Guidelines for

PROCESS SAFETY IN OUTSOURCED MANUFACTURING OPERATIONS

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PREFACE

The American Institute of Chemical Engineers (AIChE) has a 30-year history of involvement with process safety for chemical processing plants. Through its strong ties with process designers, builders, operators, safety professionals and academia, the AIChE has enhanced communication and fostered improvement in the high safety standards of the industry. AIChE publications and symposia have become an information resource for the chemical engineering profession on the causes of accidents and means of prevention.

The Center for Chemical Process Safety (CCPS), a directorate of AIChE, was established in 1985 to develop and disseminate technical information for use in the prevention of major chemical accidents. The CCPS is supported by a diverse group of industrial sponsors in the chemical process industry and related industries who provide the necessary funding and professional guidance for its projects. The CCPS Technical Steering Committee and the technical subcommittees oversee individual projects selected by CCPS. Professional representatives of the sponsoring companies staff the subcommittees, with a member of the CCPS staff coordinating the activities of the sub-committee.

Since its founding, CCPS has published many volumes in its "Guidelines" series and in smaller "Concept" texts. Although most CCPS books are written for engineers in plant design and operations and address scientific techniques and engineering practices, several guidelines cover the subject of chemical process safety management. Successful process safety programs are the products of committed and active participation of managers at all levels who apply a systematic approach to process safety as an integral part of operations management.

This Guideline describes techniques to assist the chemical processing industry in applying the CCPS chemical process safety concepts to the tolling vendor-client relationship. This Guideline book is intended to provide guidance in fundamental safety practices to technical staff and management. It is hoped that the guidance and examples provided will aid in promoting safer, more efficient tolling operations.

ACKNOWLEDGMENTS

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The members of the Subcommittee were:

Adrian L. Sepeda, Chair, *Occidental Chemical Corporation*
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Ray E. Witter was the CCPS staff liaison and was responsible for the overall administration of the project.

AntiEntropics Inc. of New Market, Maryland was the contractor for this project. Robert J. Walter and Sandra A. Baker were the principal authors of the text and would like to recognize James M. Godwin for editorial support and Paul Ponton for graphics assistance.

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Their insights, comments, and suggestions helped ensure a balanced perspective for the Guideline.

Lastly we wish to express our appreciation to Jack Weaver and Les Wittenberg of the CCPS staff for their support and guidance.

ABBREVIATIONS AND ACRONYMS

AIChE	American Institute of Chemical Engineers
ARC	Accelerating Rate Calorimeter
CCPS	Center for Chemical Process Safety
cGMP	Current Good Manufacturing Practice
CMA	Chemical Manufacturers Association
CPI	Consumer Price Index
D&B	Dun and Bradstreet
DFR	Duns Financial Records Plus
DOT	Department of Transportation
EDI	Electronic Data Interchange
EMR	Experience Modification Rate
EPA	Environmental Protection Agency
FDA	Food and Drug Administration
HS&E	Health, Safety and Environmental
Kst	Severity of Dust Explosion Scale, which is a combination of maximum pressure and rate of pressure rise.
LEL	Lower Explosive Limit
LEPC	Local Emergency Planning Committee
MACT	Maximum Achievable Control Technology
MIE	Minimum Ignition Energy
MIT	Minimum Ignition Temperature
MOC	Management of Change
MSDS	Material Safety Data Sheets
NESHAP	National Emission Standards for Hazardous Air Pollutants
NORM	Naturally occurring radioactive materials.

NOx	Collectively refers to the combustion byproducts: NO, nitric oxide, and NO_2, nitrogen dioxide
OSHA	Occupational Safety and Health Administration
PROMT	Predicasts Overview of Markets and Technologies
PSSR	Pre-startup Safety Review
SARA	Superfund Amendment Reauthorization Act
SNUR	Significant New Use Regulation
SOCMA	Synthetic Organic Chemical Manufacturers Association
SPC	Statistical Process Control
TSCA	Toxic Substances Control Act
VOC	Volatile Organic Compound

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INTRODUCTION

1.1. This Guideline's Scope

This guideline describes methods to help the chemical processing industry apply the CCPS chemical process safety concepts to outsourced manufacturing operations, specifically the tolling vendor–client relationship. In addition to the focus on process safety, information and examples provided in this text foster good practices relative to community and worker health, and environmental responsibility.

