Dissemination QAM-P306: Technical Policy Dissemination

No.	Requirement	Policy # Hyperlinks
4.3.3.3	If the laboratory's documentation control system allows for the amendment of documents by hand pending the re-issue of the documents, the procedures and authorities for such amendments shall be defined. Amendments shall be clearly marked, initialed and dated. A revised document shall be formally re-issued as soon as practicable.	QAM-P303: Operational Policy Dissemination QAM-P306: Technical Policy Dissemination
4.3.3.4	Procedures shall be established to describe how changes in documents maintained in computerized systems are made and controlled.	APP-P506: Document Numbering APP-P514: Electronic File Security
4.4	**Removal of Requests, Tenders and Contracts**	
4.4.1	The laboratory shall establish and maintain procedures for the review of requests, lenders and contracts. The policies and procedures for these reviews leading to a contract for testing and/or calibration shall ensure that:	QAM-P901: Examination Method Selection QAM-P902: Examination Request
a)	the requirements, including the methods to be used, are adequately defined, documented and understood (see 5.4.2)	QAM-P901: Examination Method Selection QAM-P902: Examination Request
b)	the laboratory has the capability and resources to meet the requirements	QAM-P901: Examination Method Selection QAM-P902: Examination Request
c)	the appropriate test and/or calibration method is selected and capable of meeting the customer's requirements; (see 5.4.2)	QAM-P901: Examination Method Selection QAM-P902: Examination Request
	Any differences between the request or tender and the contract shall be resolved before any work commences. Each contract shall be acceptable both to the laboratory and the customer.	

No.	Requirement	Policy # Hyperlinks
	Note 1: The request, tender and contract review shall be conducted in a practical and efficient manner, and the effect of financial, legal and time schedule aspects should be taken into account For internal customers, reviews of requests, tenders and contracts can be performed in a simplified way. ***Note 2:*** The review of capability should establish that the laboratory possesses the necessary physical, personnel and information resources, and that the laboratory's personnel have the skills and expertise necessary for the performance of the tests and/or calibrations in question. The review may also encompass results of earlier participation in inter laboratory comparisons or proficiency testing and/or the running of trial test or calibration programs using certified reference materials in order to determine uncertainties of measurement, limits of detection, confidence limits, etc. ***Note 3:*** A contract may be any written or oral agreement to provide a customer with testing and/or calibration services.	
4.4.2	Records of reviews, including any significant changes, shall be maintained. Records shall also be maintained of pertinent discussions with a customer relating to the customer's requirements or the results of the work during the period of execution of the contract.	QAM-P902: Examination Requests
	Note: For review of routine and other simple tasks, the date and the identification (e.g., the initials) of the person in the laboratory responsible for carrying out the contracted work are considered adequate. For repetitive routine tasks, the review need be made only at the initial enquiry stage or on granting of the contract for on-going routine work performed under a general agreement with the customer, provided that the customer's requirements remain unchanged. For new, complex or advanced testing and/or calibration tasks, a more comprehensive record should be maintained.	

No.	Requirement	Policy # Hyperlinks
4.4.3	The review shall also cover any work that is subcontracted by the laboratory.	QAM-P902: Examination Requests
4.4.4	The customer shall be informed of any deviation from the contract.	QAM-P902: Examination Requests
4.4.5	If a contract needs to be amended after work has commenced, the same contract review process shall be repeated and any amendments shall be communicated to all affected personnel.	QAM-P902: Examination Requests
4.5	**Subcontracting of Tests and Calibrations**	
4.5.1	When a laboratory subcontracts work whether because of unforeseen reasons (e.g., workload, need for further expertise or temporary incapacity) or on a continuing basis (e.g., through permanent subcontracting, agency or franchising arrangements), this work shall be placed with a competent subcontractor. A competent subcontractor is one that, for example, complies with this International Standard for the work in question.	QAM-P903: Contract Examination Services
4.5.2	The laboratory shall advise the customer of the arrangement in writing and, when appropriate, gain the approval of the customer, preferably in writing.	QAM-P903: Contract Examination Services
4.5.3	The laboratory is responsible to the customer for the subcontractor's work, except in the case where the customer or a regulatory authority specifies which subcontractor is to be used.	QAM-P903: Contract Examination Services
4.5.4	The laboratory shall maintain a register of all subcontractors that it uses for tests and/or calibrations and a record of the evidence of compliance with this International Standard for the work in question.	QAM-P903: Contract Examination Services
4.6	**Purchasing Services and Supplies**	
4.6.1	The laboratory shall have a policy and procedure(s) for the selection and purchasing of services and supplies it uses that affect the quality of the tests and/or calibrations. Procedures shall exist for the purchase, reception and storage of reagents and laboratory consumable materials relevant for the tests and calibrations.	QAM-P411: Chemical Procurement QAM-P416: Equipment Procurement QAM-P418: Reference Standard and Material Procurement

No.	Requirement	Policy # Hyperlinks
4.6.2	The laboratory shall ensure that purchased supplies and reagents and consumable materials that affect the quality of tests and/or calibrations are not used until they have been inspected or otherwise verified as complying with standard specifications or requirements defined in the methods for the tests and/or calibrations concerned. These services and supplies used shall comply with specified requirements. Records of actions taken to check compliance shall be maintained.	QAM-P412: Chemical Receipt QAM-P414: Reference Standard and Material Validation QAM-P417: Equipment Receipt QAM-P419: Reference Standard and Material Receipt
4.6.3	Purchasing documents for items affecting the quality of laboratory output shall contain data describing the services and supplies ordered. These purchasing documents shall be reviewed and approved for technical content prior to release.	QAM-P411: Chemical Procurement QAM-P412: Chemical Receipt QAM-P416: Equipment Procurement QAM-P417: Equipment Receipt QAM-P418: Reference Standard and Material Procurement QAM-P419: Reference Standard and Material Receipt
	Note: The description may include type, class, grade, precise identification, specifications, drawings, inspection instructions, other technical data including approval of test results, the quality required and the quality system standard under which they were made.	
4.6.4	The laboratory shall evaluate suppliers of critical consumables, supplies and services which affect the quality of testing and calibration, and shall maintain records of these evaluations and list those approved.	QAM-P411: Chemical Procurement QAM-P416: Equipment Procurement QAM-P418: Reference Standard and Material Procurement

No.	Requirement	Policy # Hyperlinks
4.7	**Service to the Customer**	
4.7.1.	The laboratory shall afford customers or their representatives cooperation to clarify the customer's request and to monitor the laboratory's performance in relation to the work performed, provided that the laboratory ensures confidentiality to their customers.	QAM-P110: Customer Service
09	***Note 1:*** Such cooperation may include: • providing the customer of the customer's representative reasonable access to relevant areas of the laboratory for the witnessing of tests and/or calibrations performed for the customer • preparation, packaging, and dispatch of test and/or calibration items needed by the customer for verification purposes ***Note 2:*** Customer's value the maintenance of good communication, advice and guidance in technical matters, and opinions and interpretations based on results. Communication with the customer, especially in large assignments, should be maintained throughout the work. The laboratory should inform the customer of any delays or major deviations in the performance of the tests and/or calibrations.	
4.7.2.	The laboratory shall seek feedback, both positive and negative, from its customers. The feedback shall be used and analyzed to improve the management system, testing and calibration activities and customer service.	QAM-P110: Customer Service
	NOTE: Examples of the types of feedback include customer satisfaction surveys and review of test or calibration reports with customers.	

No.	Requirement	Policy # Hyperlinks
4.8	**Complaints**	
	The laboratory shall have a policy and procedure for the resolution of complaints received from customers or other parties. Records shall be maintained of all complaints and of the investigations and corrective actions taken by the laboratory (see also 4.11).	QAM-P110: Customer Service
4.9	**Control of Nonconforming Testing and/or Calibration Work**	
4.9.1	The laboratory shall have a policy and procedures that shall be implemented when any aspect of its testing and/or calibration work, or the results of this work, do not conform to its own procedures or the agreed requirements of the customer. The policy and procedures shall ensure that:	QAM-P205: Technical Procedure Deviation QAM-P206: Control of Non-Conforming Work
a)	the responsibilities and authorities for the management of nonconforming work are designated and actions (including halting of work and withholding of test reports and calibration certificates, as necessary) are defined and taken when nonconforming work is identified.	
b)	an evaluation of the significance of the nonconforming work is made.	
c)	remedial actions are taken immediately, together with any decision about the acceptability of the nonconforming work.	
d)	where necessary, the customer is notified and work is recalled.	
e)	the responsibility for authorizing the resumption of work is defined.	
	Note: Identification of nonconforming work or problems with the quality system or with testing and/or calibration activities can occur at various places within the quality system and technical operations. Examples are customer complaints, quality control, instrument calibration, checking of consumable materials, staff observations or supervision, test report and calibration certificate checking, management reviews and internal or external audits.	

No.	Requirement	Policy # Hyperlinks
4.9.2	Where the evaluation indicates that the nonconforming work could recur or that there is doubt about the compliance of the laboratory's operations with its own policies and procedures, the corrective action procedures given in 4.11 shall be promptly followed.	QAM-P205: Technical Procedure Deviation QAM-P206: Control of Non-Conforming Work QAM-P804: Corrective Actions
4.10	**Improvement**	
	The laboratory shall continually improve the effectiveness of its management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.	QAM-P205: Technical Procedure Deviation QAM-P206: Control of Non-Conforming Work QAM-P513: Peer Groups QAM-P801: Risk Identification QAM-P802: Issue Identification QAM-P803: Corrective Action Reports QAM-P804: Corrective Actions
4.11	**Corrective Action**	
4.11.1	General	
	The laboratory shall establish a policy and procedure and shall designate appropriate authorities for implementing corrective action when nonconforming work or departures from the policies and procedures in the quality system or technical operations have been identified.	QAM-P205: Technical Procedure Deviation QAM-P206: Control of Non-Conforming Work QAM-P803: Corrective Action Reports QAM-P804: Corrective Actions
	Note: A problem with the quality system or with the technical operations of the laboratory may be identified through a variety of activities, such as control of nonconforming work, internal or external audits, management reviews, feedback from customers or staff observations.	
4.11.2	Cause Analysis	QAM-P804: Corrective Actions
	The procedure for corrective action shall start with an investigation to determine the root cause(s) of the problem.	

No.	Requirement	Policy # Hyperlinks
	Note: Cause analysis is the key and sometimes the most difficult part in the corrective action procedure. Often the root cause is not obvious and thus a careful analysis of all potential causes of the problem is required. Potential causes could include customer requirements, the samples, sample specifications, methods and procedures, staff skills and training, consumables, or equipment and its calibration.	
4.11.3	Selection and Implementation of Corrective Action	QAM-P804: Corrective Actions
	Where corrective action is needed, the laboratory shall identify potential corrective actions. It shall select and implement the action(s) most likely to eliminate the problem and to prevent recurrence.	
	Corrective actions shall be to a degree appropriate to the magnitude and the risk of the problem.	
	The laboratory shall document and implement any required changes resulting from corrective action investigations.	
4.11.4	Monitoring of Corrective Actions	QAM-P804: Corrective Actions
	The laboratory shall monitor the results to ensure that the corrective actions taken have been effective.	
4.11.5	Additional Audits	QAM-P804: Corrective Actions
	Where the identification of nonconformance's or departures casts doubts on the laboratory's compliance with its own policies and the procedures, or on its compliance with this International Standard, the laboratory shall ensure that the appropriate areas of activity are audited in accordance with 4.14 as soon as possible.	
	Note: Such additional audits often follow the implementation of the corrective actions to confirm their effectiveness. An additional audit should be necessary only when a serious issue or risk to the business is identified.	

No.	Requirement	Policy # Hyperlinks
4.12	**Preventive Actions**	
4.12.1	Needed improvements and potential sources of nonconformities, either technical or concerning the management system, shall be identified. When improvement opportunities are identified or if preventive action is required, action plans shall be developed, implemented and monitored to reduce the likelihood of the occurrence of such nonconformities and to take advantage of the opportunities for improvement.	QAM-P110: Customer Service QAM-P513: Peer Groups QAM-P801: Risk Identification QAM-P802: Issue Identification QAM-P803: Corrective Action Reports QAM-P804: Corrective Actions
4.12.2	Procedures for preventive actions shall include the initiation of such actions and application of controls to ensure that they are effective.	QAM-P110: Customer Service QAM-P513: Peer Groups QAM-P801: Risk Identification QAM-P802: Issue Identification QAM-P803: Corrective Action Reports QAM-P804: Corrective Actions
	Note 1: Preventive action is a pro-active process to identify opportunities for improvement rather than a reaction to the identification of problems or complaints. ***Note 2:*** Apart from the review of the operational procedures, the preventive action might involve analysis of data, including trend and risk analyses and proficiency-testing results.	
4.13	**Control of Records**	
4.13.1	General	
4.13.1.1	The Laboratory shall establish and maintain procedures for identification, collection, indexing, access, filing, storage, maintenance and disposal of quality and technical records. Quality records shall include reports from internal audits and management reviews as well as records of corrective and preventive actions.	APP-P501: Document Retention APP-P502: Document Disposal APP-P503: Document Inventory APP-P504: Document Approval APP-P505: Document Format

No.	Requirement	Policy # Hyperlinks
		APP-P506: Document Numbering APP-P507: Document Filing APP-P508: Report Dissemination APP-P509: Manual Dissemination APP-P510: FIA Requests APP-P511: Document Retirement APP-P512: Document Review APP-P513: File Removal APP-P514: Electronic File Security QAM-P201: Quality System Audits QAM-P202: Inspections QAM-P203: Audit Documentation QAM-P204: Audit Reviews QAM-P309: Examination Documentation QAM-P310: Examination Notes QAM-P311: Examination Notes Corrections QAM-P312: Examination Notes Dissemination QAM-P313: Examination Reports QAM-P314: Examination Report Review QAM-P315: Examination Report Corrections QAM-P316: Examination Report Dissemination QAM-P317: Examination Report Storage QAM-P404: Instrument Calibration Logs QAM-P406: Equipment Maintenance Logs QAM-P414: Reference Standards and Materials Validation QAM-P415: Reagent Preparation Logs QAM-P803: Corrective Action Reports

No.	Requirement	Policy # Hyperlinks
4.13.1.2	All records shall be legible and shall be stored and retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss. Retention times of records shall be established.	APP-P501: Document Retention APP-P502: Document Disposal APP-P503: Document Inventory APP-P507: Document Filing APP-P511: Document Retirement APP-P512: Document Review APP-P513: File Removal APP-P514: Electronic File Security QAM-P203: Audit Documentation QAM-P309: Examination Documentation QAM-P310: Examination Notes QAM-P311: Examination Notes Corrections QAM-P313: Examination Reports QAM-P315: Examination Report Corrections QAM-P317: Examination Report Storage QAM-P404: Instrument Calibration Logs QAM-P406: Equipment Maintenance Logs QAM-P414: Reference Standards and Materials Validation QAM-P415: Reagent Preparation Logs QAM-P803: Corrective Action Reports
	Note: Records may be in any media, such as hard copy or electronic media.	

No.	Requirement	Policy # Hyperlinks
4.13.1.3	All records shall be held secure and in confidence.	APP-P501: Document Retention APP-P502: Document Disposal APP-P508: Report Dissemination APP-P509: Manual Dissemination APP-P510: FIA Requests APP-P513: File Removal APP-P514: Electronic File Security QAM-P312: Examination Notes Dissemination QAM-P316: Examination Report Dissemination QAM-P317: Examination Report Storage
4.13.1.4	The laboratory shall have procedures to protect and back-up records stored electronically and to prevent unauthorized access to or amendment of these records.	APP-P514: Electronic File Security
4.13.2	Technical Records	
4.13.2.1	The laboratory shall retain records of original observations, derived data and sufficient information to establish an audit trail, calibration records, staff records and a copy of each test report or calibration certificate issued, for a defined period. The records for each test or calibration shall contain sufficient information to facilitate, if possible, identification of factors affecting the uncertainty and to enable the test or calibration to be repeated under conditions as close as possible to the original. The records shall include the identity of personnel responsible for the sampling, performance of each test and/or calibration and checking of results.	APP-P501: Document Retention APP-P513: File Removal QAM-P309: Examination Documentation QAM-P310: Examination Notes QAM-P311: Examination Notes Corrections QAM-P313: Examination Reports QAM-P315: Examination Report Corrections QAM-P317: Examination Report Storage QAM-P404: Instrument Calibration Logs QAM-P406: Equipment Maintenance Logs QAM-P414: Reference Standards and Materials Validation QAM-P415: Reagent Preparation Logs

No.	Requirement	Policy # Hyperlinks
	Note 1: In certain fields it may be impossible or impracticable to retain records of all original observations. ***Note 2:*** Technical records are accumulations of data (see 5.4.7) and information, which result from carrying out tests and/or calibrations and which indicate whether specified quality or process parameters are achieved. They may include forms, contracts, work sheets, work books, check sheets, work notes, control graphs, external and internal test reports and calibration certificates, customers' notes, papers and feedback.	
4.13.2.2	Observations, data and calculations shall be recorded at the time they are made and shall be identifiable to the specific task.	QAM-P309: Examination Documentation QAM-P310: Examination Notes QAM-P311: Examination Notes Corrections
4.13.2.3	When mistakes occur in records, each mistake shall be crossed out, not erased, made illegible or deleted, and the correct value entered alongside. All such alterations to records shall be signed or initialed by the person making the correction. In the case of records stored electronically, equivalent measures shall be taken to avoid loss or change or original data.	APP-P514: Electronic File Security QAM-P309: Examination Documentation QAM-P310: Examination Notes QAM-P311: Examination Notes Corrections
4.14	**Internal Audits**	
4.14.1	The laboratory shall periodically, and in accordance with a predetermined schedule and procedure, conduct internal audits of its activities to verify that its operations continue to comply with the requirements of the quality system and this International Standard. The internal audit program shall address all elements of the quality system, including the testing and/or calibration activities. It is the responsibility of the quality manager to plan and organize audits as required by the schedule and requested by management. Such audits shall be carried out by trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited.	QAM-P201: Quality System Audits QAM-P202: Inspections QAM-P203: Audit Documentation QAM-P204: Audit Reviews
	Note: The cycle for internal auditing shall normally be completed in one year.	

No.	Requirement	Policy # Hyperlinks
4.14.2	When audit findings cast doubt on the effectiveness of the operations or on the correctness or validity of the laboratory's test or calibration results, the laboratory shall take timely corrective action, and shall notify customers in writing if investigations show that the laboratory results may have been affected.	QAM-P201: Quality System Audits QAM-P202: Inspections QAM-P203: Audit Documentation QAM-P204: Audit Reviews QAM-P801: Risk Identification QAM-P802: Issue Identification QAM-P803: Corrective Action Reports QAM-P804: Corrective Actions
4.14.3	The area of activity audited, the audit findings and corrective actions that arise from them shall be recorded.	QAM-P201: Quality System Audits QAM-P202: Inspections QAM-P203: Audit Documentation QAM-P204: Audit Reviews QAM-P801: Risk Identification QAM-P802: Issue Identification QAM-P803: Corrective Action Reports QAM-P804: Corrective Actions
4.14.4	Follow-up audit activities shall verify and record the implementation and effectiveness of the corrective action taken.	QAM-P201: Quality System Audits QAM-P202: Inspections QAM-P203: Audit Documentation QAM-P204: Audit Reviews QAM-P801: Risk Identification QAM-P802: Issue Identification QAM-P803: Corrective Action Reports QAM-P804: Corrective Actions

No.	Requirement	Policy # Hyperlinks
4.15	**Management Reviews**	
4.15.1	In accordance with a predetermined schedule and procedure, the laboratory's executive management shall periodically conduct a review of the laboratory's quality system and testing and/or calibration activities to ensure their continuing suitability and effectiveness, and to introduce necessary changes or improvements. The review shall take account of:	QAM-P108: Change Management QAM-P201: Quality System Audits QAM-P202: Inspections QAM-P203: Audit Documentation QAM-P204: Audit Reviews QAM-P801: Risk Identification QAM-P802: Issue Identification QAM-P803: Corrective Action Reports QAM-P804: Corrective Actions
a)	the suitability of policies and procedures	
b)	reports from managerial and supervisory personnel	
c)	the outcome of recent internal audits	
d)	corrective and preventive actions	
e)	assessments by external bodies	
f)	the results of inter laboratory comparisons or proficiency tests	
g)	changes in the volume and type of the work	
h)	customer feedback	
i)	complaints	
j)	recommendations for improvement	
k)	other relevant factors, such as quality control activities, resources and staff training	

No.	Requirement	Policy # Hyperlinks
	Note 1: A typical period for conducting a management review is once every 12 months. ***Note 2:*** Results should feed into the laboratory planning system and should include the goals, objectives and action plans for the coming year. ***Note 3:*** A management review includes consideration of related subjects at regular management meetings.	
4.15.2	Findings from management reviews and the actions that arise from them shall be recorded. The management shall ensure that those actions are carried out within an appropriate and agreed timescale.	QAM-P108: Change Management QAM-P203: Audit Documentation QAM-P803: Corrective Action Reports QAM-P804: Corrective Actions
5.0	**TECHNICAL REQUIREMENTS**	
5.1	**General**	
5.1.1	Many factors determine the correctness and reliability of the tests and/or calibrations performed by a laboratory. These factors include contributions from: • human factors (5.2) • accommodation and environmental conditions (5.3) • test and calibration methods and method validation (5.4) • equipment (5.5) • measurement traceability (5.6) • sampling (5.7) • the handling of test and calibration items (5.8)	QAM-P107: Commitment to Quality
5.1.2	The extent to which the factors contribute to the total uncertainty of measurement differs considerably between (types of) tests and between (types of) calibrations. The laboratory shall take account of these factors in developing test and calibration methods and procedures, in the training and qualification of personnel, and in the selection and calibration of the equipment it uses.	QAM-P107: Commitment to Quality

No.	Requirement	Policy # Hyperlinks
5.2	**Personnel**	
5.2.1	The laboratory management shall ensure the competence of all who operate specific equipment, perform tests and/or calibrations, evaluate results, and sign test reports and calibration certificates. When using staff who are undergoing training, appropriate supervision shall be provided. Personnel performing specific tasks shall be qualified on the basis of appropriate education, training, experience and/or demonstrated skills, as required.	APP-P301: Position Descriptions APP-P302: Selection and Promotion APP-P305: Statement of Qualifications APP-P311: Training APP-P312: Professional Development APP-P315: Training Records QAM-P501: Minimum Qualifications QAM-P502: Training QAM-P509: Professional Training QAM-P510: Continuing Education QAM-P511: Professional Certification
	Note 1: In some technical areas (e.g., non-destructive testing) it may be required that the personnel performing certain tasks hold personnel certification. The laboratory is responsible for fulfilling specified personnel certification requirements. The requirements for personnel certification might by regulatory, included in the standards for specific technical field, or required by the customer. ***Note 2:*** The personnel responsible for the opinions and interpretation included in test reports should, in addition to the appropriate qualifications, training, experience and satisfactory knowledge of the testing carried out, also have: • relevant knowledge of the technology used for the manufacturing of the items, materials, products, etc. tested, or the way they are used or intended to be used, and of the defects or degradations which may occur during or in service • knowledge of the general requirements expressed in the legislation and standards • an understanding of the significance of deviations found with regard to the normal use of the items, materials, products, etc. concerned	

No.	Requirement	Policy # Hyperlinks
5.2.2	The management of the laboratory shall formulate the goals with respect to the education, training and skills of the laboratory personnel. The laboratory shall have a policy and procedures for identifying training needs and providing training of personnel. The training program shall be relevant to the present and anticipated tasks of the laboratory.	APP-P301: Position Descriptions APP-P302: Selection and Promotion APP-P305: Statement of Qualifications APP-P311: Training APP-P312: Professional Development APP-P315: Training Records QAM-P501: Minimum Qualifications QAM-P502: Training QAM-P509: Professional Training QAM-P510: Continuing Education QAM-P511: Professional Certification
5.2.3	The laboratory shall use personnel who are employed by, or under contract to, the laboratory. Where contracted and additional technical and key support personnel are used, the laboratory shall ensure that such personnel are supervised and competent and that they work in accordance with the laboratory's quality system.	QAM-P516: Contract Labor
5.2.4	The laboratory shall maintain current job descriptions for managerial, technical and key support personnel involved in tests and/or calibrations.	APP-P301: Position Descriptions APP-P305: Statement of Qualifications APP-PDxx: All Position Descriptions SOQ-xxx: Individual Statement of Qualifications

No.	Requirement	Policy # Hyperlinks
	Note: Job descriptions can be defined in may ways. As a minimum, the following should be defined: • the responsibilities with respect to performing tests and/or calibrations • the responsibilities with respect to the planning of tests and/or calibrations and evaluation of results • the responsibilities for reporting opinions and interpretations • the responsibilities with respect to method modification and development and validation of new methods • expertise and experience required • qualifications and training programs • managerial duties	
5.2.5	The management shall authorize specific personnel to perform particular types of sampling, test and/or calibration, to issue test reports and calibration certificates, to give opinions and interpretations and to operate particular types of equipment. The laboratory shall maintain records of the relevant authorization(s), competence, educational and professional qualifications training, skills and experience of all technical personnel, including contracted personnel. This information shall be readily available and shall include the date on which authorization and/or competence is confirmed.	APP-P305: Statement of Qualifications APP-P315: Training Files QAM-P503: Proficiency Test Evaluations QAM-P504: Proficiency Test Documentation QAM-P505: Testimony Review QAM-P506: Testimony Review Documentation QAM-P516: Contract Labor
5.3	**Accommodation and Environmental Conditions**	
5.3.1	Laboratory facilities for testing and/or calibration, including but not limited to energy sources, lighting and environmental conditions, shall be such as to facilitate correct performance of the tests and/or calibrations.	APP-P201: Space APP-P202: Design APP-P203: Construction

No.	Requirement	Policy # Hyperlinks
	The laboratory shall ensure that the environmental conditions do not invalidate the results or adversely affect the required quality of any measurement. Particular care shall be taken when sampling and test and/or calibrations are undertaken at sites other than a permanent laboratory facility. The technical requirements for accommodation and environmental conditions that can affect the results of tests and calibrations shall be documented.	
5.3.2	The laboratory shall monitor, control and record environmental conditions as required by the relevant specifications, methods and procedures or where thy influence the quality of the results. Due attention shall be paid, for example, to biological sterility, dust, electromagnetic disturbances, radiation, humidity, electrical supply, temperature, and sound and vibration levels, as appropriate to the technical activities concerned. Tests and calibrations shall be stopped when the environmental conditions jeopardize the results of the tests and/or calibrations.	QAM-P904: Environmental Factors
5.3.3	There shall be effective separation between neighboring areas in which there are incompatible activities. Measures shall be taken to prevent cross-contamination.	APP-P201: Space QAM-P603: Loss Cross Transfer and Contamination
5.3.4	Access to and use of areas affecting the quality of the tests and/or calibrations shall be controlled. The laboratory shall determine the extent of control based on its particular circumstances.	APP-P204: Access Control APP-P205: Key Control APP-P206: Alarms APP-P601: Authorized Access APP-P602: Escort Policy APP-P603: Entry Log APP-P604: Hours of Operation APP-P605: Alarms APP-P606: Security Staff APP-P607: Breach of Security

No.	Requirement	Policy # Hyperlinks
5.3.5	Measures shall be taken to ensure good housekeeping in the laboratory. Special procedures shall be prepared where necessary.	APP-P207: House Keeping
5.4	**Test and Calibration Methods and Methods Validation**	
5.4.1	General	
	The laboratory shall use appropriate methods and procedures for all tests and/or calibrations within its scope. These include sampling, handling, transport, storage and preparation of items to be tested and/or calibrated, and, where appropriate, an estimation of the measurement uncertainty as well as statistical techniques for analysis of test and/or calibration data.	
	The laboratory shall have instructions on the use and operation of all relevant equipment, and on the handling and preparation of items for testing and/or calibration, or both, where the absence of such instructions could jeopardize the results of tests and/or calibrations. All instructions, standards, manuals and reference data relevant to the work of the laboratory shall be kept up to date and shall be made readily available to personnel (see 4.3). Deviation from test and calibration methods shall occur only if the deviation has been documented, technically justified, authorized, and accepted by the customer.	
	Note: International, regional or national standards or other recognized specifications that contain sufficient and concise information on how to perform the tests and/or calibrations do not need to be supplemented or rewritten as internal procedures if these standards are written in a way that they can be used as published by the operating staff in a laboratory. It may be necessary to provide additional documentation for optional steps in the method or additional details.	

No.	Requirement	Policy # Hyperlinks
5.4.2	**Selection of Methods**	QAM-P205: Technical Procedure Deviation QAM-P318: Technical Procedure Acceptance QAM-P901: Examination Method Selection QAM-P905: Examination Method Validation
	The laboratory shall use test and/or calibration methods, including methods for sampling, which meet the needs of the customer and which are appropriate for the tests and/or calibrations it undertakes. Methods published in international, regional, or national standards shall preferably be used. The laboratory shall ensure that it uses the latest valid edition of a standard unless it is not appropriate or possible to do so. When necessary, the standard shall be supplemented with additional details to ensure consistent application.	
	When the customer does not specify the method to be used, the laboratory shall select appropriate methods that have been published either in international, regional or national standards, or by reputable technical organizations, or in relevant scientific texts or journals, or as specified by the manufacturer of the equipment. Laboratory-developed methods or methods adopted by the laboratory may also be used if they are appropriate for the intended use and if they are validated. The customer shall be informed as to the method chosen. The laboratory shall confirm that it can properly operate standard methods before introducing the tests or calibrations. If the standard method changes, the confirmation shall be repeated.	

No.	Requirement	Policy # Hyperlinks
	The laboratory shall inform the customer when the method proposed by the customer is considered to be inappropriate or out of date.	
5.4.3	Laboratory Developed Methods	QAM-P305: Technical Policy Development QAM-P318: Technical Procedure Acceptance QAM-P905: Examination Method Validation
	The introduction of test and calibration methods developed by the laboratory for its own use shall be a planned activity and shall be assigned to qualified personnel equipped with adequate resources.	
	Plans shall be updated as development proceeds and effective communication amongst all personnel involved shall be ensured.	
5.4.4	Non-standard Methods	QAM-P205: Technical Procedure Deviation QAM-P206: Control of Non-conforming work QAM-P305: Technical Policy Development QAM-P318: Technical Procedure Acceptance QAM-P901: Examination Method Selection QAM-P905: Examination Method Validation
	When it is necessary to use methods not covered by standard methods, these shall be subject to agreement with the customer and shall include a clear specification of the customer's requirements and the purpose of the test and/or calibration. The method developed shall have been validated appropriately before use.	

No.	Requirement	Policy # Hyperlinks
	Note: For new test and/or calibration methods, procedures should be developed prior to the tests and/or calibrations being performed and should contain at least the following information: • parameters or quantities and ranges to be determined • apparatus and equipment, including technical performance requirements • reference standards and reference materials required • environmental conditions required and any stabilization period needed • Description of the procedure, including: ◦ affixing of identification marks, handling, transporting, storing and preparation of items ◦ checks to be made before the work is started ◦ checks that the equipment is working properly and, where required calibration and adjustment of the equipment before each use ◦ the method of recording the observations and results ◦ any safety measures to be observed • criteria and/or requirements for approval/rejection • data to be recorded and method of analysis and presentation • the uncertainty or the procedure for estimating uncertainty	
5.4.5	Validation of Methods	
5.4.5.1	Validation is the confirmation by examination and the provision of objective evidence that the particular requirements for a specific intended use are fulfilled.	APP-P101: Definitions

No.	Requirement	Policy # Hyperlinks
5.4.5.2	The laboratory shall validate non-standard methods, laboratory-designed/ developed methods, standard methods used outside their intended scope, and amplifications and modifications of standard methods to confirm that the methods are fit for the intended use. The validation shall be as extensive as is necessary to meet the needs of the given application or field of application. The laboratory shall record the results obtained, the procedure used for the validation, and a statement as to whether the method is fit for the intended use.	QAM-P305: Technical Policy Development QAM-P318: Technical Procedure Acceptance QAM-P905: Examination Method Validation
	Note 1: Validation may include procedures for sampling, handling and transportation. ***Note 2:*** The techniques used for the determination of the performance of a method should be one of, or a combination of the following: • calibration using reference standards or reference materials • comparison of results achieved with other methods • interlaboratory comparisons • systematic assessment of the factors influencing the results • assessment of the uncertainty of the results based on scientific understanding of the theoretical principles of the method and practical experience ***Note 3:*** When some changes are made in the validated non-standard methods, the influence of such changes should be documented and, if appropriate, a new validation should be carried out.	
5.4.5.3	The range and accuracy of the values obtainable from validated methods (e.g. the uncertainty of the results, detection limit, selectivity of the method, linearity, limit of repeatability and/or reproducibility, robustness against external influences and/ or cross-sensitivity against interference from the matrix of the sample/test object), as assessed for the intended use, shall be relevant to the customers' needs.	QAM-P305: Technical Policy Development QAM-P318: Technical Procedure Acceptance QAM-P905: Examination Method Validation

No.	Requirement	Policy # Hyperlinks
	Note 1: Validation includes specification of the requirements, determination of the characteristics of the methods, a check that the requirements can be fulfilled by using the method, and a statement on the validity. ***Note 2:*** As method-development proceeds, regular review should be carried out to verify that the needs of the customer are still being fulfilled. Any change in requirements requiring modifications to the development plan should be approved and authorized. ***Note 3:*** Validation is always a balance between costs, risks and technical possibilities. There are many cases in which the range and uncertainty of the values (e.g., accuracy, detection limit, selectivity, linearity, repeatability, reproducibility, robustness and cross-sensitivity) can only be given in a simplified way due to lack of information.	
5.4.6	Estimation of Uncertainty of Measurements	
5.4.6.1	A calibration laboratory, or a testing laboratory performing its own calibrations, shall have and shall apply a procedure to estimate the uncertainty of measurement for all calibrations and types of calibrations.	QAM-P906: Examination Method Uncertainty
5.4.6.2	Testing laboratories shall have and shall apply procedures for estimating uncertainty of measurement. In certain cases the nature of the test method may preclude rigorous, metrologically and statistically valid calculation of uncertainty of measurement. In these cases the laboratory shall at least attempt to identify all the components of uncertainty and make a reasonable estimation, and shall ensure that the form of reporting of the result does not give a wrong impression of the uncertainty. Reasonable estimation shall be based on knowledge of the performance of the method and on the measurement scope and shall make use of, for example, previous experience and validation data.	QAM-P906: Examination Method Uncertainty

No.	Requirement	Policy # Hyperlinks
	Note 1: The degree of rigor needed in an estimation of uncertainty of measurement depends on factors such as: • the requirements of the test method • the requirements of the customer • the existence of narrow limits on which decisions on conformance to a specification are based ***Note 2:*** In those cases where a well-recognized test method specifies limits to the values of the major sources of uncertainty of measurement and specifies the form of presentation of calculated results, the laboratory is considered to have satisfied this clause by following the test method and reporting instructions (see 5.10).	
5.4.6.3	When estimating the uncertainty of measurement, all uncertainty components which are of importance in the given situation shall be taken into account using appropriate methods of analysis.	QAM-P906: Examination Method Uncertainty
	Note 1: Sources contributing to the uncertainty include, but are not necessarily limited to, the reference standards and reference materials used, methods and equipment used, environmental conditions, properties and condition of the item being tested or calibrated, and the operator. ***Note 2:*** The predicted long-term behavior of the tested and/or calibrated item is not normally taken into account when estimating the measurement uncertainty. ***Note 3:*** For further information, see ISO 5725 and the Guide to the Expression of Uncertainty in Measurement.	
5.4.7	Control of Data	
5.4.7.1	Calculations and data transfers shall be subject to appropriate checks in a systematic manner.	QAM-P314: Examination Report Review

No.	Requirement	Policy # Hyperlinks
5.4.7.2	When computers or automated equipment are used for the acquisition, processing, recording, reporting, storage or retrieval of test or calibration data, the laboratory shall ensure that:	QAM-P310: Examination Notes
a)	computer software developed by the user is documented in sufficient detail and is suitably validated as being adequate for use	
b)	procedures are established and implemented for protecting data; such procedures shall include, but not be limited to, integrity and confidentiality of data entry or collection, data storage, data transmission and data processing	
c)	computers and automated equipment are maintained to ensure proper functioning and are provided with the environmental and operating conditions necessary to maintain the integrity of test and calibration data	
	Note: Commercial off-the-shelf software (e.g., word processing, database and statistical programs) in general use within their designed application range may be considered to be sufficiently validated. However, laboratory software configuration/modifications should be validated as in 5.4.7.2.a.	
5.5	**Equipment**	
5.5.1	The laboratory shall be furnished with all items of sampling, measurement and test equipment required for the correct performance of the tests and/or calibrations (including sampling, preparation of test and/or calibration items, processing and analysis of test and/or calibration data). In those cases where the laboratory needs to use equipment outside its permanent control, it shall ensure that the requirements of this International Standard are met.	QAM-P405: Equipment Inventories QAM-P407: External Equipment Use

No.	Requirement	Policy # Hyperlinks
5.5.2	Equipment and its software used for testing, calibration and sampling shall be capable of achieving the accuracy required and shall comply with specifications relevant to the tests and/or calibrations concerned. Calibration programs shall be established for key quantities or values of the instruments where these properties have a significant effect on the results. Before being placed into service, equipment (including that used for sampling) shall be calibrated or checked to establish that it meets the laboratory's specification requirements and complies with the relevant standard specifications. It shall be checked and/or calibrated before use (see 5.6).	QAM-P403: Instrument Calibration
5.5.3	Equipment shall be operated by authorized personnel. Up-to-date instructions on the use and maintenance of equipment (including any relevant manuals provided by the manufacturer of the equipment) shall be readily available for use by the appropriate laboratory personnel.	QAM-P420: Equipment use
5.5.4	Each item of equipment and its software used for testing and calibration and significant to the result shall, when practicable, be uniquely identified.	QAM-P405: Equipment Inventories
5.5.5	Records shall be maintained for each item of equipment and its software significant to the tests and/or calibrations performed. The records shall include at least the following: • the identity of the item of equipment and its software • the manufacturer's name, type identification, and serial number or other unique identification • check that equipment complies with the specification (see 5.5.2) • the current location, where appropriate • the manufacturer's instructions, if available, or reference to their location • dates, results and copies of reports and certificates of all calibrations, adjustments, acceptance criteria, and the due date of next calibration • the maintenance plan, where appropriate, and maintenance carried out to date • any damage, malfunction, modification or repair to the equipment	QAM-P402: Measuring Device Calibration QAM-P403: Instrument Calibration QAM-P404: Instrument Calibration Logs QAM-P405: Equipment Inventories QAM-P406: Equipment Maintenance Logs QAM-P417: Equipment Receipt

No.	Requirement	Policy # Hyperlinks
5.5.6	The laboratory shall have procedures for safe handling, transport, storage, use and planned maintenance of measuring equipment to ensure proper functioning and in order to prevent contamination or deterioration.	QAM-P420: Equipment Use
	Note: Additional procedures may be necessary when measuring equipment is used outside the permanent laboratory for tests, calibrations or sampling.	
5.5.7	Equipment that has been subjected to overloading or mishandling, gives suspect results, or has been shown to be defective or outside specified limits, shall be taken out of service. It shall be isolated to prevent its use or clearly labeled or marked as being out of service until it has been repaired and shown by calibration or test to perform correctly. The laboratory shall examine the effect of the defect or departure from specified limits on previous tests and/or calibrations and shall institute the "Control of nonconforming work" procedure (see 4.9).	QAM-P403: Instrument Calibration QAM-P420: Equipment Use
5.5.8	Whenever practicable, all equipment under the control of the laboratory and requiring calibration shall be labeled, coded or otherwise identified to indicate the status of calibration, including the date when last calibrated and the date or expiration criteria when recalibration is due.	QAM-P402: Measuring Device Calibration
5.5.9	When, for whatever reason, equipment goes outside the direct control of the laboratory, the laboratory shall ensure that the function and calibration status of the equipment are checked and shown to be satisfactory before the equipment is returned to service.	QAM-P402 Measuring Device Calibration QAM-P403: Instrument Calibration
5.5.10	When intermediate checks are needed to maintain confidence in the calibration status of the equipment, these checks shall be carried out according to a defined procedure.	QAM-P402 Measuring Device Calibration QAM-P403: Instrument Calibration
5.5.11	Where calibrations give rise to a set of correction factors, the laboratory shall have procedures to ensure that copies (e.g. in computer software) are correctly updated.	QAM-P402 Measuring Device Calibration QAM-P403: Instrument Calibration

No.	Requirement	Policy # Hyperlinks
5.5.12	Test and calibration equipment, including both hardware and software, shall be safeguarded from adjustments which would invalidate the test and/or calibration results.	QAM-P402 Measuring Device Calibration QAM-P403: Instrument Calibration
5.6	**Measurement Traceability**	
5.6.1	General	
	All equipment used for tests and/or calibrations, including equipment for subsidiary measurements (e.g., for environmental conditions) having a significant effect on the accuracy or validity of the result of the test, calibration or sampling shall be calibrated before being put into service. The laboratory shall have an established program and procedure for the calibration of its equipment.	
	***Note*:** Such a program should include a system for selecting, using, calibrating, checking, controlling and maintaining measurement standards, reference materials used as measurement standards, and measuring and test equipment used to perform tests and calibrations.	
5.6.2	Specific Measurements	
5.6.2.1	Calibration	QAM-P402: Measuring Device Calibration QAM-P403: Instrument Calibration
5.6.2.1.1	For calibration laboratories, the program for calibration of equipment shall be designated and operated so as to ensure that calibrations and measurements made by the laboratory are traceable to the International System of Units (SI).	

No.	Requirement	Policy # Hyperlinks
	A calibration laboratory establishes traceability of its own measurement standards and measuring instruments to the SI by means of an unbroken chain of calibrations or comparisons linking them to relevant primary standards of the SI units of measurement. The link to SI units may be achieved by reference to national measurement standards. National measurement standards may be primary standards, which are primary realizations of the SI units or agreed representations of SI units based on fundamental physical constants, or they may be secondary standards which are standards calibrated by another national metrology institute. When using external calibration services, traceability of measurement shall be assured by the use of calibration services from laboratories that can demonstrate competence, measurement capability and traceability. The calibration certificates issued by these laboratories shall contain the measurement results, including the measurement uncertainty and/or a statement of compliance with an identified metrological specification (see also 5.10.4.2).	
	Note 1: Calibration laboratories fulfilling the requirements of this International Standard are considered to be competent. A calibration certificate bearing an accreditation body logo from a calibration laboratory accredited to this International Standard, for the calibration concerned, is sufficient evidence of traceability to the calibration data reported. ***Note 2:*** Traceability of SI units of measurement may be achieved by reference to an appropriate primary standard (see VIM:1993, 6.4) or by reference to a natural constant, the value of which in terms of the relevant SI unit is known and recommended by the General Conference of Weight and Measures (CGPM) and the International Committee for Weights and Measures (CIPM).	