The techniques presented in this book will help improve the performance of tollers as well as companies seeking to use tolled services in the areas of:

- Safety
- Industrial hygiene
- Catastrophic incident prevention
- Off-site and on-site environmental responsibilities, and
- Quality production and packaging of contracted materials

The final item in the list—*Quality*—should be measured in a way that includes how well the previous four items are achieved. This is depicted in Figure 1-1.

All five elements combine to help ensure that the tolling operation is performed safely, efficiently, and in an environmentally sound manner. The ultimate reward to industry for embracing applicable good practices presented in this guideline is a vibrant business with minimized risk. The flowchart on page 3 shows the basic process for tolling as presented in this guideline.

Figure 1-1. A complete quality model

1.2. The Guideline's Audience

Both parties involved in a tolling operation are the intended audience for this book. Listed below are various terms used for companies that provide tolling services.

- Contract manufacturer
- Contract processor
- Custom chemical manufacturer
- External contract manufacturer
- Outsourced manufacturer
- Supplier of outside services
- Third party service provider
- Toll processor
- Toller

For simplicity's sake, we have selected the following two terms, as referenced in the definition for tolling, for the two entities involved. They will be used throughout the book. They are:

- Tollers, and
- Client or company letting the toll.

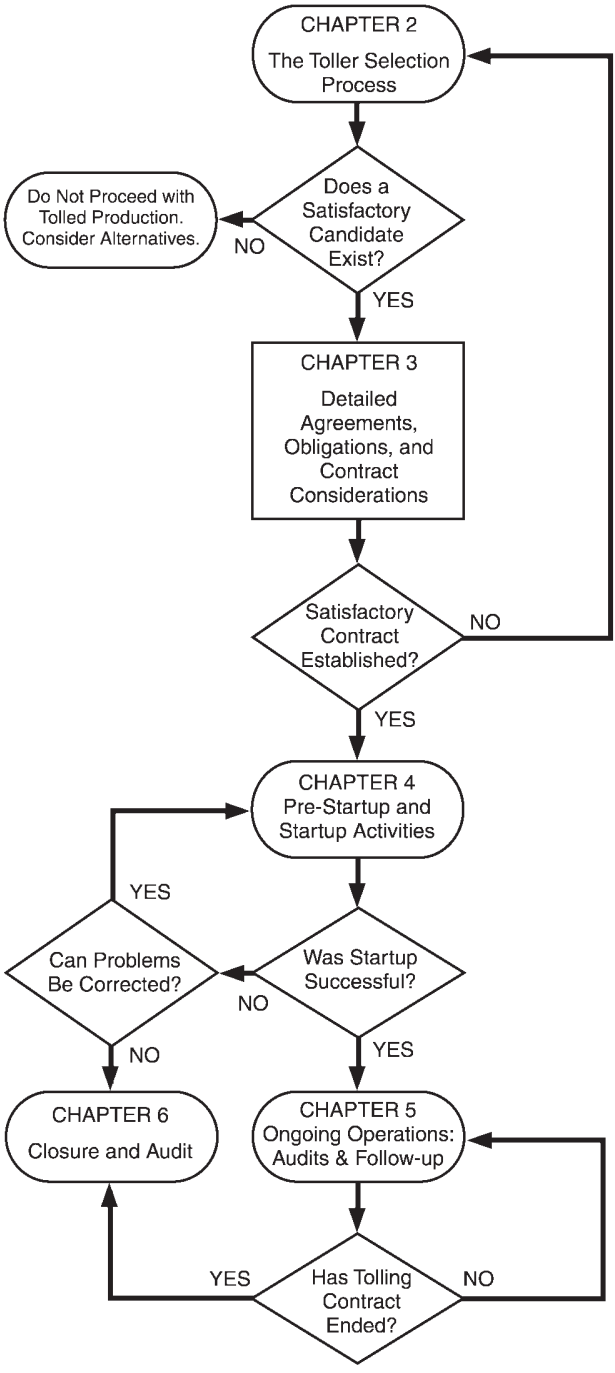

Figure 1-2. Tolling operations process flowchart.