No.	Requirement	Policy # Hyperlinks
	Note 3: Calibration laboratories that maintain their own primary standard or representation of SI units based on fundamental physical constants can claim traceability to the SI system only after these standards have been compared, directly or indirectly, with other similar standards of a national metrology institute. ***Note 4:*** The term "identified metrological specification" means that it must be clear from the calibration certificate which specification the measurements have been compared with, by including the specification or by giving an unambiguous reference to the specification. ***Note 5:*** When the terms "international standard" or "national standard" are used in connection with traceability, it is assumed that these standards fulfil the properties of primary standards for the realization of SI units. ***Note 6:*** Traceability to national measurement standards does not necessarily require the use of the national metrology institute of the country in which the laboratory is located. ***Note 7:*** If a calibration laboratory wishes or needs to obtain traceability from a national metrology institute other than in its own country, this laboratory should select a national metrology institute that actively participated in the activities of BIPM either directly or through regional groups. ***Note 8:*** The unbroken chain of calibrations or comparisons may be achieved in several steps carried out by different laboratories that can demonstrate traceability.	
5.6.2.1.2	There are certain calibrations that currently cannot be strictly made in SI units. In these cases calibration shall provide confidence in measurements by establishing traceability to appropriate measurement standards such as:	QAM-P402: Measuring Device Calibration QAM-P403: Instrument Calibration
a)	the use of certified reference materials provided by a competent supplier to give a reliable physical or chemical characterization of a material	

No.	Requirement	Policy # Hyperlinks
b)	the use of specified methods and/or consensus standards that are clearly described and agreed by all parties concerned	
	Participation in a suitable program of interlaboratory comparisons is required where possible.	
5.6.2.2	Testing	
5.6.2.2.1	For testing laboratories, the requirements given in 5.6.2.1 apply for measuring and test equipment with measuring functions used, unless it has been established that the associated contribution from the calibration contributes little to the total uncertainty of the test result. When this situation arises, the laboratory shall ensure that the equipment used can provide the uncertainty of measurement needed.	QAM-P402: Measuring Device Calibration QAM-P403: Instrument Calibration
	Note: The extent to which the requirements in 5.6.2.1 should be followed depends on the relative contribution of the calibration uncertainty to the total uncertainty. If calibration is the dominant factor, the requirements should be strictly followed.	
5.6.2.2.2	Where traceability of measurements to SI units is not possible and/or not relevant, the same requirements for traceability to, for example, certified reference materials, agreed methods and/or consensus standards are required as for calibration laboratories (see 5.6.2.1.2).	QAM-P402: Measuring Device Calibration QAM-P403: Instrument Calibration
5.6.3	Reference Standards and Reference Materials	
5.6.3.1	Reference Standards	QAM-P414: Reference Standard and Material Validation
	The laboratory shall have a program and procedure for the calibration of its reference standards. Reference standards shall be calibrated by a body that can provide traceability as described in 5.6.2.1. Such reference standards of measurement held by the laboratory shall be used for calibration only and for no other purpose, unless it can be shown that their performance as reference standards would not be invalidated. Reference standards shall be calibrated before and after any adjustment.	

No.	Requirement	Policy # Hyperlinks
5.6.3.2	Reference Materials	QAM-P414: Reference Standard and Material Validation
	Reference materials shall, where possible, be traceable to SI units of measurement, or to certified reference materials. Internal reference materials shall be checked as far as is technically and economically practicable.	
5.6.3.3	Intermediate Checks	QAM-P414: Reference Standard and Material Validation
	Checks needed to maintain confidence in the calibration status of reference, primary, transfer or working standards and reference materials shall be carried out according to defined procedures and schedules.	
5.6.3.4	Transport and Storage	QAM-P413: Reference Standard and Material Inventory
	The laboratory shall have procedures for safe handling, transport, storage and use of reference standards and reference materials in order to prevent contamination or deterioration and in order to protect their integrity. ***Note*:** Additional procedures may be necessary when reference standards and reference materials are used outside the permanent laboratory for tests, calibrations or sampling.	
5.7	**Sampling**	
5.7.1	The laboratory shall have a sampling plan and procedures for sampling when it carries out sampling of substances, materials or products for subsequent testing or calibration. The sampling plan as well as the sampling procedure shall be available at the location where sampling is undertaken. Sampling plans shall, whenever reasonable, be based on appropriate statistical methods. The sampling process shall address the factors to be controlled to ensure the validity of the test and calibration results.	QAM-P904: Sampling

No.	Requirement	Policy # Hyperlinks
	Note 1: Sampling is a defined procedure whereby a part of a substance, material or product is taken to provide for testing or calibration of a representative sample of the whole. Sampling may also be required by the appropriate specification for which the substance, material or product is to be tested or calibrated. In certain cases (e.g., forensic analysis), the sample may not be representative but is determined by availability. ***Note 2:*** Sampling procedures should describe the selection, sampling plan, withdrawal and preparation of a sample or samples from a substance, material or product to yield the required information.	
5.7.2	Where the customer requires deviations, additions or exclusions from the documented sampling procedure, these shall be recorded in detail with the appropriate sampling data and shall be included in all documents containing test and/or calibration results, and shall be communicated to the appropriate personnel.	QAM-P904: Sampling
5.7.3	The laboratory shall have procedures for recording relevant data and operations relating to sampling that forms part of the testing or calibration that is undertaken. These records shall include the sampling procedure used, the identification of the sampler, environmental conditions (if relevant) and diagrams or other equivalent means to identify the sampling location as necessary and, if appropriate, the statistics the sampling procedures are based upon.	QAM-P904: Sampling

No.	Requirement	Policy # Hyperlinks
5.8	**Handling of Test and Calibration Items**	
5.8.1	The laboratory shall have procedures for the transportation, receipt, handling, protection, storage, retention and/or disposal of test and/or calibration items, including all provisions necessary to protect the integrity of the test or calibration item, and to protect the interests of the laboratory and the customer.	APP-P401: Sampling Numbering APP-P402: Sample Submission QAM-P601: Sample Submission QAM-P602: Sample Transfers QAM-P604: Item and Sub-Item Creation QAM-P605: Intra Laboratory Transfer Documentation QAM-P606: Sample Return QAM-P607: Sample Release QAM-P609: Sample Control Manual
5.8.2	The laboratory shall have a system for identifying test and/or calibration items. The identification shall be retained throughout the life of the item in the laboratory. The system shall be designed and operated so as to ensure that items cannot be confused physically or when referred to in records or other documents. The system shall, if appropriate, accommodate a sub-division of groups of items and the transfer of items within and from the laboratory.	APP-P401: Sampling Numbering APP-P402: Sample Submission QAM-P601: Sample Submission QAM-P602: Sample Transfers QAM-P604: Item and Sub-Item Creation QAM-P605: Intra Laboratory Transfer Documentation QAM-P606: Sample Return QAM-P607: Sample Release QAM-P608: Individual Characteristic Database Samples QAM-P609: Sample Control Manual

No.	Requirement	Policy # Hyperlinks
5.8.3	Upon receipt of the test or calibration item, abnormalities or departures from normal or specified conditions, as described in the test or calibration method, shall be recorded. When there is doubt as to the suitability of an item for test or calibration, or when an item does not conform to the description provided, or the test or calibration required is not specified in sufficient detail, the laboratory shall consult the customer for further instructions before proceeding and shall record the discussion.	APP-P401: Sampling Numbering APP-P402: Sample Submission QAM-P601: Sample Submission QAM-P602: Sample Transfers QAM-P603: Loss, Cross Transfer and Contamination QAM-P604: Item and Sub-Item Creation QAM-P605: Intra Laboratory Transfer Documentation QAM-P606: Sample Return QAM-P607: Sample Release QAM-P608: Individual Characteristic Database Samples QAM-P609: Sample Control Manual
5.8.4	The laboratory shall have procedures and appropriate facilities for avoiding deterioration, loss or damage to the test or calibration item during storage, handling and preparation. Handling instructions provided with the item shall be followed. When items have to be stored or conditioned under specified environmental conditions, these conditions shall be maintained, monitored and recorded. Where a test or calibration item or a portion of an item is to be held secure, the laboratory shall have arrangements for storage and security that protect the condition and integrity of the secured items or a portion of an item is to be held secure, the laboratory shall have arrangements for storage and security that protect the condition and integrity of the secured items or portions concerned.	APP-P401: Sampling Numbering APP-P402: Sample Submission QAM-P601: Sample Submission QAM-P602: Sample Transfers QAM-P603: Loss, Cross Transfer and Contamination QAM-P604: Item and Sub-Item Creation QAM-P605: Intra Laboratory Transfer Documentation QAM-P606: Sample Return QAM-P607: Sample Release QAM-P608: Individual Characteristic Database Samples QAM-P609: Sample Control Manual

No.	Requirement	Policy # Hyperlinks
	Note 1: Where test items are to be returned into service after testing, special care is required to ensure that they are not damaged or injured during the handling, testing or storing/waiting process. ***Note 2:*** A sampling procedure and information on storage and transport of samples, including information on sampling factors influencing the test or calibration result, should be provided to those responsible for taking and transporting the samples. ***Note 3:*** Reasons for keeping a test or calibration item secure can be the reasons of record, safety or value, or to enable complementary tests and/or calibrations to be performed later.	
5.9	**Assuring the Quality of Test and Calibration Results**	
5.9.1.	The laboratory shall have quality control procedures for monitoring the validity of tests and calibrations undertaken. The resulting data shall be recorded in such a way that trends are detectable and where practicable, statistical techniques shall be applied to the reviewing of the results. This monitoring shall be planned and reviewed and may include, but not be limited to the following:	QAM-P402: Measuring Device Calibration QAM-P403: Instrument Calibration QAM-P413: Reference Standard and Material Inventory QAM-P414: Reference Standard and Material Validation QAM-P420: Equipment Use QAM-P503: Proficiency Test Evaluation QAM-P504: Proficiency Test Documentation QAM-P801: Risk Identification QAM-P802: Issue Identification
a)	regular use of certified reference materials and/or internal quality control using secondary reference materials	
b)	participation in interlaboratory comparison or proficiency-testing programs	
c)	replicate tests or calibrations using the same or different methods	
d)	retesting or recalibration of retained items	

No.	Requirement	Policy # Hyperlinks
e)	correlation of results for different characteristics of an item	
	Note: The selected methods should be appropriate for the type and volume of work undertaken.	
5.9.2	Quality control data shall be analyzed and, where they are found to be outside pre-defined criteria, planned action shall be taken to correct the problem and to prevent incorrect results from being reported.	QAM-P801: Risk Identification QAM-P802: Issue Identification QAM-P803: Corrective Action Reports
5.10	**Reporting the Results**	
5.10.1	General	APP-P505: Document Format APP-P508: Report Dissemination QAM-P313: Examination Reports QAM-P314: Examination Report Review QAM-P315: Examination Report Corrections QAM-P316: Examination Report Dissemination
	The results of each test, calibration, or series of tests or calibrations carried out by the laboratory shall be reported accurately, clearly, unambiguously and objectively, and in accordance with any specific instructions in the test or calibration methods.	
	The results shall be reported, usually in a test report or a calibration certificate (see Note 1), and shall include all the information requested by the customer and necessary for the interpretation of the test or calibration results and all information required by the method used. This information is normally that required by 5.10.2, and 5.10.3 or 5.10.4.	
	In the case of tests or calibrations performed for internal customers, or in the case of a written agreement with the customer, the results may be reported in a simplified way. Any information listed in 5.10.2 to 5.10.4 which is not reported to the customer shall be readily available in the laboratory which carried out the tests and/or calibrations.	

No.	Requirement	Policy # Hyperlinks
	Note 1: Test reports and calibration certificates are sometimes called test certificates and calibration reports, respectively. ***Note 2:*** The test reports or calibration certificates may be issued as hard copy or by electronic data transfer provided that the requirements of this International Standard are met.	
5.10.2	Test Reports and Calibration Certificates	APP-P505: Document Format QAM-P313: Examination Reports
	Each test report or calibration certificate shall include at least the following information, unless the laboratory has valid reasons for not doing do: 1. A title (e.g., "Test Report" or Calibration Certificate") 2. the name and address of the laboratory, and the location where the tests and/or calibrations were carried out, if different from the address of the laboratory 3. unique identification of the test report or calibration certificate (such as the serial number), and on each page the identification in order to ensure that the page is recognized as part of the test report or calibration certificate, and a clear identification of the end of the test report or calibration certificate 4. the name and address of the customer 5. identification of the method used 6. a description of, the condition of, and unambiguous identification of the item(s) tested or calibrated 7. the date of receipt of the test or calibration item(s) where this is critical to the validity and application of the results, and the date(s) of performance of the test or calibration 8. reference to the sampling plan and procedures used by the laboratory or other bodies where these are relevant to the validity or application of the results	

No.	Requirement	Policy # Hyperlinks
	9. the test or calibration results with, where appropriate, the units of measurement 10. the name(s), function(s) and signature(s) or equivalent identification of person(s) authorizing the test report or calibration certificate 11. where relevant, a statement to the effect that the results relate only to the items tested or calibrated	
	Note 1: Hard copies of test reports and calibration certificates should also include the page number and total number of pages. ***Note 2:*** It is recommended that laboratories include a statement specifying that the test report or calibration certificate shall not be reproduced except in full, without written approval of the laboratory.	
5.10.3	Test Reports	APP-P505: Document Format QAM-P313: Examination Reports
5.10.3.1	In addition to the requirements listed in 5.10.2, test reports shall, where necessary for the interpretation of the test results, include the following:	
a)	deviations from, additions to, or exclusions from the test method, and information on specific test conditions, such as environmental conditions	
b)	where relevant, a statement of compliance/non-compliance with requirements and/or specifications	
c)	where applicable, a statement on the estimated uncertainty of measurement; information on uncertainty is needed in test reports when it is relevant to the validity or application of the test results, when a customer's instructions so requires, or when the uncertainty affects compliance to a specification limit	
d)	where appropriate and needed, opinions and interpretations (see 5.10.5)	
e)	additional information which may be required by specific methods, customers or groups of customers	

No.	Requirement	Policy # Hyperlinks
5.10.3.2	In addition to the requirements listed in 5.10.2 and 5.10.3.1, test reports containing the results of sampling shall include the following, where necessary for the interpretation of test results: • the date of sampling • unambiguous identification of the substance, material or product sampled (including the name of the manufacturer, the model or type of designation and serial numbers as appropriate) • the location of sampling, including any diagrams, sketches or photographs • a reference to the sampling plan and procedures used • details of any environmental conditions during sampling that may affect the interpretation of the test results • any standard or other specification for the sampling method or procedure, and deviations, additions to or exclusions from the specification concerned	
5.10.4	Calibration Certificates	
	In addition to the requirements listed in 5.10.2, calibration certificates shall include the following, where necessary for the interpretation of calibration results: • the conditions (e.g., environmental) under which the calibrations were made that have an influence on the measurement results • the uncertainty of measurement and/or a statement of compliance with an identified metrological specification or clauses thereof • evidence that the measurements are traceable (see ***Note 2*** in 5.6.2.1.1)	
5.10.4.2	The calibration certificate shall relate only to quantities and the results of functional tests. If a statement of compliance with a specification is made, this shall identify which clauses of the specification are met or net met.	
	When a statement of compliance with a specification is made omitting the measurement results and associated uncertainties, the laboratory shall record those results and maintain them for possible future reference.	

No.	Requirement	Policy # Hyperlinks
	When statements of compliance are made, the uncertainty of measurement shall be taken into account.	
5.10.4.3	When an instrument for calibration has been adjusted or repaired, the calibration results before and after adjustment or repair, if available, shall be reported.	
5.10.4.4	A calibration certificate (or calibration label) shall not contain any recommendation on the calibration interval except where this has been agreed with the customer. This requirement may be superseded by legal regulations.	
5.10.5	Opinions and Interpretations	APP-P505: Document Format QAM-P313: Examination Reports
	When opinions and interpretations are included, the laboratory shall document the basis upon which the opinions and interpretations have been made. Opinions and interpretations shall be clearly marked as such in a test report.	
	Note 1: Opinions and interpretations should not be confused with inspections and product certifications as intended in ISO/IEC 17020 and ISO/IEC Guide 65. ***Note 2:*** Opinions and interpretations included in a test report may comprise, but not be limited to the following: • an opinion on the statement of compliance/noncompliance of the results with requirements • fulfillment of contractual requirements • recommendations on how to use the results • guidance to be used for improvements ***Note 3*:** In many cases it might be appropriate to communicate the opinions and interpretations by direct dialogue with the customer. Such dialogue should be written down.	

No.	Requirement	Policy # Hyperlinks
5.10.6	Testing Calibration Results Obtained from Subcontractors	QAM-P310: Examination Notes QAM-P313: Examination Report QAM-P903: Contract Examinations
	When the test report contains results of tests performed by subcontractors, these results shall be clearly identified. The subcontractor shall report the results in writing or electronically.	
	When a calibration has been subcontracted, the laboratory performing the work shall issue the calibration certificate to the contracting laboratory.	
5.10.7	Electronic Transmission of Results	APP-P508: Report Dissemination QAM-P316: Examination Report Dissemination
	In the case of transmission of test or calibration results by telephone, telex, facsimile or other electronic or electromagnetic means, the requirements of this International Standard shall be met (see also 5.4.7).	
5.10.8	Format of Reports and Certificates	APP-P505: Document Format QAM-P313: Examination Reports
	The format shall be designed to accommodate each type of test or calibration carried out and to minimize the possibility of misunderstanding or misuse.	
	Note 1: Attention should be given to the lay-out of the test report or calibration certificate, especially with regard to the presentation of the test or calibration data and ease of assimilation by the reader. ***Note 2:*** The headings should be standardized as far as possible.	

No.	Requirement	Policy # Hyperlinks
5.10.9	Amendments to Test Reports and Calibration Certificates	QAM-P803: Corrective Action Reports QAM-P315: Examination Report Corrections QAM-P316: Examination Report Dissemination
	Material amendments to a test report or calibration certificate after issue shall be made only in the form of a further document, or data transfer, which includes the statement: "Supplement to Test Report (or Calibration Certificate), serial number…(or otherwise identified)", or an equivalent form of wording.	
	Such amendments shall meet all the requirements of this International Standard.	
	When it is necessary to issue a complete new report or calibration certificate, this shall be uniquely identified and shall contain a reference to the original that it replaces.	

Appendix L

ASCLD/LAB (2005) Criteria File

http://www.ascld-lab.org/legacy/forms/word/legacyInteractiveCriteriaFileContentGuide2005revised52506.doc

(Rev. 2006-1)

Underlined Text = hyperlink directly to file or book-marked area of file

OBJECTIVES		
(I) 1.1.1.1	Does the laboratory have a written statement of objectives?	APP-P104: Organization Goals and Objectives QAM-P103: Quality Program Goals and Objectives
(I) 1.1.1.2	Do the objectives appear relevant to needs of community serviced by the laboratory?	APP-P104: Organization Goals and Objectives QAM-P103: Quality Program Goals and Objectives
(D) 1.1.1.3	Does the laboratory staff understand and support the objectives?	APP-P104: Organization Goals and Objectives QAM-P103: Quality Program Goals and Objectives

ADMINISTRATIVE PRACTICES		
(I) 1.1.2.1	Does the laboratory or its parent organization have a formal written budget?	APP-P106: Budget
(I) 1.1.2.2	Is budget adequate to meet written objectives?	APP-P106: Budget

Do clearly written and well understood procedures exist for the following:		
(E) 1.1.2.3	Handling and preserving the integrity of evidence?	See Sample Control Manual APP-P401: Sample Numbering APP-P402: Sample Submission APP-P403: Sample Return APP-P404: Sample Database QAM-P601: Sample Submission QAM-P602: Sample Transfers QAM-P603: Loss, Cross Transfer and Contamination QAM-P604: Item and Sub-Item Creation QAM-P605: Intra Laboratory Transfer Documentation QAM-P606: Sample Return QAM-P607: Sample Release QAM-P608: Individual Characteristic Database Samples
(E) 1.1.2.4	Laboratory security?	APP-P601: Authorized Access APP-P602: Escort Policy APP-P603: Entry Log APP-P604: After Hours Access APP-P605: Alarms APP-P606: Security Staff APP-P607: Security Breach APP-P608: Safety Violation

(E) 1.1.2.5	Preparation, storage, security & disposition of case records or reports?	APP-P507: Document Filing APP-P508: Report Dissemination APP-P510: Freedom of Information Act Requests APP-P513: File Removal APP-P514: Electronic File Security QAM-P009: Examination Documentation QAM-P010: Examination Notes QAM-P011: Examination Notes Corrections QAM-P012: Examination Notes Dissemination QAM-P013: Examination Reports QAM-P014: Examination Report Review QAM-P015: Examination Report Corrections QAM-P016: Examination Report Storage
(E) 1.1.2.6	Control of materials and supplies?	QAM-P412: Chemical Procurement QAM-P413: Chemical Receipt QAM-P416: Equipment Procurement QAM-P417: Equipment Receipt
(E) 1.1.2.7	Maintenance and calibration of equipment and instruments?	QAM-P402: Measuring Device Calibration QAM-P403: Instrument Calibration QAM-P404: Instrument Calibration Logs QAM-P406: Instrument Maintenance Logs
(E) 1.1.2.8	The operation of individual characteristic databases?	QAM-P608: Individual Characteristic Database Samples
(D) 1.1.2.9	Job requirements and descriptions?	APP-P301: Job Descriptions APP-PDxx: Specific Job Descriptions QAM-P105: Quality Manager QAM-P501: Minimum Qualifications QAM-P512: Technical Leaders
(D) 1.1.2.10	Personnel evaluations and objectives	APP-P302: Selection and Promotion APP-P303: Evaluations

(D) 1.1.2.11	Employee complaints concerning the quality system?	APP-306: Grievances and Complaints QAM-P801: Risk Identification QAM-P802: Issue Identification
(I) 1.1.2.12	Does the laboratory have and use an information management system?	QAM-P701: Laboratory Information Management System LIMS Users Manual

ORGANIZATIONAL STRUCTURE		
(D) 1.2.1.1	Does the organizational structure group the work and personnel in a manner that allows for efficiency of operation, taking into account the interrelation of various forensic disciplines?	APP-P110: Organizational Structure APP-P111: Work Content APP-SDxx: Associated Organizational Charts
(D) 1.2.1.2	Has the laboratory director considered and taken appropriate action to correct any discrepancies with regard to numbers of personnel when grouping work and resources?	APP-P110: Organizational Structure

DELEGATION OF AUTHORITY		
(I) 1.2.2.1	Is the laboratory director's authority well defined?	APP-PDxx: Position Description, Director
(I) 1.2.2.2	Does the laboratory director have authority commensurate with responsibilities?	APP-P112: Delegation of Authority
(I) 1.2.2.3	Is there sufficient delegation of authority?	APP-P112: Delegation of Authority APP-F005: Acting Authority Roster
(I) 1.2.2.4	Is the authority of supervisors commensurate with their responsibilities?	APP-P112: Delegation of Authority APP-P113: Supervision
(I) 1.2.2.5	Is each subordinate accountable to one and only one immediate supervisor per function?	APP-P112: Delegation of Authority APP-P113: Supervision
(I) 1.2.2.6	Are performance expectations established and are they understood by laboratory personnel?	APP-P303: Evaluations

SUPERVISION		
(D) 1.3.1.1	Is there constructive discussion between supervisors & subordinates?	APP-P114: Communication APP-P303: Evaluations
(I) 1.3.1.2	Do supervisors carefully & objectively review laboratory activities & personnel?	APP-P303: Evaluations QAM-P314: Examination Report Review QAM-P503: Proficiency Test Evaluations QAM-P505: Testimony Review
(D) 1.3.1.3	Do supervisory techniques encourage creative, objective thinking & recognize meritorious performance?	APP-P113: Supervision

COMMUNICATION		
(D) 1.3.2.1	Does and effective means of communication exist with the laboratory?	APP-P114: Communication

TRAINING AND DEVELOPMENT		
(E) 1.3.3.1	Does the laboratory have and use a documented training program in each functional area for employees who are new, untrained or in need of remedial training?	APP-P311: Training APP-P315: Training Records QAM-P502: Training
(I) 1.3.3.2	Does the laboratory have an employee development program?	APP-P312: Professional Development QAM-P507: Professional Association Affiliation QAM-P508: Professional Meeting Attendance QAM-P509: Professional Training QAM-P510: Continuing Education QAM-P511: Professional Certification
(I) 1.3.3.3	Does the forensic library contain current books, journals & other literature dealing with each functional area?	APP-P313: Literature Resources
(I) 1.3.3.4	Does a system exist to encourage each examiner to review appropriate new literature?	APP-P314: Periodical Circulation

EVIDENCE CONTROL		
(E) 1.4.1.1	Does the laboratory have a written or secure electronic chain of custody record with all necessary data which provides for complete tracking of evidence?	See Sample Control Manual APP-P402: Sample Submission APP-P403: Sample Return APP-P404: Sample Database APP-P407: LIMS QAM-P601: Sample Submission QAM-P602: Sample Transfers QAM-P604: Item, Sub Item Creation QAM-P605: Intra Laboratory Transfer Documentation QAM-P606: Sample Return QAM-P607: Sample Release QAM-P608: Individual Characteristic Database Samples QAM-P701: LIMS
(E) 1.4.1.2	Is all evidence marked for identification?	See Sample Control Manual QAM-P601: Sample Submission
(E) 1.4.1.3	Is evidence stored under proper seal?	See Sample Control Manual QAM-P601: Sample Submission
(E) 1.4.1.4	Is evidence protected from loss, cross transfer, contamination and/or deleterious change?	See Sample Control Manual QAM-P603: Loss, Cross Transfer and Contamination
(E) 1.4.1.5	Is there a secure area for overnight and/or long term storage of evidence?	See Sample Control Manual
(E) 1.4.1.6	Has the laboratory established whether individual characteristic database samples are treated as evidence, reference materials, or examination documentation?	See Sample Control Manual QAM-P608: Individual Characteristic Database Samples
(E) 1.4.1.7	Is each individual characteristic database sample under control of the laboratory uniquely identified?	See Sample Control Manual QAM-P608: Individual Characteristic Database Samples

(E) 1.4.1.8	Are individual characteristic database samples protected from loss, cross transfer, contamination and/or deleterious change?	See Sample Control Manual QAM-P603: Loss, Cross Transfer and Contamination QAM-P608: Individual Characteristic Database Samples
(E) 1.4.1.9	Is access to characteristic database samples restricted to those persons authorized by the laboratory Director?	See Sample Control Manual QAM-P608: Individual Characteristic Database Samples

QUALITY SYSTEM		
(E) 1.4.2.1	Does the laboratory have a comprehensive Quality Manual?	APP-P115: Quality Assurance Program Quality Assurance Manual: In total QAM-P301: Manuals
(E) 1.4.2.2	Is there an individual designated as Quality Manager?	APP-P110: Organizational Structure APP-SDxx: Relevant Organizational Charts QAM-P105: Quality Manager
(E) 1.4.2.3	Did the laboratory conduct and document an annual audit of its operations and submit an annual accreditation audit report to ASCLD/LAB by the required deadline?	QAM-P201: Quality System Audits QAM-P203: Audit Documentation
(E) 1.4.2.4	Does the laboratory conduct and document an annual review of its quality system?	QAM-P201: Quality System Audits QAM-P203: Audit Documentation QAM-P204: Audit Reviews
(E) 1.4.2.5	Are the procedures used generally accepted in the field or supported by data gathered & recorded in a scientific manner?	QAM-P305: Technical Policy Development QAM-P318: Technical Procedure Acceptance
(E) 1.4.2.6	Are new technical procedures scientifically validated before being used in casework and is the validation documentation available for review?	QAM-P305: Technical Policy Development
(E) 1.4.2.7	Are the technical procedures used by the laboratory documented and available to laboratory personnel for review?	APP-P509: Manual Dissemination QAM-P205: Technical Procedure Deviations QAM-P301: Manuals QAM-P306: Technical Policy Dissemination

(E) 1.4.2.8	Are appropriate controls & standards specified in the procedures & are they used and documented in the case record to ensure the validity of examination results?	QAM-P310: Examination Notes
(E) 1.4.2.9	Is the quality of standard samples & reagents adequate for procedures used?	QAM-P409: Expired Chemical Use QAM-P414: Reference Standards and Materials Validation QAM-P415: Reagent Preparation Logs
(E) 1.4.2.10	Does the laboratory routinely check reliability of its reagents?	QAM-P415: Reagent Preparation Logs
(I) 1.4.2.11	Are the instruments/equipment adequate for procedure used?	QAM-P407: External Equipment Use
(I) 1.4.2.12	Are the instruments/equipment in proper working order?	QAM-P402: Measuring Devise Calibration QAM-P403: Instrument Calibration QAM-P404: Instrument Calibration Logs
(E) 1.4.2.13	Are the instruments/equipment properly calibrated?	QAM-P402: Measuring Devise Calibration QAM-P403: Instrument Calibration QAM-P404: Instrument Calibration Logs
(E) 1.4.2.14	Does the laboratory create and maintain a uniquely identified case record for all examination and administrative documentation generated and/or received by the laboratory for each case involving the analysis of evidence?	APP-P401: Case Numbering APP-P506: Document Numbering QAM-P309: Examination Documentation
(E) 1.4.2.15	Does the laboratory's unique case identifier appear on each page o the examination documentation and does the handwritten initials (or secure electronic equivalent) of the persons generating the examination documentation appear on each page generated by that person?	QAM-P310: Examination Notes
(E) 1.4.2.16	Are conclusions and opinions in reports supported by data available in the case record, and are the examination documents sufficiently detailed such that in the absence of the examiner(s) an other competent examiner or supervisor could evaluate what was done and interpret the data?	QAM-P310: Examination Notes QAM-P313: Examination Reports

(E) 1.4.2.17	Is examination documentation of a permanent nature and free of obliterations and erasures?	QAM-P310: Examination Notes
(E) 1.4.2.18	Has each person(s) in the laboratory who issued findings based on the examination documentation generated by another person, completes a review of all relevant pages of examination documentation and documented the review in the case record?	QAM-P313: Examination Reports
(E) 1.4.2.19	Does the laboratory generate written reports for all analytical work performed on evidence, and do the reports contain the conclusions and opinions that address the purpose for which the analytical work was undertaken?	QAM-P313: Examination Reports
(E)1.4.2.20	Where associations are made, is the significance of the association communicated clearly and qualified properly in the report?	QAM-P313: Examination Reports
(E)1.4.2.21	Does the name of the author(s) appear in the report?	QAM-P313: Examination Reports
(E)1.4.2.22	Does the laboratory have, use and document a system of technical review of the reports to ensure that the conclusions of its examiners are reasonable and within the constraints of scientific knowledge?	QAM-P314: Examination Report Review
(E)1.4.2.23	Does the laboratory conduct and document administrative reviews of all reports issued?	QAM-P314: Examination Report Review
(E)1.4.2.24	Does the laboratory monitor the testimony of each examiner at least annually and is the examiner given feedback from the evaluation?	QAM-P505: Testimony Review QAM-P506: Testimony Review Documentation
(E)1.4.2.25	If the laboratory has an indication of a significant technical problem, is there a procedure in writing and in use whereby the laboratory initiates a review and takes any corrective action required?	QAM-P801: Risk Identification QAM-P802: Issue Identification QAM-P803: Corrective Action Reports

PROFICIENCY TESTING		
(E) 1.4.3.1	Does the laboratory have a documented program of proficiency testing?	APP-P303: Evaluations QAM-P503: Proficiency Test Evaluations QAM-P504: Proficiency Test Documentation QAM-P515: Proficiency Test Program

(E) 1.4.3.2	Does the laboratory participate in proficiency testing programs conducted by approved test providers, or by other external providers(s) when no approved provider is available?	QAM-P503: Proficiency Test Evaluations QAM-P515: Proficiency Test Program
(I) 1.4.3.3	Was each examiner proficiency tested annually in each subdiscipline in which casework was performed?	QAM-P503: Proficiency Test Evaluations QAM-P515: Proficiency Test Program
(I) 1.4.3.4.	Does the laboratory conduct proficiency testing using re-examination or blind techniques?	QAM-P515: Proficiency Test Program

MANAGEMENT		
(I) 2.1.1	Does the laboratory director possess degree in a natural science, criminalistics or in a closely related field, or is the laboratory director supported by scientific personnel of sufficient managerial rank & authority?	APP-PDxx: Position Description; Director Statement of Qualifications; Director
(D) 2.1.2	Does the laboratory director have at least 5 years of forensic science experience?	APP-PDxx: Position Description; Director Statement of Qualifications; Director
(D) 2.1.3	Does the laboratory director have some formal training in management?	APP-PDxx: Position Description; Director Statement of Qualifications; Director
(D) 2.1.4	Does the laboratory director have at least 2 years of managerial experience?	APP-PDxx: Position Description; Director Statement of Qualifications; Director

CONTROLLED SUBSTANCES		
(E) 2.2.1	Does each examiner have a Baccalaureate degree in a natural science, criminalistics, or in a closely related field & does each have experience/ training commensurate with the examinations & testimony provided?	APP-PDxx: Position Description; Controlled Substances Statement of Qualifications; Controlled Substance Examiners
(E) 2.2.2	Does each examiner understand the instruments & the methods & procedures used?	QAM-P515: Proficiency Test Program

(E) 2.2.3	Did each examiner successfully complete a competency test prior to assuming casework responsibility?	QAM-P515: Proficiency Test Program
(E) 2.2.4	Did each examiner successfully complete an annual proficiency test?	QAM-P515: Proficiency Test Program

TOXICOLOGY		
(E) 2.3.1	Does each examiner have a Baccalaureate degree in a natural science, toxicology, criminalistics, or in a closely related field & does each have experience/training commensurate with the examinations & testimony provided?	APP-PDxx: Position Description; Toxicology Statement of Qualifications; Toxicology Examiners
(E) 2.3.2	Does each examiner understand the instruments & the methods & procedures used?	QAM-P515: Proficiency Test Program
(E) 2.3.3	Did each examiner successfully complete a competency test prior to assuming casework responsibility?	QAM-P515: Proficiency Test Program
(E) 2.3.4	Did each examiner successfully complete an annual proficiency test?	QAM-P515: Proficiency Test Program

TRACE EVIDENCE		
(E) 2.4.1	Does each examiner have a Baccalaureate degree in a natural science, criminalistics, or in a closely related field & does each have experience/training commensurate with the examinations & testimony provided?	APP-PDxx: Position Description; Trace Evidence Statement of Qualifications; Trace Evidence Examiners
(E) 2.4.2	Does each examiner understand the instruments & methods & procedures used?	QAM-P515: Proficiency Test Program
(E) 2.4.3	Did each examiner successfully complete a competency test in each of the subdisciplines processed prior to assuming casework responsibility?	QAM-P515: Proficiency Test Program

(E) 2.4.4	Did each examiner successfully complete an annual proficiency test?	QAM-P515: Proficiency Test Program

BIOLOGY		
(E) 2.5.1	Does each examiner have a Baccalaureate degree in a natural science, criminalistics, or in a closely related field & does each have experience/ training commensurate with the examinations & testimony provided?	APP-PDxx: Position Description; Biology Statement of Qualifications; Biology Examiners
(E) 2.5.2	Does each examiner performing DNA analysis have education, training and experience consistent with those required by the Quality Assurance Audit Document?	APP-PDxx: Position Description; DNA Statement of Qualifications; DNA Examiners
(E) 2.5.3	Does each examiner understand the instruments & methods & procedures used?	QAM-P515: Proficiency Test Program
(E) 2.5.4	Did each examiner successfully complete a competency test prior to assuming casework responsibility?	QAM-P515: Proficiency Test Program
(E) 2.5.5	Did each examiner successfully complete an annual proficiency test?	QAM-P515: Proficiency Test Program
(E) 2.5.6	Did each examiner performing DNA analysis successfully complete two annual proficiency tests from an approved test provider?	QAM-P515: Proficiency Test Program

FIREARMS/TOOLMARKS		
(I) 2.6.1	Does each examiner have a Baccalaureate degree with science courses?	APP-PDxx: Position Description; Firearms and Toolmarks Statement of Qualifications; Firearms and Toolmark Examiners
(E) 2.6.2	Does each examiner understand the instruments and the methods & procedures used?	QAM-P515: Proficiency Test Program

(E) 2.6.3	Did each examiner have extensive training from a qualified examiner & does each have experience commensurate with the examinations & testimony provided?	QAM-P515: Proficiency Test Program
(E) 2.6.4	Did each examiner successfully complete a competency test prior to assuming casework responsibility?	QAM-P515: Proficiency Test Program
(E) 2.6.5	Did each examiner successfully complete an annual proficiency test?	QAM-P515: Proficiency Test Program

QUESTIONED DOCUMENTS		
(I) 2.7.1	Does each examiner have a Baccalaureate degree with science courses?	APP-PDxx: Position Description; Questioned Documents Statement of Qualifications; Questioned Document Examiners
(E) 2.7.2	Does each examiner understand the instruments & the methods & procedures used?	QAM-P515: Proficiency Test Program
(E) 2.7.3	Did each examiner have extensive training from a qualified examiner & does each have experience commensurate the examinations & testimony provided?	QAM-P515: Proficiency Test Program
(E) 2.7.4	Did each examiner successfully complete a competency test prior to assuming casework responsibility?	QAM-P515: Proficiency Test Program
(E) 2.7.5	Did each examiner successfully complete an annual proficiency test?	QAM-P515: Proficiency Test Program

LATENT PRINTS		
(I) 2.8.1	Does each examiner have a Baccalaureate degree with science courses?	APP-PDxx: Position Description; Latent Prints Statement of Qualifications; Latent Print Examiners
(E) 2.8.2	Does each examiner understand the instruments & the methods & procedures used?	QAM-P515: Proficiency Test Program

(E) 2.8.3	Did each examiner have extensive training from a qualified examiner and does each have experience commensurate the examinations a testimony provided?	QAM-P515: Proficiency Test Program
(E) 2.8.4	Did each examiner successfully complete a competency test prior to assuming casework?	QAM-P515: Proficiency Test Program
(E) 2.8.5	Did each examiner successfully complete an annual proficiency test?	QAM-P515: Proficiency Test Program

TECHNICAL SUPPORT		
(E) 2.9.1	Do technical support personnel meet the requirements of their job descriptions?	APP-PDxx: Position Description; Technical Support Personnel Statement of Qualifications; Technical Support Personnel
(E) 2.9.2	Are the job descriptions & the duties performed in agreement?	APP-PDxx: Position Description; Technical Support Personnel
(E) 2.9.3	Did each member of the technical support staff successfully complete an appropriate competency test prior to assuming casework responsibility?	QAM-P515: Proficiency Test Program
(E) 2.9.4	Did all technical support personnel complete an appropriate proficiency test, annually?	QAM-P515: Proficiency Test Program
(E) 2.9.5	Did DNA analytical support personnel successfully complete two annual proficiency tests from an approved test provider?	QAM-P515: Proficiency Test Program

CRIME SCENE		
(E) 2.10.1	Do examiners meet the requirements of their job descriptions?	APP-PDxx: Position Description; Crime Scene Investigators Statement of Qualifications; Crime Scene Investigatiors
(E) 2.10.2	Does each examiner understand the equipment, methods and procedures used?	QAM-P515: Proficiency Test Program

(E) 2.10.3	Did each examiner have extensive training and experience commensurate with their examinations?	QAM-P515: Proficiency Test Program
(E) 2.10.4	Did each examiner successfully complete a competency test prior to primary responsibility for the examination, documentation and processing of a crime scene?	QAM-P515: Proficiency Test Program
(E) 2.10.5	Did each examiner successfully complete an annual proficiency test?	QAM-P515: Proficiency Test Program

DIGITAL EVIDENCE		
(I) 2.11.1	Does each examiner have a Baccalaureate degree with science courses?	APP-PDxx: Position Description; Digital Evidence Statement of Qualifications; Digital Evidence Examiners
(E) 2.11.2	Does each examiner understand the equipment, programs, methods and procedures used?	QAM-P515: Proficiency Test Program
(E) 2.11.3	Did each examiner have experience commensurate the examinations/ documentation & testimony provided?	QAM-P515: Proficiency Test Program
(E) 2.11.4	Did each examiner successfully complete a competency test in each sub-discipline prior to assuming casework?	QAM-P515: Proficiency Test Program
(E) 2.11.5	Did each examiner successfully complete an annual proficiency test?	QAM-P515: Proficiency Test Program

SPACE		
(I) 3.1.1	Does each employee have adequate work space to accomplish assigned tasks?	APP-P201: Space
(D) 3.1.2	Is there sufficient space provided for storage of supplies, equipment & tools?	APP-P201: Space
(I) 3.1.3	Is there adequate space available for examiners for writing reports & other official communications?	APP-P201: Space

(I) 3.1.4	Is there adequate & appropriate space available for records, reference works & other necessary documents?	APP-P201: Space
(I) 3.1.5	Is there adequate space available for each instrument/equipment to facilitate its operation?	APP-P201: Space
(D) 3.1.6	Are accessories stored near instrumentation/equipment to facilitate its use & operation?	APP-P201: Space

DESIGN		
(I) 3.2.1	Does the physical design permit the efficient flow of evidence from the time of its acceptance until its proper disposal?	APP-P202: Design
(D) 3.2.2	Do the relative locations of functional areas facilitate the use of equipment & instruments?	APP-P202: Design
(I) 3.2.3	Is there adequate & proper lighting available for personnel to carry out assigned tasks?	APP-P202: Design
(I) 3.2.4	Is there adequate & proper plumbing & wiring available & accessible to carry out assigned tasks?	APP-P202: Design
(I) 3.2.5	Does the laboratory have proper general ventilation?	APP-P202: Design
(I) 3.2.6	Is the heating, cooling & humidity control in the laboratory adequate?	APP-P202: Design

SECURITY		
(E) 3.3.1	Is access to the operational area of the laboratory controllable & limited?	APP-P204: Access Control APP-P205: Key Control APP-P601: Authorized Access APP-P602: Escort Policy APP-P603: Entry Log APP-P604: Hours of Operation

(E) 3.3.2	Do all exterior entrance/exit points have adequate security control?	APP-P204: Access Control APP-P206: Alarm Systems
(E) 3.3.3	Do all internal areas requiring limited/controlled access have a lock system?	APP-P204: Access Control APP-P205: Key Control
(E) 3.3.4	Is distribution of all keys, magnetic cards, etc., documented and is distribution limited to those individuals designated by the laboratory director to have access?	APP-P205: Key Control APP-P601: Authorized Access APP-P602: Escort Policy APP-P603: Entry Log APP-P604: Hours of Operation
(E) 3.3.5	Is the laboratory secured during vacant hours by means of an intrusion alarm or by security personnel?	APP-P206: Alarms APP-P605: Alarm Systems APP-P606: Security Staff
(I) 3.3.6	Does the laboratory have a fire detection system?	APP-P206: Alarms APP-P605: Alarm Systems

HEALTH AND SAFETY		
(I) 3.4.1	Does the laboratory have an effective health & safety program documented in a manual?	See Health An Safety Manual
(I) 3.4.2	Is an individual designated as the Health & Safety Manager?	See Health An Safety Manual
(I) 3.4.3	Is the health & safety program monitored regularly & reviewed annually to ensure that its requirements are being?	See Health An Safety Manual
(I) 3.4.4	Does the laboratory have available & encourage the use of safety devices, particularly those required by its health & safety manual?	See Health An Safety Manual
(I) 3.4.5	Does the laboratory have proper equipment & material available for the handling of carcinogenic, toxic and/or other dangerous material spills?	See Health An Safety Manual
(I) 3.4.6	Does the laboratory have safety shower & eye wash equipment in appropriate locations & in good working condition?	See Health An Safety Manual

(I) 3.4.7	Are sufficient exhaust hoods available to maintain a safe work environment?	See Health An Safety Manual
(I) 3.4.8	Are sufficient first aid kits available & strategically located?	See Health An Safety Manual
(I) 3.4.9	Does the laboratory have an adequate number of personnel holding current certification in first aid?	See Health An Safety Manual
(I) 3.4.10	Is appropriate space provided for safe storage of volatile, flammable, explosive & other hazardous materials?	See Health An Safety Manual
(I) 3.4.11	Are the emergency exits from the laboratory adequate for safe exit in an emergency?	See Health An Safety Manual
(D) 3.4.12	Is there general cleanliness & apparent good housekeeping in the laboratory?	See Health An Safety Manual

The signatures below recognize the above Administrative Policy and Procedure is approved and effective the date of the Laboratory Director's signature.

John Smith, Laboratory Director — Date

Mary Doe, Quality Assurance Manager — Date

End Of Document

Appendix M

Administrative Policy/Procedure Association

Doc. #	Rev. #	Description	Status	Related Policy	Related Procedures	Related Forms

Health and Safety Policy/Procedure Association

Doc. #	Rev. #	Description	Status	Related Policy	Related Procedures	Related Forms

Quality Policy/Procedure Association

Doc. #	Rev. #	Description	Status	Related Policy	Related Procedures	Related Forms

Sample Control Policy/Procedure Association

Doc. #	Rev. #	Description	Status	Related Policy	Related Procedures	Related Forms

Technical Methods Policy/Procedure Association

Doc. #	Rev. #	Description	Status	Related Policy	Related Procedures	Related Forms

Appendix N

PROJECT CLOSURE REPORT

Project Name		**Report Date**	
Executive Sponsor		**Department**	
Project Manager		**Depart ID**	

Schedule and Budget			
Planned Start Date		**Actual Start Date**	
Planned End Date		**Actual End Date**	
Planned (Budget) Cost:		**Actual (Total) Cost:**	
• **Professional Services**		• **Professional Services**	
• **Hardware**		• **Hardware**	
• **Software**		• **Software**	
• **Network**		• **Network**	
• **Other**		• **Other**	

Funding Sources				
General Fund	**Other State Funds (Indicate Fund)**	**Internal Svc Funds/ Inter-Agency Transfer**	**Federal Funds (Indicate Grant Number(s))**	**Total**

Scope Verification			
Requirements Review	**Yes**	**No**	**Explanation/ Notes**
Did the delivered product (ex., quality manual and procedures documentation) meet the specified requirements and goals of the project?			
Are the project stakeholders satisfied with the end product(s)? If not, why not?			
Did the project meet budget requirements? If not, why not?			
Was the schedule met? If not, why not?			
Were risks identified and mitigated? If not, why not?			
Was the schedule met? If not, why not?			
Did the project management methodology work? If not, what could have been done to improve the process?			
What bottlenecks or hurdles were experienced that			
Are the stakeholders satisfied with the results?			

Maintenance/Operations			
Are there recurring maintenance/operational costs for the product/service?			$:
Are there any recommended enhancements or updates?			(Attach comments)
Where will the funds come from to pay for the maintenance/operational costs? (Attach comments)			

Business Performance Measures for Project Life-Cycle (Complete for all phases) Comments:			
Phases	**Completion Date**	**Goals/Objectives**	**Results**
Discovery			
Design			
Development			
Quality Assurance			

Project Sign Off:		
The signatures below certify that this project was completed in accordance to the specified budget, schedule, scope, and achieved the intended outcome. Also, the stakeholders are satisfied with the results.		
Stakeholders	**Signature Certifying Results**	**Date**
Executive Sponsor (or Designee)		
Lead Department Head (or Designee)		
Project Manager		

(List the Key Lessons Learned from this Project):		
Comments:		
Project Manager Signature		**Date:**

Project Workbook Information	
The Project workbook allows Project managers, team members, sponsors, and stakeholders to easily track and monitor Project activities. Any of these worksheets can easily be broken out into separate documents.	
Suggested Sheets for All Projects	
A&C	The Assumptions and Constraints sheet allows you to track Project assumptions and constraints.
Action	The Action Items sheet allows you to track and monitor action items assigned to team members. Action items are tasks that must be done but are too insignificant from a time perspective to track in your Project schedule.
Budget	The Budget sheet allows you to track original budget, expenditures to date, and any cost variance.
CBA	The Cost/Benefit Analysis sheet allows you to review the proposed Project and potential alternatives and make a Project selection based on a greater ROI (return on investment).
Chg Log	The Change Control Log sheet allows you to track all change requests that are in process or finalized.
Comm	The Communication Plan sheet allows you to detail your communication plan: how you are going to communicate, whom you will be communicating with, how often, in what format, etc.
Data	Filling out the Data sheet completes the header portion of all remaining sheets in the Project workbook.
Decision	The Decision Log sheet allows you to track all major decisions made during the course of the Project.
Deliver	The Deliverable Acceptance Log sheet allows you to track the status of deliverable acceptances.
Expectations	The Expectations sheet allows you to identify and track the expectations of various stakeholders.
Issues	The Issues Log sheet allows you to identify and monitor Project issues (unplanned events that have happened).
Miles	The Deliverable Milestones sheet allows you to identify major deliverable milestones and the due dates, objectives, assumptions, and constraints relevant to that deliverable milestone.
Minicharter	The Project Minicharter sheet can be used as a charter for small Projects or a summarization of a full charter for larger Projects.
R&R	The Roles and Responsibilities sheet shows the primary role of team members, any deliverables in which they are involved, and the percentage of time they are expected to work on the Project.

RAM	The Resource Assignment Matrix sheet shows you what type of resource is responsible for, or somehow involved with, each deliverable. The tasks listed are samples; you should update the RAM with tasks appropriate for your Project.
RCM	The Resource Commitment Matrix sheet shows how many effort hours each person on the Project has been allocated by month.
Risks	The Risk Management Matrix sheet allows you to identify, qualify, quantify, and prioritize risks (events that might happen; the uncertainty of a Project), create mitigation and contingency plans, and assign risks owners.
Roster	The Roster sheet provides contact information for all those involved on the Project.
Stake	The Stakeholder Analysis sheet allows you to identify stakeholders, their role, and their requirements.
Stoplight	The Stoplight Report sheet contains a status report that can be used to keep sponsors, team members, and stakeholders informed of Project progress.
WBS	The Work Breakdown Structure sheet includes the activities that must be completed during a Project, the effort required, all relevant dates, and the resources assigned to do the work.

PROJECT STATUS REPORT

A. General Information

Information to be provided in this section gives a specific name to the project as well as pertinent information about the personnel involved.

Project Name: _____ *Date:* _____

Controlling Agency: _____ *Modification Date:* _____

Prepared by: _____ *Authorized by:* _____

Project is: **On Plan** **Ahead of Plan** **Behind Plan**

Reporting Period: **From:** **To:**

B. Current Activity Status

Attach any relevant Change Control Requests.

The description of activity should not span more than 2 to 3 lines. Activities should be linked to the project tasks list or Work Breakdown Structure.

C. Significant Accomplishments for Current Period

A summary of the significant accomplishments and project deliverables during the reporting period.

D. Planned Activities for Next Period

The description of activity should not span more than 2 to 3 lines. Activities should be linked to the project tasks list or Work Breakdown Structure.

E. Financial Status

Covers planned versus actual costs and budgets.

	Planned (to date)	Actual (to date)
Costs		
Schedule		
Staffing		
Estimate to Complete (ETC) Review		
Estimate at Completion (EAC Projection)		

F. Technical Status/Issues

Identify technical issues impacting the project. Attach any relevant Issues Documents to this status report.

Discusses any relevant technical issues at this point in the project.

G. Previous Action Items

Covers any open action items from previous status reports.

H. Last Risk Update/Status

Covers any risk status reports since the last status report.

[Insert Project Name]

PROJECT CHARTER

Executive Sponsor – [Insert Name]

Business Owner - [Insert Name]

Project Manager – [Insert Name]

Original Plan Date: [Insert Date, Spelled Out]

Revision Date: [Insert Date, Spelled Out]

Revision: [Insert Number]

CONTENTS

Revision History

Revision Number	Date	Comment
1.0	December 31, 2008	Created
2.0		
2.1		
2.2		

Preparing the Project Charter Document

The Project Charter (Template PM I-1) is a document that the addresses stakeholder needs, clarifies the project objectives and goals, defines the project scope, identifies the duration, budget and funding sources, establishes project governance and formally authorizes the project. The project manager obtains their authority to proceed and manage the project from this document.

In addition to the areas noted above, project charters at a minimum should include information related to the project title and description, assignment of the project manager and team, business objectives success criteria and constraints, business case and approvals of the project sponsor and owners. It is important that all the key stakeholders (i.e. Project Owner, Project Sponsor, and Steering Committee) are in agreement on all of the points above before proceeding to the planning phase.

1 Overview and Summary

2 Objectives

2.1 Project Objectives

2.1.1 Business Objectives

NUMBER	DESCRIPTION
Bus. Objective 1	

2.1.2 Technical Objectives

NUMBER	DESCRIPTION
Tech. Objective 1	

3 Scope

3.1 Scope Statement

3.2 Project Exclusions

3.3 Critical Success Factors

[0] Identify the critical success factors for achieving success in this project. Metric are key to understanding the ability of the project to meet the end goals of the Executive Sponsor and the Business Owner, as well as the ability of the project team to stay within schedule and budget. See also section 6.7 Quality Objectives and Controls.

NUMBER	DESCRIPTION
Quality Metrics 1	

4 Duration and Milestones

Phase	Summary of Phase	Estimated Duration

5 Budget and Funding Sources

5.1 Project Budget

Costs estimates are the costs applied to an activity in a project by assigning resources with associated rates or fees. Resources can include equipment, material, technology, processing cycles, or people. The total cost is critical and should be consistent with the proposal; include breakdowns as needed. Match these cost estimates with the actual billed amounts. Use an appropriate format for the project size and customer requirements (e.g., by WBS, milestone, or deliverable).

Identifier	Work Package or Budget Category	Cost

Phase/Activity	Associated Deliverables	Estimated Budget
Umbrella Tasks		
PHASE 1 Project Preparation & Planning	Project plan Project schedule	
PHASE 2		
PHASE 3		
PHASE 4 Project Closing		

5.2 Funding Sources

6 Alternative Analysis

7 Assumptions, Constraints, and Risks

7.1 Assumptions

Item	Description

7.2 Constraints

Item	Description

7.3 Risks

Item	Description	Impact	Mitigation

8 Project Authority and Organizational Structure

The Project Organization describes the roles and responsibilities of the project team. It also identifies the other organizational groups that are part of the project and graphically depicts the hierarchical configuration of those groups. It exists to clarify interaction with the project team.

8.1 Stakeholders

List all of the major stakeholders in this project, and state why they have a stake. Stakeholders are individuals and organizations that are actively involved in the project, or whose interests may be positively or negatively affected as a result of project execution or project completion. They may also exert influence over the project and its results.

Name	Stake in Project	Organization	Title

8.2 Project Governance Structure

8.2.1 Describe the Organizational Structure – Org Chart

Insert a graphical Organization Chart here. The Organizational Structure (OS) is a hierarchical configuration defining levels of program management and may identify all project personnel. The OS should be simple and straightforward. Include role names and people's names. Consider identifying the core project team by shading their respective boxes on the chart. On complex projects, consider using a second OS to identify core project team. The OS can also be used for management reporting.

8.2.2 Describe the Role and Members of the Project Steering Committee

List the team members, their role, responsibility and functional manager. Make sure to include a comprehensive listing including those from the organization managing the project, business members involved to ensure business objectives are met and the vendor members that may have a specific role.

Role	Responsibility	Name	Functional Area

Attachments

Attachments are included for additional information, but are not formally considered part of the Project Plan for approvals and change management purposes. Examples

- Acronyms, abbreviations, and definitions
- Technical glossary of IT terms
- Project work breakdown schedule
- Project timeline

Approvals

Indicate the status of the charter following submission for approval. List the names and positions of the individuals who must approve the charter, particularly the project sponsor. You may wish to add some descriptive text to make sure all of these individuals agree on what their signature of approval means. For example, approving the charter could mean that the signatory agrees with the content as presented here, agrees to use this charter as a basis for the project, and agrees to keep the information in the charter current and relevant.

Approval Decision:

☐ Approved, development of detailed project plan is authorized
☐ Approved, project execution is authorized
☐ Approved, but project is on hold until future notice
☐ Revise charter and resubmit for approval
☐ Charter and project proposal are rejected

Role or Title	Name and Signature	Date

Change Request

A. General Information

Information to be provided in this section gives a specific name to the project as well as pertinent information about the personnel involved.

Project Name: _____ *Date:* _____

Controlling Agency: _____ *Modification Date:* _____

Prepared By: _____ *Control Number: (From Change Log):* _____

B. Issue Background

Proposed Change Description and References:

The requestor will provide information concerning the requested change along with any supporting documentation.

Justification

Impact of NOT Implementing Proposed Change:

Alternatives:

C. Initial Review Results of Change Request

Initial Review Date:	Assigned to:	
☐ Approve for Impact Analysis	☐ Reject	☐ Defer Until:
Reason:		

D. Initial Impact Analysis

Baselines Affected:			
Configuration Items Affected:			
Cost / Schedule Impact Analysis Required?	Yes ☐	No ☐	
Impact on Cost:			
Impact on Schedule:			
Impact on Resources:			
Final Review Results:			
Review Date:			
Classification:	☐ High	☐ Medium	☐ Low

E. Impact Analysis Results

Specific Requirements Definition

Additional Resource Requirements	*Work Days*	*Cost*
Total		

Impact of NOT Implementing Proposed Change:

Alternative to the Proposed Changes:

Final Recommendation:

E. Signatures

The signatures of the people below relay an understanding in the purpose and content of this document by those signing it.

Name/Title	Signature	Date

Impact Analysis Checklist for Change Request

Implications of the Proposed Change

— Identify any existing requirements in the baseline that conflict with the proposed change.
— Identify any other pending requirement changes that conflict with the proposed change.
— What are the consequences of not making the change?
— What are possible adverse side effects or other risks of making the proposed change?
— Will the proposed change adversely affect performance requirements or other quality attributes?
— Will the change affect any system component that affects critical properties such as safety and security, or involve a product change that triggers recertification of any kind?
— Is the proposed change feasible within known technical constraints and current staff skills?
— Will the proposed change place unacceptable demands on any computer resources required for the development, test, or operating environments?
— Must any tools be acquired to implement and test the change?
— How will the proposed change affect the sequence, dependencies, effort, or duration of any tasks currently in the project plan?
— Will prototyping or other user input be required to verify the proposed change?
— How much effort that has already been invested in the project will be lost if this change is accepted?
— Will the proposed change cause an increase in product unit cost, such as by increasing third-party product licensing fees?
— Will the change affect any marketing, manufacturing, training, or customer support plans?

System Elements Affected by the Proposed Change

— Identify any user interface changes, additions, or deletions required.
— Identify any changes, additions, or deletions required in reports, databases, or data files.
— Identify the design components that must be created, modified, or deleted.
— Identify hardware components that must be added, altered, or deleted.
— Identify the source code files that must be created, modified, or deleted.
— Identify any changes required in build files.
— Identify existing unit, integration, system, and acceptance test cases that must be modified or deleted.
— Estimate the number of new unit, integration, system, and acceptance test cases that will be required.
— Identify any help screens, user manuals, training materials, or other documentation that must be created or modified.
— Identify any other systems, applications, libraries, or hardware components affected by the change.

— Identify any third party software that must be purchased.
— Identify any impact the proposed change will have on the project's software project management plan, software quality assurance plan, software configuration management plan, or other plans.
— Quantify any effects the proposed change will have on budgets of scarce resources, such as memory, processing power, network bandwidth, real-time schedule.
— Identify any impact the proposed change will have on fielded systems if the affected component is not perfectly backward compatible.

Effort Estimation for a Requirements Change

Effort (Labor Hours)	Task
_____	Update the SRS or requirements database with the new requirement
_____	Develop and evaluate prototype
_____	Create new design components
_____	Modify existing design components
_____	Develop new user interface components
_____	Modify existing user interface components
_____	Develop new user publications and help screens
_____	Modify existing user publications and help screens
_____	Develop new source code
_____	Modify existing source code
_____	Purchase and integrate third party software
_____	Identify, purchase, and integrate hardware components; qualify vendor
_____	Modify build files
_____	Develop new unit and integration tests
_____	Modify existing unit and integration tests
_____	Perform unit and integration testing after implementation
_____	Write new system and acceptance test cases
_____	Modify existing system and acceptance test cases
_____	Modify automated test drivers
_____	Perform regression testing at unit, integration, and system levels
_____	Develop new reports
_____	Modify existing reports
_____	Develop new database elements
_____	Modify existing database elements
_____	Develop new data files
_____	Modify existing data files
_____	Modify various project plans
_____	Update other documentation

Effort (Labor Hours)	Task
_____	Update requirements traceability matrix
_____	Review modified work products
_____	Perform rework following reviews and testing
_____	Recertify product as being safe, secure, and compliant with standards.
_____	Other additional tasks
_____	**TOTAL ESTIMATED EFFORT**

Procedure:

1. Identify the subset of the above tasks that will have to be done.
2. Allocate resources to tasks.
3. Estimate effort required for pertinent tasks listed above, based on assigned resources.
4. Total the effort estimates.
5. Sequence tasks and identify predecessors.
6. Determine whether change is on the project's critical path.
7. Estimate schedule and cost impact.

Impact Analysis Report Template

Change Request ID: _____

Title: _____

Description: _____

_____

Analyst: _____

Date Prepared: _____

Prioritization Estimates:

- Relative Benefit: _____ (1–9)
- Relative Penalty: _____ (1–9)
- Relative Cost: _____ (1–9)
- Relative Risk: _____ (1–9)
- Calculated Priority: _____ (relative to other pending requirements)

Estimated total effort: _____ labor hours

Estimated lost effort: _____ labor hours (from discarded work)

Estimated schedule impact: _____ days

Additional cost impact: _____ dollars

Quality impact: _____

_____

Other requirements affected:

_____

_____

Other tasks affected: _____

_____

Integration issues: _____

Life cycle cost issues: _____

Other components to examine _____

for possible changes: _____

ISSUE NOTIFICATION

A. General Information

Information to be provided in this section gives a specific name to the project as well as pertinent information about the personnel involved.

Project Name: _____ *Date:* _____

Controlling Agency: _____ *Modification Date:* _____

Prepared by: _____ *Issue Number : (From Issue Log):* _____

B. Issue Background

Issue Type (check one):

Request for Information	**System Problem**
Procedural Problem	**Other**
(Specify)	

Date Resolution Needed: **Proposed Assignee:** **Attachments (if any):** **Reviewer:** **Reviewer Completion Date:** **Reviewer Comments:**	**YES** **NO**

Issue Description:

Initial Recommendation:

Potential Impact (if not resolved):

Cost / Schedule Impact Analysis Required? **Yes** **No**
Estimate of Additional Effort:

Resources Required	Work Days/Costs

C. Recommendation

Final Recommendation and Comments:

Name/Title	Signature	Date
(Project Manager)		

D. Management Action

Recommendation status (check one):

Accept	**Defer**	**Need Additional Information**	**Reject**
Assigned to:		**Organization:**	
Planned Completion Date:			

E. Signatures

The signatures of the people below relay an understanding in the purpose and content of this document by those signing it.

Name/Title	Signature	Date

[Insert Project Name]

Project Management Plan (PMP)

Executive Sponsor – [Insert Name]
Business Owner - [Insert Name]
Project Manager – [Insert Name]
Original Plan Date: [Insert Date, Spelled Out]
Revision Date: [Insert Date, Spelled Out]
Revision: [Insert Number]

CONTENTS

Revision History

Revision Number	Date	Comment
1.0	January 1, 2008	Created
2.0		
2.1		
2.2		

Preparing the Project Management Plan

The workbook for preparation of the Project Management Plan is built around helping the project manager and the project team to use the Project Management Plan in support of successful projects. Please refer to it while developing this PMP for your project.

About This Document

"Project management plan" is a formal document approved by the project sponsor, business owner and other key stakeholders. It is developed during the Planning phase and is used to manage project execution, control, and project close.

The primary uses of the project plan are to document planning assumptions and decisions, facilitate communication among stakeholders, and documents approved scope, cost and schedule baselines.

1 Project Overview

The Project Overview sets the stage for the details of the project and begins the "story" of the project and plan.

Copy this information from the Project Charter.

1.1 Executive Summary - Rationale for the Project

1.2 Funding and Sources

Source	Amount	Associated Restrictions	Approvers

1.3 Constraints

Constraints are factors that restrict the project by scope, resource, or schedule.

Number	Description

1.4 Dependencies

Types include the following and should be associated with each dependency listed.

- **M**andatory dependencies are dependencies that are inherent to the work being done.
- **D- D**iscretionary dependencies are dependencies defined by the project management team. This may also encompass particular approaches because a specific sequence of activities is preferred, but not mandatory in the project life cycle.
- **E-E**xternal dependencies are dependencies that involve a relationship between project activities and non-project activities such as purchasing/procurement

Number	Description	Type M,D,E

1.5 Assumptions

Assumptions are planning factors that, for planning purposes, will be considered true, real, or certain.

Number	Description

1.6 Initial Project Risks Identified

In this section identify and describe how each risk will be managed. Include the steps that will be taken to maximize activity that will result in minimizing probability and impact of each risk.

[Risk 1 Name]

Description - [0]	Probability	Impact
	Mitigation Strategy	
	Contingency Plan	

[Risk 2 Name]

Description - [0]	Probability	Impact
	Mitigation Strategy	
	Contingency Plan	

2 Project Authority and Organizational Structure

The Project Organization describes the roles and responsibilities of the project team. It also identifies the other organizational groups that are part of the project and graphically depicts the hierarchical configuration of those groups. It exists to clarify interaction with the project team.

2.1 Stakeholders

List all of the major stakeholders in this project, and state why they have a stake. Stakeholders are individuals and organizations that are actively involved in the project, or whose interests may be positively or negatively affected as a result of project execution or project completion. They may also exert influence over the project and its results.

Name	Stake in Project	Organization	Title

2.2 Project Governance Structure

2.2.1 Describe the Organizational Structure – Org Chart

2.2.2 Describe the Role and Members of the Project Steering Committee

2.2.3 Organizational Boundaries, Interfaces, and Responsibilities

Use this section to describe any special considerations regarding contact between the project team, the project manager, and individuals from various organizations involved in the project: Boundary, interface and responsibilities at the interface.

2.3 Executive Reporting

3 Scope

3.1 Project Objectives

3.1.1 Business Objectives

Number	Description
Bus. Objective 1	

3.1.2 Technical Objectives

Number	Description
Tech. Objective 1	

3.2 Project Exclusions

3.3 Critical Success Factors

Identify the critical success factors for achieving success in this project. Metric are key to understanding the ability of the project to meet the end goals of the Executive Sponsor and the Business Owner, as well as the ability of the project team to stay within schedule and budget. See also section 6.7 Quality Objectives and Controls.

Number	Description
Quality Metrics 1	

4 Project Deliverables and Phases

4.1 Project Phases (ex., Analysis, Design, Development, Testing, Transition)

Phase	Summary of Phase	Key Deliverables

4.2 Project Deliverables

4.2.1 Project Management Deliverables

Project Deliverables are work products or artifacts that are driven by the project management methodology requirements and standard project management practices regardless of the product requirements of the project.

4.2.1.1 [Deliverable 1 Name]

Description -	Deliverable Acceptance Criteria
	Standards for Content and Format -
	Quality Review -.

4.2.1.2 [Deliverable 2 Name]

Description -	Deliverable Acceptance Criteria -
	Standards for Content and Format -
	Quality Review -

4.2.2 Deliverable Approval Authority Designations

Complete the following table to identify the deliverables this project is to produce, and to name the person or persons who have authority to approve each deliverable.

Deliverable Number	Deliverable	Approvers (Who can approve)	Date Approved
PRJ-DEL-001	Project Management Plan (PMP)		

4.3.1 Deliverable Acceptance Procedure

Describe the process that this project will use for the formal acceptance of all deliverables.

5 Project Work

5.1 Work Breakdown Structure (WBS)

A WBS is a deliverable-oriented grouping of project elements that organizes and defines the total work scope of the project. Describe the work activities that comprise the work breakdown structure (WBS) or the work packages within the WBS. Identify the WBS element or other work package identifier and provide a general description of the tasks or activities, the definition or objectives, and the milestones and deliverables of each work package.

Use the chart below for highest level presentation, and provide a more detailed WBS as an attachment to this project plan.

Identifier	Work Package Description	Definition/ Objective	Milestone/ Deliverable

5.2 Schedule Allocation - Project Timeline

The project timeline is a high-level view of project activities with a focus on project milestones. The project timeline does not replace the need for a detailed project schedule and it is to highlight key events such as deliverable due dates and when go/no-go decisions are made.

The table below should provide a high level view of the project time line, or a summary-level Gantt chart can be used to meet the timeline requirement.

Please provide a more detailed project schedule as an attachment to this plan

Identifier	Task/ Activity Name	Resource Name	Milestone (Y/N)	Effort/ Duration	Start	Finish	Dependent Task

5.3 Project Budget

Costs estimates are the costs applied to an activity in a project by assigning resources with associated rates or fees. Resources can include equipment, material, technology, processing cycles, or people. The total cost is critical and should be consistent with the proposal; include breakdowns as needed. Match these cost estimates with the actual billed amounts. Use an appropriate format for the project size and customer requirements (e.g., by WBS, milestone, or deliverable).

Identifier	Work Package or Budget Category	Cost

Or..

Phase/Activity	Associated Deliverables	Estimated Budget
Umbrella Tasks		
Phase 1 Project Preparation & Planning	Project plan Project schedule	
Phase 2		
Phase 3		
Phase 4 Project Closing		
TOTALS		

5.4 Project Team

5.4.1 Project Team Organizational Structure

Insert a graphical Organization Chart here. The Organizational Structure (OS) is a hierarchical configuration defining levels of program management and may identify all project personnel. The OS should be simple and straightforward. Include role names and people's names. Consider identifying the core project team by shading their respective boxes on the chart. On complex projects, consider using a second OS to identify core project team. The OS can also be used for management reporting.

5.4.2 Project Team Roles and Responsibilities

List the team members, their role, responsibility and functional manager. Make sure to include a comprehensive listing including those from the organization managing the project, business members involved to ensure business objectives are met and the vendor members that may have a specific role.

Role	Responsibility	Name	Functional Area

5.5 Staff Planning and Resource Acquisition

Complete the chart below identifying the project team members and details concerning their project commitment. Project staff should include State, Contract, Customer (Business Owner), or Vendor team members

5.5.1 Project Staff

Resource	Cost Estimate	Estimated Hours	Availability	Skill Set	Work Product/ Deliverable

5.5.2 Non-Personnel Resources

Use this section to list services or product (HW/SW and such) needed for project

Resource	Cost Estimate	Estimated Units/Hours	Availability	Source	Work Product/ Deliverable

5.6 Project Logistics

Logistics describes how the project manager, project team, the business owner/customer and any vendor resources will physically work together. Include anything to do with moving or starting resources. Training specifically related to project team members should be included here.

5.6.1 Project Team Training

Describe training if any needed by project team members. This is not to include training for end users, system administrators or business owners; those should be handled within a training document or part of the transition to operations planning.

Resource	Cost Estimate	Estimated Hours	Availability	Skill Set	Work Product/ Deliverable

6 Project Management and Controls

6.1 Change Management Plan

Describe the process that is going to be used to manage the scope of the project. Make sure to address managing stakeholder expectations.

6.1.1 Change Control

6.1.1.1 Change Control Process Change Control establishes how change will be managed, including capturing, tracking, communicating, and resolving change. Due to much ambiguity regarding change, it is vital that we document and discuss the change process with the executive sponsor.

6.1.1.2 Change Control Board (CCB) Insert a graphic or textual description identifying the Change Control Board (or function) for this project. The CCB may be an individual or group of individuals authorized to approve changes to the project plan.

6.2 Risk and Issue Management

PMBOK©:
Risk: "An uncertain event or condition that, if it occurs, has a positive or negative effect on a project's objectives."
Issue: "A point or matter in question or dispute, or a point or matter that is not settled and is under discussion or over which there are opposing views or disagreements."
Both Risks and Issues can significant impact a project's success, and both should be handled in similar ways.

6.2.1 Risk Management Strategy

Provide a detailed explanation on the strategy for how risks are identified, analyzed/ quantified, mitigated, reported, escalated and tracked. Include the use of tools such as project management software, forms, and templates. A separate risk management plan may also be developed if needed for the project and included as an Appendix to this document. If that is the case, a high level summary of this plan needs to be included here with the specific reference.

6.2.2 Project Risk Identification

6.2.3 Project Risk Mitigation Approach

6.2.4 Risk Reporting and Escalation Strategy

6.2.5 Project Risk Tracking Approach

6.2.6 Internal Issue Escalation and Resolution Process

This internal process is provided for issues that involve project resources, processes, procedures, or methodology that should be resolved within the Division that is responsible for managing the project without affecting the overall project schedule, cost, or quality. This process should be used for improving project processes as the project is executed and where the implementation of such improvements should not be postponed to Lessons Learned during Project Close.

6.2.7 External Issue Escalation and Resolution Process

The external process is provided for issues that involve project resources, processes, procedures, or methodology that cannot be resolved within the Division that is responsible for managing the project without affecting the overall project schedule, cost, or quality.

6.3 Issue Management

Issue Management (or corrective action management) describes the project's process for managing project issues. Issues are generated by things like unmediated disputes, unaddressed concerns, and unresolved decision-making. Issues arise in all Project Phases and may have tremendous negative impacts on the project if not addressed properly.

6.3.1 Process for Raising an Issue

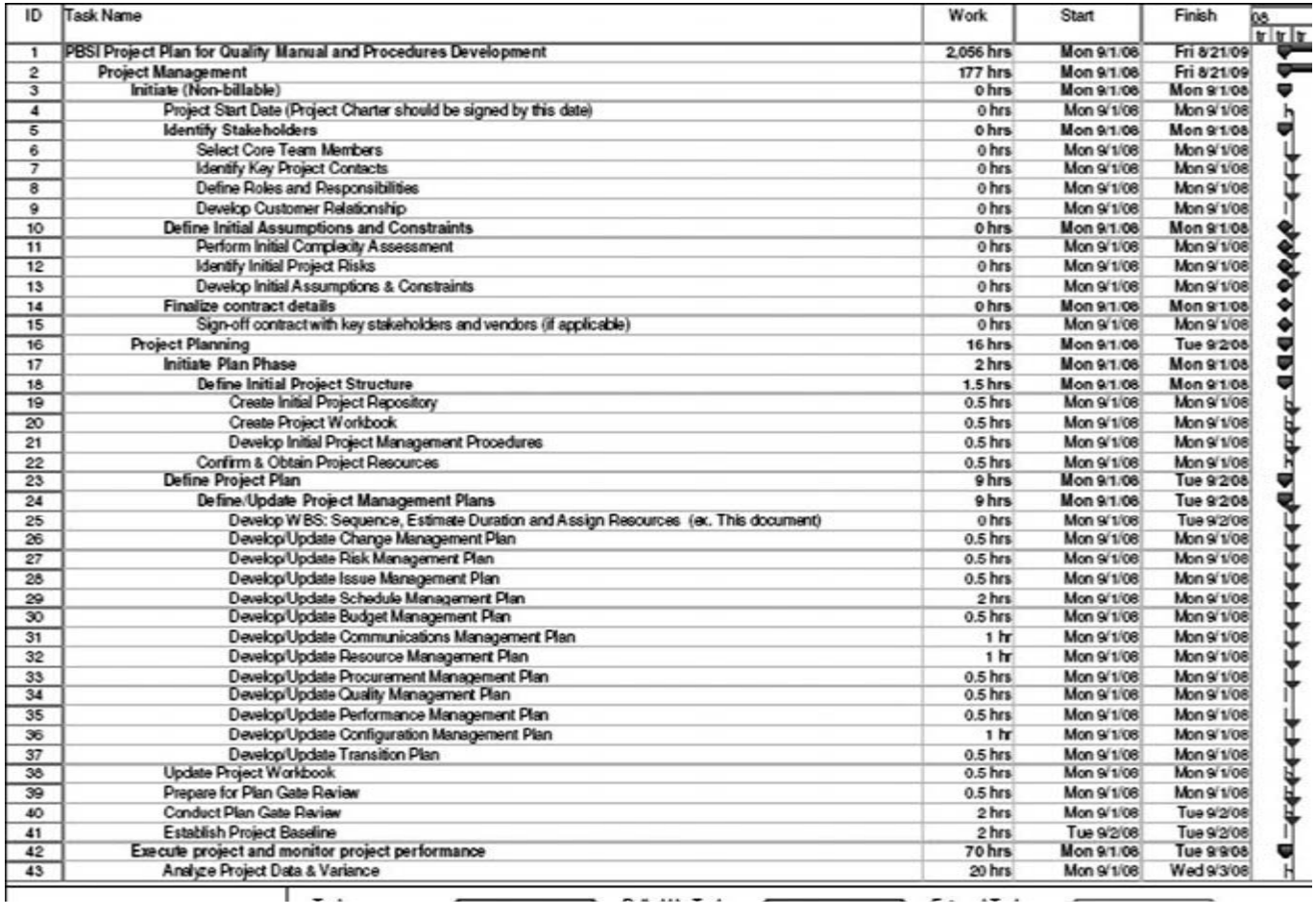
6.3.2 Process for Logging and Tracking Issues

6.3.3 Describe How Issues Are Assigned for Evaluation and Planning of Resolution

6.3.4 Process for Implementing Issue Resolution Actions

6.4 Schedule Management

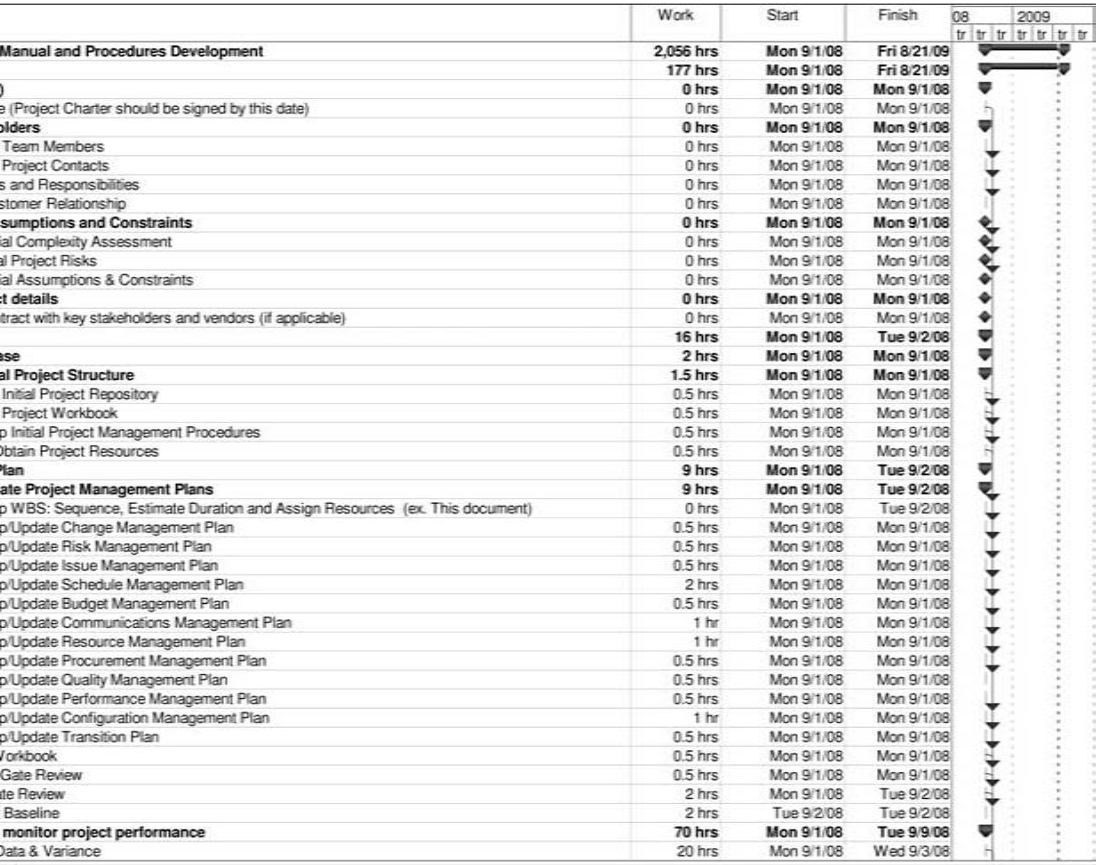
The schedule management plan establishes how schedule management will be carried out in the project. It serves as guidance for the scheduling process and formats and defines the roles and responsibilities for stakeholders in those processes. It is not the detailed schedule information (that will be included in your GANTT Chart, Microsoft Excel Spreadsheet or other tool) but instead explains how that information will be captured, expressed, and modified (if or when necessary.) Because it is integrated with other baseline issues (including cost, requirements, and risk), the schedule management plan should be coordinated with any management plans that have been developed for those areas.



ID	Task Name	Work	Start	Finish
1	PBSI Project Plan for Quality Manual and Procedures Development	2,056 hrs	Mon 9/1/08	Fri 8/21/09
2	Project Management	177 hrs	Mon 9/1/08	Fri 8/21/09
3	Initiate (Non-billable)	0 hrs	Mon 9/1/08	Mon 9/1/08
4	Project Start Date (Project Charter should be signed by this date)	0 hrs	Mon 9/1/08	Mon 9/1/08
5	Identify Stakeholders	0 hrs	Mon 9/1/08	Mon 9/1/08
6	Select Core Team Members	0 hrs	Mon 9/1/08	Mon 9/1/08
7	Identify Key Project Contacts	0 hrs	Mon 9/1/08	Mon 9/1/08
8	Define Roles and Responsibilities	0 hrs	Mon 9/1/08	Mon 9/1/08
9	Develop Customer Relationship	0 hrs	Mon 9/1/08	Mon 9/1/08
10	Define Initial Assumptions and Constraints	0 hrs	Mon 9/1/08	Mon 9/1/08
11	Perform Initial Complexity Assessment	0 hrs	Mon 9/1/08	Mon 9/1/08
12	Identify Initial Project Risks	0 hrs	Mon 9/1/08	Mon 9/1/08
13	Develop Initial Assumptions & Constraints	0 hrs	Mon 9/1/08	Mon 9/1/08
14	Finalize contract details	0 hrs	Mon 9/1/08	Mon 9/1/08
15	Sign-off contract with key stakeholders and vendors (if applicable)	0 hrs	Mon 9/1/08	Mon 9/1/08
16	Project Planning	16 hrs	Mon 9/1/08	Tue 9/2/08
17	Initiate Plan Phase	2 hrs	Mon 9/1/08	Mon 9/1/08
18	Define Initial Project Structure	1.5 hrs	Mon 9/1/08	Mon 9/1/08
19	Create Initial Project Repository	0.5 hrs	Mon 9/1/08	Mon 9/1/08
20	Create Project Workbook	0.5 hrs	Mon 9/1/08	Mon 9/1/08
21	Develop Initial Project Management Procedures	0.5 hrs	Mon 9/1/08	Mon 9/1/08
22	Confirm & Obtain Project Resources	0.5 hrs	Mon 9/1/08	Mon 9/1/08
23	Define Project Plan	9 hrs	Mon 9/1/08	Tue 9/2/08
24	Define/Update Project Management Plans	9 hrs	Mon 9/1/08	Tue 9/2/08
25	Develop WBS: Sequence, Estimate Duration and Assign Resources (ex. This document)	0 hrs	Mon 9/1/08	Tue 9/2/08
26	Develop/Update Change Management Plan	0.5 hrs	Mon 9/1/08	Mon 9/1/08
27	Develop/Update Risk Management Plan	0.5 hrs	Mon 9/1/08	Mon 9/1/08
28	Develop/Update Issue Management Plan	0.5 hrs	Mon 9/1/08	Mon 9/1/08
29	Develop/Update Schedule Management Plan	2 hrs	Mon 9/1/08	Mon 9/1/08
30	Develop/Update Budget Management Plan	0.5 hrs	Mon 9/1/08	Mon 9/1/08
31	Develop/Update Communications Management Plan	1 hr	Mon 9/1/08	Mon 9/1/08
32	Develop/Update Resource Management Plan	1 hr	Mon 9/1/08	Mon 9/1/08
33	Develop/Update Procurement Management Plan	0.5 hrs	Mon 9/1/08	Mon 9/1/08
34	Develop/Update Quality Management Plan	0.5 hrs	Mon 9/1/08	Mon 9/1/08
35	Develop/Update Performance Management Plan	0.5 hrs	Mon 9/1/08	Mon 9/1/08
36	Develop/Update Configuration Management Plan	1 hr	Mon 9/1/08	Mon 9/1/08
37	Develop/Update Transition Plan	0.5 hrs	Mon 9/1/08	Mon 9/1/08
38	Update Project Workbook	0.5 hrs	Mon 9/1/08	Mon 9/1/08
39	Prepare for Plan Gate Review	0.5 hrs	Mon 9/1/08	Mon 9/1/08
40	Conduct Plan Gate Review	2 hrs	Mon 9/1/08	Tue 9/2/08
41	Establish Project Baseline	2 hrs	Tue 9/2/08	Tue 9/2/08
42	Execute project and monitor project performance	70 hrs	Mon 9/1/08	Tue 9/9/08
43	Analyze Project Data & Variance	20 hrs	Mon 9/1/08	Wed 9/3/08

GANTT Chart.

ID	Task Name	Work	Start	Finish
1	**PBSI Project Plan for Quality Manual and Procedures Development**	**2,056 hrs**	**Mon 9/1/08**	**Fri 8/21/09**
2	**Project Management**	**177 hrs**	**Mon 9/1/08**	**Fri 8/21/09**
3	**Initiate (Non-billable)**	**0 hrs**	**Mon 9/1/08**	**Mon 9/1/08**
4	Project Start Date (Project Charter should be signed by this date)	0 hrs	Mon 9/1/08	Mon 9/1/08
5	**Identify Stakeholders**	**0 hrs**	**Mon 9/1/08**	**Mon 9/1/08**
6	Select Core Team Members	0 hrs	Mon 9/1/08	Mon 9/1/08
7	Identify Key Project Contacts	0 hrs	Mon 9/1/08	Mon 9/1/08
8	Define Roles and Responsibilities	0 hrs	Mon 9/1/08	Mon 9/1/08
9	Develop Customer Relationship	0 hrs	Mon 9/1/08	Mon 9/1/08
10	**Define Initial Assumptions and Constraints**	**0 hrs**	**Mon 9/1/08**	**Mon 9/1/08**
11	Perform Initial Complexity Assessment	0 hrs	Mon 9/1/08	Mon 9/1/08
12	Identify Initial Project Risks	0 hrs	Mon 9/1/08	Mon 9/1/08
13	Develop Initial Assumptions & Constraints	0 hrs	Mon 9/1/08	Mon 9/1/08
14	**Finalize contract details**	**0 hrs**	**Mon 9/1/08**	**Mon 9/1/08**
15	Sign-off contract with key stakeholders and vendors (if applicable)	0 hrs	Mon 9/1/08	Mon 9/1/08
16	**Project Planning**	**16 hrs**	**Mon 9/1/08**	**Tue 9/2/08**
17	**Initiate Plan Phase**	**2 hrs**	**Mon 9/1/08**	**Mon 9/1/08**
18	**Define Initial Project Structure**	**1.5 hrs**	**Mon 9/1/08**	**Mon 9/1/08**
19	Create Initial Project Repository	0.5 hrs	Mon 9/1/08	Mon 9/1/08
20	Create Project Workbook	0.5 hrs	Mon 9/1/08	Mon 9/1/08
21	Develop Initial Project Management Procedures	0.5 hrs	Mon 9/1/08	Mon 9/1/08
22	Confirm & Obtain Project Resources	0.5 hrs	Mon 9/1/08	Mon 9/1/08
23	**Define Project Plan**	**9 hrs**	**Mon 9/1/08**	**Tue 9/2/08**
24	**Define/Update Project Management Plans**	**9 hrs**	**Mon 9/1/08**	**Tue 9/2/08**
25	Develop WBS: Sequence, Estimate Duration and Assign Resources (ex. This document)	0 hrs	Mon 9/1/08	Tue 9/2/08
26	Develop/Update Change Management Plan	0.5 hrs	Mon 9/1/08	Mon 9/1/08
27	Develop/Update Risk Management Plan	0.5 hrs	Mon 9/1/08	Mon 9/1/08
28	Develop/Update Issue Management Plan	0.5 hrs	Mon 9/1/08	Mon 9/1/08
29	Develop/Update Schedule Management Plan	2 hrs	Mon 9/1/08	Mon 9/1/08
30	Develop/Update Budget Management Plan	0.5 hrs	Mon 9/1/08	Mon 9/1/08
31	Develop/Update Communications Management Plan	1 hr	Mon 9/1/08	Mon 9/1/08
32	Develop/Update Resource Management Plan	1 hr	Mon 9/1/08	Mon 9/1/08
33	Develop/Update Procurement Management Plan	0.5 hrs	Mon 9/1/08	Mon 9/1/08
34	Develop/Update Quality Management Plan	0.5 hrs	Mon 9/1/08	Mon 9/1/08
35	Develop/Update Performance Management Plan	0.5 hrs	Mon 9/1/08	Mon 9/1/08
36	Develop/Update Configuration Management Plan	1 hr	Mon 9/1/08	Mon 9/1/08
37	Develop/Update Transition Plan	0.5 hrs	Mon 9/1/08	Mon 9/1/08
38	Update Project Workbook	0.5 hrs	Mon 9/1/08	Mon 9/1/08
39	Prepare for Plan Gate Review	0.5 hrs	Mon 9/1/08	Mon 9/1/08
40	Conduct Plan Gate Review	2 hrs	Mon 9/1/08	Tue 9/2/08
41	Establish Project Baseline	2 hrs	Tue 9/2/08	Tue 9/2/08
42	**Execute project and monitor project performance**	**70 hrs**	**Mon 9/1/08**	**Tue 9/9/08**
43	Analyze Project Data & Variance	20 hrs	Mon 9/1/08	Wed 9/3/08



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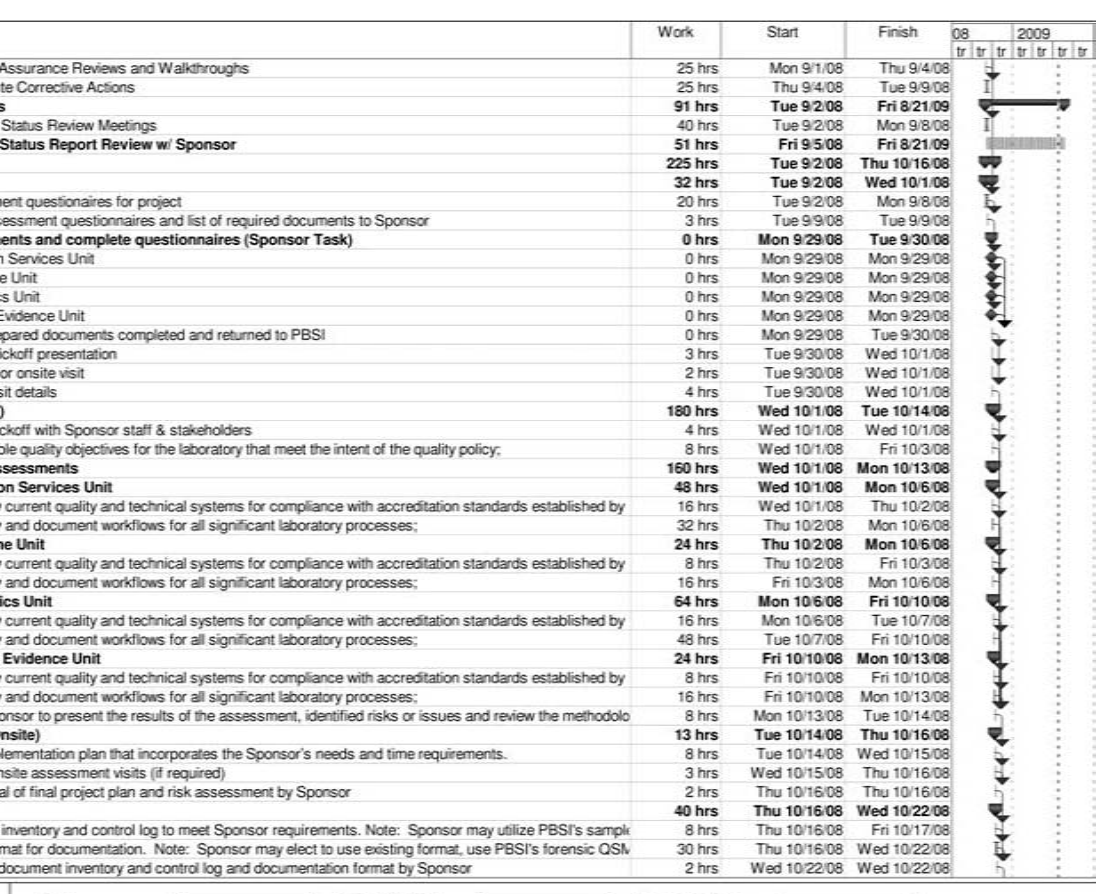
ID	Task Name	Work	Start	Finish
44	Conduct Quality Assurance Reviews and Walkthroughs	25 hrs	Mon 9/1/08	Thu 9/4/08
45	Develop & Execute Corrective Actions	25 hrs	Thu 9/4/08	Tue 9/9/08
46	**Communicate Status**	**91 hrs**	**Tue 9/2/08**	**Fri 8/21/09**
47	Conduct Internal Status Review Meetings	40 hrs	Tue 9/2/08	Mon 9/8/08
48	**Weekly Project Status Report Review w/ Sponsor**	**51 hrs**	**Fri 9/5/08**	**Fri 8/21/09**
100	**Analysis**	**225 hrs**	**Tue 9/2/08**	**Thu 10/16/08**
101	**Pre-Assessment**	**32 hrs**	**Tue 9/2/08**	**Wed 10/1/08**
102	Finalize assessment questionaires for project	20 hrs	Tue 9/2/08	Mon 9/8/08
103	Mail SPDCL assessment questionnaires and list of required documents to Sponsor	3 hrs	Tue 9/9/08	Tue 9/9/08
104	**Compile documents and complete questionnaires (Sponsor Task)**	**0 hrs**	**Mon 9/29/08**	**Tue 9/30/08**
105	Identification Services Unit	0 hrs	Mon 9/29/08	Mon 9/29/08
106	Crime Scene Unit	0 hrs	Mon 9/29/08	Mon 9/29/08
107	Criminalistics Unit	0 hrs	Mon 9/29/08	Mon 9/29/08
108	Property & Evidence Unit	0 hrs	Mon 9/29/08	Mon 9/29/08
109	Sponsor prepared documents completed and returned to PBSI	0 hrs	Mon 9/29/08	Tue 9/30/08
110	Finalize project kickoff presentation	3 hrs	Tue 9/30/08	Wed 10/1/08
111	Finalize agenda for onsite visit	2 hrs	Tue 9/30/08	Wed 10/1/08
112	Finalize onsite visit details	4 hrs	Tue 9/30/08	Wed 10/1/08
113	**Assessment (Onsite)**	**180 hrs**	**Wed 10/1/08**	**Tue 10/14/08**
114	Coduct project kickoff with Sponsor staff & stakeholders	4 hrs	Wed 10/1/08	Wed 10/1/08
115	Identify measurable quality objectives for the laboratory that meet the intent of the quality policy;	8 hrs	Wed 10/1/08	Fri 10/3/08
116	**Conduct unit assessments**	**160 hrs**	**Wed 10/1/08**	**Mon 10/13/08**
117	**Identification Services Unit**	**48 hrs**	**Wed 10/1/08**	**Mon 10/6/08**
118	Review current quality and technical systems for compliance with accreditation standards established by	16 hrs	Wed 10/1/08	Thu 10/2/08
119	Identify and document workflows for all significant laboratory processes;	32 hrs	Thu 10/2/08	Mon 10/6/08
120	**Crime Scene Unit**	**24 hrs**	**Thu 10/2/08**	**Mon 10/6/08**
121	Review current quality and technical systems for compliance with accreditation standards established by	8 hrs	Thu 10/2/08	Fri 10/3/08
122	Identify and document workflows for all significant laboratory processes;	16 hrs	Fri 10/3/08	Mon 10/6/08
123	**Criminalistics Unit**	**64 hrs**	**Mon 10/6/08**	**Fri 10/10/08**
124	Review current quality and technical systems for compliance with accreditation standards established by	16 hrs	Mon 10/6/08	Tue 10/7/08
125	Identify and document workflows for all significant laboratory processes;	48 hrs	Tue 10/7/08	Fri 10/10/08
126	**Property & Evidence Unit**	**24 hrs**	**Fri 10/10/08**	**Mon 10/13/08**
127	Review current quality and technical systems for compliance with accreditation standards established by	8 hrs	Fri 10/10/08	Fri 10/10/08
128	Identify and document workflows for all significant laboratory processes;	16 hrs	Fri 10/10/08	Mon 10/13/08
129	Meet with the Sponsor to present the results of the assessment, identified risks or issues and review the methodolo	8 hrs	Mon 10/13/08	Tue 10/14/08
130	**Post Assessment (Onsite)**	**13 hrs**	**Tue 10/14/08**	**Thu 10/16/08**
131	Develop final implementation plan that incorporates the Sponsor's needs and time requirements.	8 hrs	Tue 10/14/08	Wed 10/15/08
132	Plan additional onsite assessment visits (if required)	3 hrs	Wed 10/15/08	Thu 10/16/08
133	Review & approval of final project plan and risk assessment by Sponsor	2 hrs	Thu 10/16/08	Thu 10/16/08
134	**Design**	**40 hrs**	**Thu 10/16/08**	**Wed 10/22/08**
135	Establish a document inventory and control log to meet Sponsor requirements. Note: Sponsor may utilize PBSI's sample	8 hrs	Thu 10/16/08	Fri 10/17/08
136	Establish template format for documentation. Note: Sponsor may elect to use existing format, use PBSI's forensic QSM	30 hrs	Thu 10/16/08	Wed 10/22/08
137	Review & approval of document inventory and control log and documentation format by Sponsor	2 hrs	Wed 10/22/08	Wed 10/22/08



Project: PBSI Project Plan for RFP 08R
Date: Thu 7/23/09

Task
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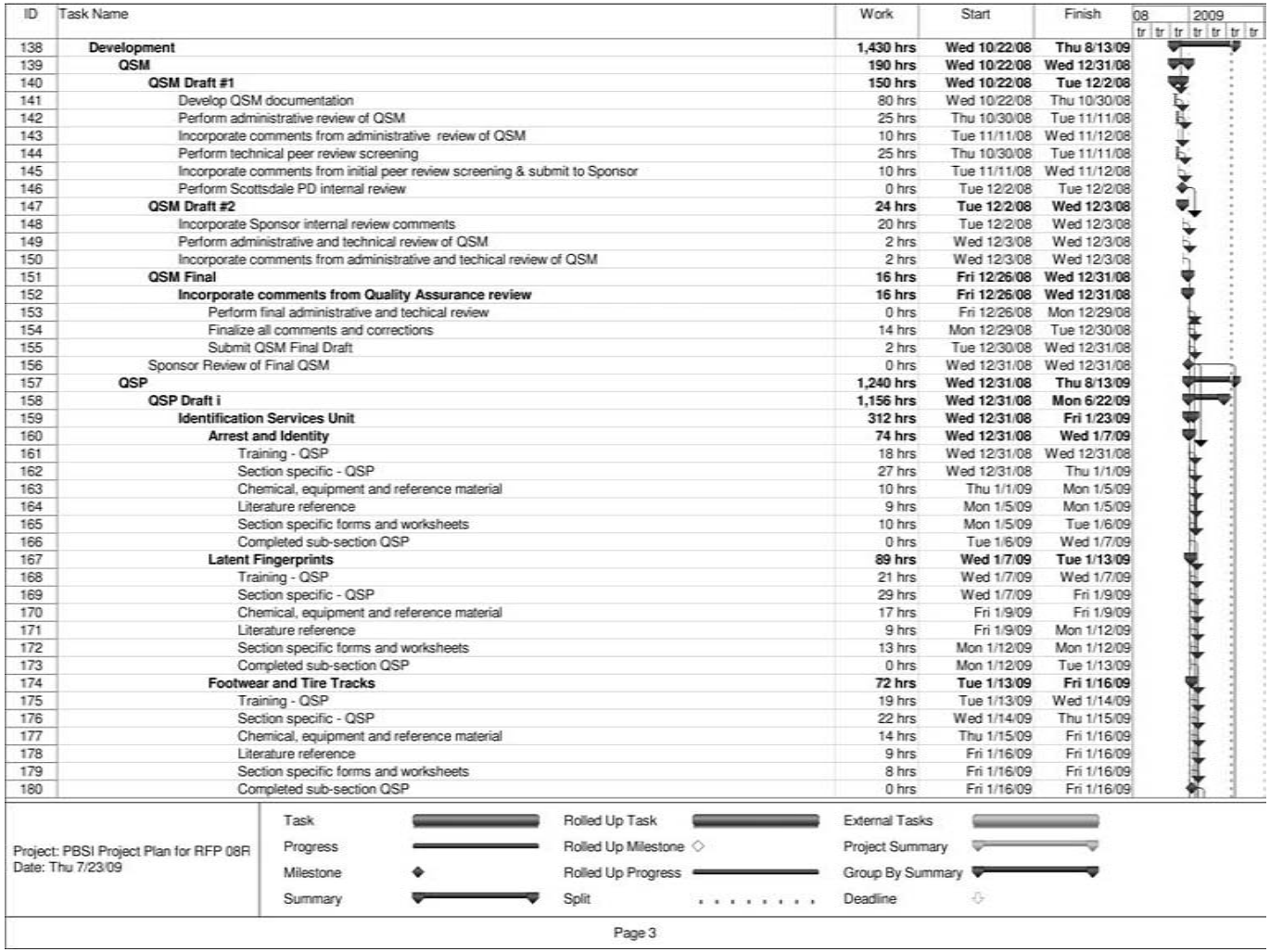

ID	Task Name	Work	Start	Finish
138	**Development**	**1,430 hrs**	**Wed 10/22/08**	**Thu 8/13/09**
139	**QSM**	**190 hrs**	**Wed 10/22/08**	**Wed 12/31/08**
140	**QSM Draft #1**	**150 hrs**	**Wed 10/22/08**	**Tue 12/2/08**
141	Develop QSM documentation	80 hrs	Wed 10/22/08	Thu 10/30/08
142	Perform administrative review of QSM	25 hrs	Thu 10/30/08	Tue 11/11/08
143	Incorporate comments from administrative review of QSM	10 hrs	Tue 11/11/08	Wed 11/12/08
144	Perform technical peer review screening	25 hrs	Thu 10/30/08	Tue 11/11/08
145	Incorporate comments from initial peer review screening & submit to Sponsor	10 hrs	Tue 11/11/08	Wed 11/12/08
146	Perform Scottsdale PD internal review	0 hrs	Tue 12/2/08	Tue 12/2/08
147	**QSM Draft #2**	**24 hrs**	**Tue 12/2/08**	**Wed 12/3/08**
148	Incorporate Sponsor internal review comments	20 hrs	Tue 12/2/08	Wed 12/3/08
149	Perform administrative and technical review of QSM	2 hrs	Wed 12/3/08	Wed 12/3/08
150	Incorporate comments from administrative and techical review of QSM	2 hrs	Wed 12/3/08	Wed 12/3/08
151	**QSM Final**	**16 hrs**	**Fri 12/26/08**	**Wed 12/31/08**
152	**Incorporate comments from Quality Assurance review**	**16 hrs**	**Fri 12/26/08**	**Wed 12/31/08**
153	Perform final administrative and techical review	0 hrs	Fri 12/26/08	Mon 12/29/08
154	Finalize all comments and corrections	14 hrs	Mon 12/29/08	Tue 12/30/08
155	Submit QSM Final Draft	2 hrs	Tue 12/30/08	Wed 12/31/08
156	Sponsor Review of Final QSM	0 hrs	Wed 12/31/08	Wed 12/31/08
157	**QSP**	**1,240 hrs**	**Wed 12/31/08**	**Thu 8/13/09**
158	**QSP Draft i**	**1,156 hrs**	**Wed 12/31/08**	**Mon 6/22/09**
159	**Identification Services Unit**	**312 hrs**	**Wed 12/31/08**	**Fri 1/23/09**
160	**Arrest and Identity**	**74 hrs**	**Wed 12/31/08**	**Wed 1/7/09**
161	Training - QSP	18 hrs	Wed 12/31/08	Wed 12/31/08
162	Section specific - QSP	27 hrs	Wed 12/31/08	Thu 1/1/09
163	Chemical, equipment and reference material	10 hrs	Thu 1/1/09	Mon 1/5/09
164	Literature reference	9 hrs	Mon 1/5/09	Mon 1/5/09
165	Section specific forms and worksheets	10 hrs	Mon 1/5/09	Tue 1/6/09
166	Completed sub-section QSP	0 hrs	Tue 1/6/09	Wed 1/7/09
167	**Latent Fingerprints**	**89 hrs**	**Wed 1/7/09**	**Tue 1/13/09**
168	Training - QSP	21 hrs	Wed 1/7/09	Wed 1/7/09
169	Section specific - QSP	29 hrs	Wed 1/7/09	Fri 1/9/09
170	Chemical, equipment and reference material	17 hrs	Fri 1/9/09	Fri 1/9/09
171	Literature reference	9 hrs	Fri 1/9/09	Mon 1/12/09
172	Section specific forms and worksheets	13 hrs	Mon 1/12/09	Mon 1/12/09
173	Completed sub-section QSP	0 hrs	Mon 1/12/09	Tue 1/13/09
174	**Footwear and Tire Tracks**	**72 hrs**	**Tue 1/13/09**	**Fri 1/16/09**
175	Training - QSP	19 hrs	Tue 1/13/09	Wed 1/14/09
176	Section specific - QSP	22 hrs	Wed 1/14/09	Thu 1/15/09
177	Chemical, equipment and reference material	14 hrs	Thu 1/15/09	Fri 1/16/09
178	Literature reference	9 hrs	Fri 1/16/09	Fri 1/16/09
179	Section specific forms and worksheets	8 hrs	Fri 1/16/09	Fri 1/16/09
180	Completed sub-section QSP	0 hrs	Fri 1/16/09	Fri 1/16/09

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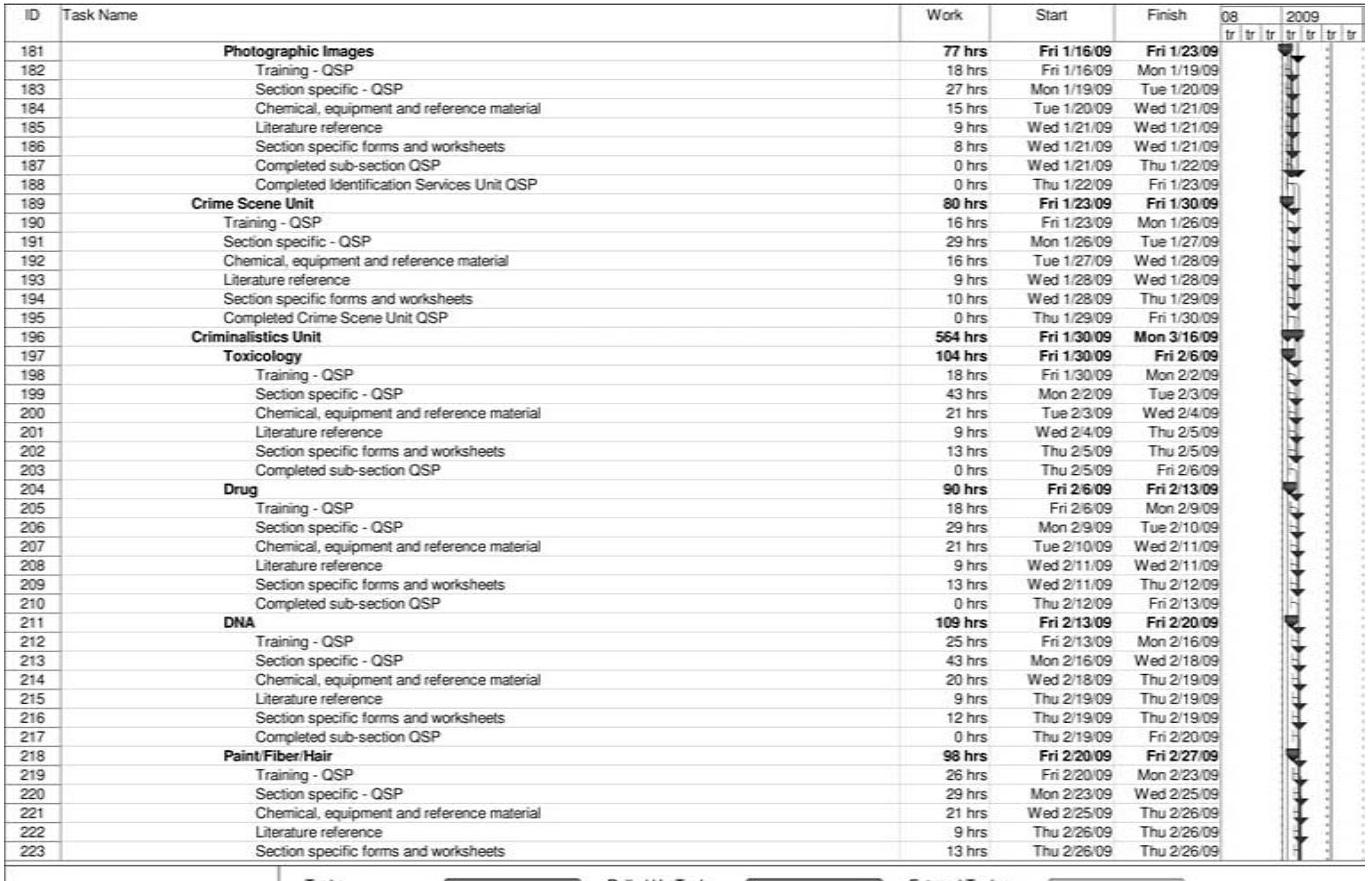
ID	Task Name	Work	Start	Finish
181	**Photographic Images**	**77 hrs**	**Fri 1/16/09**	**Fri 1/23/09**
182	Training - QSP	18 hrs	Fri 1/16/09	Mon 1/19/09
183	Section specific - QSP	27 hrs	Mon 1/19/09	Tue 1/20/09
184	Chemical, equipment and reference material	15 hrs	Tue 1/20/09	Wed 1/21/09
185	Literature reference	9 hrs	Wed 1/21/09	Wed 1/21/09
186	Section specific forms and worksheets	8 hrs	Wed 1/21/09	Wed 1/21/09
187	Completed sub-section QSP	0 hrs	Wed 1/21/09	Thu 1/22/09
188	Completed Identification Services Unit QSP	0 hrs	Thu 1/22/09	Fri 1/23/09
189	**Crime Scene Unit**	**80 hrs**	**Fri 1/23/09**	**Fri 1/30/09**
190	Training - QSP	16 hrs	Fri 1/23/09	Mon 1/26/09
191	Section specific - QSP	29 hrs	Mon 1/26/09	Tue 1/27/09
192	Chemical, equipment and reference material	16 hrs	Tue 1/27/09	Wed 1/28/09
193	Literature reference	9 hrs	Wed 1/28/09	Wed 1/28/09
194	Section specific forms and worksheets	10 hrs	Wed 1/28/09	Thu 1/29/09
195	Completed Crime Scene Unit QSP	0 hrs	Thu 1/29/09	Fri 1/30/09
196	**Criminalistics Unit**	**564 hrs**	**Fri 1/30/09**	**Mon 3/16/09**
197	**Toxicology**	**104 hrs**	**Fri 1/30/09**	**Fri 2/6/09**
198	Training - QSP	18 hrs	Fri 1/30/09	Mon 2/2/09
199	Section specific - QSP	43 hrs	Mon 2/2/09	Tue 2/3/09
200	Chemical, equipment and reference material	21 hrs	Tue 2/3/09	Wed 2/4/09
201	Literature reference	9 hrs	Wed 2/4/09	Thu 2/5/09
202	Section specific forms and worksheets	13 hrs	Thu 2/5/09	Thu 2/5/09
203	Completed sub-section QSP	0 hrs	Thu 2/5/09	Fri 2/6/09
204	**Drug**	**90 hrs**	**Fri 2/6/09**	**Fri 2/13/09**
205	Training - QSP	18 hrs	Fri 2/6/09	Mon 2/9/09
206	Section specific - QSP	29 hrs	Mon 2/9/09	Tue 2/10/09
207	Chemical, equipment and reference material	21 hrs	Tue 2/10/09	Wed 2/11/09
208	Literature reference	9 hrs	Wed 2/11/09	Wed 2/11/09
209	Section specific forms and worksheets	13 hrs	Wed 2/11/09	Thu 2/12/09
210	Completed sub-section QSP	0 hrs	Thu 2/12/09	Fri 2/13/09
211	**DNA**	**109 hrs**	**Fri 2/13/09**	**Fri 2/20/09**
212	Training - QSP	25 hrs	Fri 2/13/09	Mon 2/16/09
213	Section specific - QSP	43 hrs	Mon 2/16/09	Wed 2/18/09
214	Chemical, equipment and reference material	20 hrs	Wed 2/18/09	Thu 2/19/09
215	Literature reference	9 hrs	Thu 2/19/09	Thu 2/19/09
216	Section specific forms and worksheets	12 hrs	Thu 2/19/09	Thu 2/19/09
217	Completed sub-section QSP	0 hrs	Thu 2/19/09	Fri 2/20/09
218	**Paint/Fiber/Hair**	**98 hrs**	**Fri 2/20/09**	**Fri 2/27/09**
219	Training - QSP	26 hrs	Fri 2/20/09	Mon 2/23/09
220	Section specific - QSP	29 hrs	Mon 2/23/09	Wed 2/25/09
221	Chemical, equipment and reference material	21 hrs	Wed 2/25/09	Thu 2/26/09
222	Literature reference	9 hrs	Thu 2/26/09	Thu 2/26/09
223	Section specific forms and worksheets	13 hrs	Thu 2/26/09	Thu 2/26/09



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Task
Progress
Milestone
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Split
External Tasks
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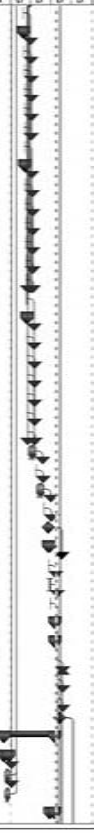
Deadline

ID	Task Name	Work	Start	Finish
224	Completed sub-section QSP	0 hrs	Thu 2/26/09	Fri 2/27/09
225	**Firearms and Toolmarks**	**84 hrs**	**Fri 2/27/09**	**Fri 3/6/09**
226	Training - QSP	22 hrs	Fri 2/27/09	Mon 3/2/09
227	Section specific - QSP	21 hrs	Mon 3/2/09	Tue 3/3/09
228	Chemical, equipment and reference material	20 hrs	Tue 3/3/09	Wed 3/4/09
229	Literature reference	9 hrs	Wed 3/4/09	Wed 3/4/09
230	Section specific forms and worksheets	12 hrs	Wed 3/4/09	Thu 3/5/09
231	Completed sub-section QSP	0 hrs	Thu 3/5/09	Fri 3/6/09
232	**Fire Debris**	**79 hrs**	**Fri 3/6/09**	**Fri 3/13/09**
233	Training - QSP	12 hrs	Fri 3/6/09	Mon 3/9/09
234	Section specific - QSP	18 hrs	Mon 3/9/09	Tue 3/10/09
235	Chemical, equipment and reference material	21 hrs	Tue 3/10/09	Wed 3/11/09
236	Literature reference	19 hrs	Wed 3/11/09	Wed 3/11/09
237	Section specific forms and worksheets	9 hrs	Wed 3/11/09	Thu 3/12/09
238	Completed sub-section QSP	0 hrs	Thu 3/12/09	Fri 3/13/09
239	Completed Criminalistics Unit QSP	0 hrs	Fri 3/13/09	Mon 3/16/09
240	**Property & Evidence Unit**	**80 hrs**	**Mon 3/16/09**	**Fri 3/20/09**
241	Training - QSP	16 hrs	Mon 3/16/09	Mon 3/16/09
242	Section specific - QSP	32 hrs	Mon 3/16/09	Wed 3/18/09
243	Chemical, equipment and reference material	12 hrs	Wed 3/18/09	Wed 3/18/09
244	Literature reference	10 hrs	Wed 3/18/09	Thu 3/19/09
245	Section specific forms and worksheets	10 hrs	Thu 3/19/09	Thu 3/19/09
246	Completed Property & Evidence QSP	0 hrs	Thu 3/19/09	Fri 3/20/09
247	Perform administrative review of QSP	40 hrs	Fri 3/20/09	Fri 4/24/09
248	Incorporate comments from administrative and techical review of QSP	20 hrs	Fri 4/24/09	Mon 4/27/09
249	Perform technical review of QSP	40 hrs	Mon 4/27/09	Mon 6/1/09
250	Incorporate comments from technical review	20 hrs	Mon 6/1/09	Tue 6/2/09
251	Perform Scottsdale PD internal review	0 hrs	Mon 6/22/09	Mon 6/22/09
252	**QSP Draft #2**	**60 hrs**	**Mon 6/22/09**	**Mon 6/29/09**
253	Incorporate Sponsor internal review comments	40 hrs	Mon 6/22/09	Tue 6/23/09
254	Perform administrative and technical review of QSP	10 hrs	Tue 6/23/09	Mon 6/29/09
255	Incorporate comments from administrative and techical review of QSP	10 hrs	Mon 6/29/09	Mon 6/29/09
256	**QSP Final**	**24 hrs**	**Wed 7/22/09**	**Fri 7/24/09**
257	**Incorporate comments from Quality Assurance review**	**24 hrs**	**Wed 7/22/09**	**Fri 7/24/09**
258	Perform final administrative and techical review	0 hrs	Wed 7/22/09	Thu 7/23/09
259	Finalize all comments and corrections	20 hrs	Thu 7/23/09	Thu 7/23/09
260	Submit QSP Final Draft	4 hrs	Thu 7/23/09	Fri 7/24/09
261	Sponsor Review of Final QSP	0 hrs	Thu 8/13/09	Thu 8/13/09
262	**Quality Assurance ("Final": Peer Review - initial reviews in Development)**	**160 hrs**	**Wed 12/3/08**	**Wed 7/22/09**
263	**QSM Final Peer Review**	**80 hrs**	**Wed 12/3/08**	**Fri 12/26/08**
264	Final Administrative Review	40 hrs	Wed 12/3/08	Fri 12/26/08
265	Final Technical Review	40 hrs	Wed 12/3/08	Fri 12/26/08
266	**QSP Final Peer Review**	**80 hrs**	**Mon 6/29/09**	**Wed 7/22/09**



Project: PBSI Project Plan for RFP 08R
Date: Thu 7/23/09

Task
Progress
Milestone
Summary
Rolled Up Task
Rolled Up Milestone
Rolled Up Progress
Split
External Tasks
Project Summary
Group By Summary
Deadline

Page 5

(*Continued*)

6.4.1 Description of the Scheduling Process
6.4.2 Identify the Individuals Responsible for Maintaining the Project Schedule
6.4.3 Describe the Process for Modifying the Schedule
6.5 Budget Management

Costs estimates are the costs applied to an activity in a project by assigning resources with associated rates or fees. Resources can include equipment, material, technology, processing cycles, or people. The total cost is critical and should be consistent with the proposal; include breakdowns as needed. Match these cost estimates with the actual billed amounts. Use an appropriate format for the project size and customer requirements (e.g., by WBS, milestone, or deliverable).

6.5.1 Provide a Description of the Budgeting Process
6.5.2 Identify the Individuals Responsible for Maintaining the Project Budget
6.5.3 Describes the Process for Modifying the Budget
6.6 Communication Plan

Communication planning involves determining the information and communication needs of the stakeholders, executive sponsors, project team and others as needed. The communication plan needs to address who needs what information, when they will need it, how it will be given to them, and by whom. The complexity of the project may require a separate communication plan; however a high level summary of that plan will need to be included here and a reference made to the appropriate Appendix.

6.6.1 Communication Matrix
6.6.2 Status Meetings
6.6.3 Project Status Reports
6.6.4 Identify the Individuals Responsible for Maintaining the Communication Plan
6.6.5 Describes the Process for Modifying the Plan
6.7 Resource Management Plan

Resource planning is necessary to obtain the resources needed to complete project work. Some laboratories have a dedicated quality assurance staff that will be involved in the development of the quality assurance methods, manual and procedures. Other laboratories temporarily assign individuals from various areas of the laboratory to do the work. All of these individuals generally have full time duties and assignment to the project will create extra work. A resource plan should address how these resources will be assigned, who they report to (the project manager or their department head) and how the project work will be prioritized against their regular duties.

6.7.1 Number of Staff by Project Phase

Include the number of staff required by skill level, the project phases in which the numbers of personnel and types of skills are needed, the source of personnel and the duration of need.

Resource Gantt charts, resource histograms, spreadsheets, and tables may be used to depict the staffing plan by skill level, by project phase, and by aggregations of skill levels and project phases. If project resources are obtained from multiple departments or organizations, the resource management plan should address who the resources are, their allocation to the project (ex., part time, full time etc.) who they report to and how their project work is to be prioritized against their regular work.

Phase	Skill	Quantity	Duration	Source	Allocation

6.7.2 Identify the Individuals Responsible for Maintaining the Resource Management Plan

6.7.3 Describe the Process for Modifying the Plan

6.8 Procurement Management Plan

Projects often have some element of procurement, i.e. the requirement to purchase goods and/or services from outside the organization. The procedures to be used to handle these procurements should be included here. Activities such as a make-or-buy analysis; writing requirements; solicitation planning, evaluation and selection; inspection and acceptance; contract closeout should all be included. Note: If the organization has a procurement code, the procedures and standards contained in the procurement code should be followed in managing procurement activities of the project.

6.8.1 Provide a Description of the Procurement Process

6.8.2 Identify the Individuals Responsible for Maintaining the Procurement Plan

6.8.3 Describe Process for Modifying the Plan

6.9 Quality Management Plan

Quality Management includes the processes required to ensure that the project will satisfy the needs for which it was undertaken. It includes all activities of the overall management function that determine the quality policy, objectives, quality assurance, quality control, and quality improvement, within the quality system. If a separate Quality Plan is used, include a high level summary in this document and refer to the appropriate appendix.

6.9.1 Quality Standards

Describe the agency, industry or regulatory project performance standards that will be followed and assessed by the project. These quality standards will be used to assess whether the quality objectives were achieved.

Identify each of the project quality standards that are directly related to the project and not to the performance of the actual product and/or service. For each quality standard, identify the tracking tool or measure such as number of project reviews or Project Status.

No.	Quality Standard	Tracking Tool or Measure
1		
2		
3		
4		
5		

6.9.2 Project and Product Review and Assessment

The quality management plan describes the review processes that will be used to verify quality of project work processes and project work products. Include details on assessments or reviews, when they will be conducted, who will conduct them, scope of review, success criteria, QA reporting formats and review processes.

Review Type	Quality Standard	Tools	Reviewer	Reports
Requirements				
Plans				
Milestones				
Testing				

6.9.3 Customer Satisfaction

The project manager should assess the on-going sense of the customer about how they feel the project is going, and how team members are acting on the project. This feedback would be helpful to the success of the project and the professional growth of the project team members.

Examples:

Areas of Feedback	When	How Often
Customer awareness		
Quality of communications		
Manages project tasks		
Productive meetings		

6.9.4 Identify the Individuals Responsible for Maintaining the Quality Plan
6.9.5 Describe Process for Modifying the Plan
6.10 Performance Measurement (Project Metrics)

The Project Manager and Executive Sponsor define the project metrics that will be used to control the project. Each project will need to have an established metrics program. Metrics are collected for measuring the progress of a project against its planned budget, schedule, resource usage, and error rates, and of establishing a historical database, which will aid in planning and forecasting future projects. At a minimum metrics must be established for time (schedule), cost (budget) and quality.

6.10.1 Baselines

Project Area	Category	Measure

6.10.2 Metrics Library

Metric	Frequency	Calculation
Budgeted Cost of Work Scheduled (BCWS)	At the start of project	Performance baseline; the total of all project work hours.
Schedule variance (SPI)	Weekly	Budgeted cost of work product/ actual cost of work product
Cost variance (CPI)	Weekly	Budgeted cost of work product/ actual cost of work scheduled
Estimate at completion (EAC)	Weekly	Budgeted actual costs/CPI
Earned To Complete (ETC)	Weekly	EAC minus Actual Costs

6.10.3 Identify the Individuals Responsible for Maintaining the Performance Measurement Plan
6.10.4 Describe Process for Modifying the Plan
6.11 Configuration Management

Configuration Management determines how project information (files, reports, designs, memos, documents, etc.) will be managed (tracked, approved, stored, secured, accessed, version control, etc.) and owned by (e.g., Agency managing the project or the Customer). Standards and team awareness are critical.

6.11.1 Version Control

6.11.2 Project Repository (Project Library)

"Provide to the Department all project management and product deliverables. Deliverables shall include but not limited to the project plan, project schedule, initial and periodic risk assessments, quality strategies and plan, periodic project reports, requirements and design documents for entire project. The lead agency must make available all deliverables in a repository with open access for the Department to review" PROJECT OVERSIGHT PROCESS Memorandum.

6.11.3 Identify the Individuals Responsible for Maintaining the Performance Measurement Plan

6.11.4 Describe Process for Modifying the Plan

7 Project Transition

The Transition Management component includes the development and management of a transition action plan, identification of the transition objective and outcomes, and engagement of resources necessary to complete the transition. Transition Management is an ongoing activity throughout the life of the transition. Transition Management involves constant monitoring of activities to ensure all tasks are completed on time, all risks are identified and mitigated, and all issues are addressed in a timely manner. Activities related to the transition planning will include:

7.1 Identify Support Group and Transition Contacts

7.2 Identify Support Requirements

1. Review project schedule and projected turn-over date
2. Review production requirements
3. Set expectations of responsibilities
4. Review training needs
5. Review support documentation needs
6. Review communication mechanisms
7. Review reporting requirements

7.3 Engage Support People in Knowledge Transfer Activities

1. Testing application
2. Participating in project meetings
3. Reviewing user & support documentation
4. Participate in user training if appropriate

7.4 Turn-Over Meeting Topics

1. Production Issue Management
2. Production Escalation procedure
3. Production procedures

8 Project Close

Project Close will always consist of administrative project activities and possibly contractual project activities and an external vendor is employed. Completing both sets of activities is a mandatory step in the project life cycle. Administrative activities complete the internal needs for the Agency/Unit that is responsible for managing the project, such as lessons learned, recording the last hours against the project, and providing transition for the staff to other assignments. Contractual activities meet the contractual needs, such as executing a procurement audit and formal acceptance of the project work products.

8.1 Administrative Close

Administrative Close occurs at both the end of phase and end of project. This closure consists of verification that objectives and deliverables were met. Acceptance is formalized and phase activities are administratively closed out. Administrative closure occurs on a "by-phase" basis in accordance with the WBS and should not be delayed to project end. At that point, the burden of closing is too great and audits inaccurate. The specific project close activities for a given project are contingent on the project's complexity and size. Project managers should work with the project's project management consultant to tailored Project Close procedures to compliment the project's objectives

8.2 Contract Close

Contract close is similar to administrative close in that it involves product and process verification for contract close.

ATTACHMENTS

Attachments are included for additional information, but are not formally considered part of the Project Plan for approvals and change management purposes. Examples

- Acronyms, abbreviations, and definitions
- Technical glossary
- Project work breakdown schedule
- Project timeline

Index

B

C

D

E

G

H

I

J

K

L

M

P

Q

R

S

T

Implementing Quality in Laboratory Policies and Processes

Using Templates, Project Management, and Six Sigma

In order to gain accreditation, every laboratory must have a superior quality assurance program. The keys to a successful program are the operational and technical manuals and associated documents which define the program and its various components. Written by experts with global experience in setting up laboratories, ***Implementing Quality in Laboratory Policies and Processes: Using Templates, Project Management, and Six Sigma*** provides templates for the various policies, procedures, and forms that should be contained in the quality assurance, operational, and technical manuals of a laboratory seeking accreditation.

The book begins with a general introduction and overview of quality assurance and then moves on to cover implementation strategies. It contains best practices and templates for the project management of the design and implementation of the laboratory operational and technical manuals required to establish a quality assurance program. The templates span the entire project life cycle, from initiation, to planning, to execution, to monitoring, and finally, to closure. The book also examines how Six Sigma concepts can be used to optimize laboratories, and contains templates that cover administrative issues, quality assurance, sample control, and health and safety issues. In addition, there is a section of criteria files that relate the individual document templates to specific accreditation criterion.

The results of any laboratory examination have the potential to be presented in court and can ultimately affect the life and liberty of the parties involved. Therefore, a stringent quality assurance program, including well-documented policies and a procedure manual, is essential. Ensuring that laboratories meet the standards of ISO 17025, this volume is a critical component of any laboratory's accreditation process.

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