Within these two audiences, our objective is to appeal to both the technical staff and management by providing guidance and examples that can help promote safer, more efficient tolling operations. Our goal is to provide a concise reference source and template for a comprehensive health, safety, and environmental (HS&E) effort that engages both the tollers and their clients. Involving the health, safety and environmental staff up front in the tolling contract process can save time and money later.

In addition to technical staff and management, we hope to reach the commercial staff, purchasing group or marketing group within client companies. Business needs sometimes drive these groups to arrange for tolling contracts to meet special market or production requirements. Commercial staff can use the concepts presented in this text when they arrange for tolling contracts.

Although this book discusses some specific regulatory issues in the United States, its overall message is intended to apply globally. The reader should keep in mind that the U.S. regulations referenced throughout the text may be mirrored by similar regulations applicable to tolling operations performed in any other country.

1.3. What Is Outsourced Manufacturing?

Companies in the chemical processing industry use a wide range of terminology to describe the types of contractual arrangements for outsourced manufacturing (tolling) discussed in this text. This situation requires us to define what we mean by tolling. The definition that follows is intended to apply throughout this book.

"Tolling" means to provide manufacturing services for a fee by a contractor (the toller), to a company issuing (letting) a contract for those services. Tolled services can include:

- *Reaction processes, formulation, blending, mixing or*
- *Size reduction, separation, agglomeration, packaging/repackaging, and others or*
- *A combination of the above.*

Tolling implies that processing of materials takes place. Handling or storage of the product, such as warehousing, bulk storage

or distribution through a terminal where no processing occurs would not in itself constitute tolling, but may be incidental to other tolling activity.

The innate expertise within the two parties, plus the specific tolling situation, determine the responsibility for providing a technology package for the operation. Normally, the company letting the toll contract prepares the technology package. The package includes:

- health, safety, and environmental (HS&E) related data,
- chemical process information,
- raw material and product specifications, and
- waste characteristics and disposition instructions.

The contributions from the toller and the company issuing the contract will vary according to circumstances. However, the toller typically provides:

- equipment required,
- operating personnel,
- technical support,
- analytical resources,
- maintenance resources,
- engineering resources,
- standard raw materials,
- infrastructure,
- utilities, and
- limited warehousing.

The combination of the contributions should result in complete process safety information for the toll. As you can see in this definition, there are many facets to both sides of the tolling contract that can be impacted by either party's philosophy of process safety.

1.4. Why Toll? Business, Technical, and Safety Considerations

When would a company want to engage in tolling? What could make a specific toller attractive to a client? Here are some basic business

reasons for considering the use of a toller or selecting between potential tollers.

Equipment—A client may not have the equipment required to manufacture a specific product. It may be that available capital and installation time are limited such that they simply can not design, acquire, install and test the process equipment to reach the desired capacity within the available budget and time. If a product is in the early stages of its life cycle, the capital required may be hard to justify. This could be based upon the low initial volume anticipated while developing the market or the need to take advantage of a time-sensitive business opportunity. Tolling can provide a means to safely produce introductory, short-term, or small volume products that would otherwise be uneconomic.

Expertise—A client may seek to issue a toll contract if it chooses to produce a new product of unfamiliar chemistry or formulation type. A toller may already have knowledge, equipment, and personnel uniquely suited for a given process that cannot be readily duplicated. A toller with expertise in that particular type of chemistry or formulation could speed production and assist them in building a higher level of in-house expertise through close interaction. This may enhance the level of process safety and personnel safety should the client ever bring the process in-house.

Cost—Outsourcing can often be economically advantageous. A cost comparison may show that a toller can produce a product for less than it can be manufactured in-house. Even if manufacturing costs are similar, the cost associated with distributing the product may be significantly less if the product is made and hence distributed geographically closer to the end user. However, savings in cost should not come from compromising vigilance in the areas of health, safety or environmental responsibility.

Logistics—If a company is geographically located such that it can not meet the desired service level and delivery requirements of its customers, tolling may provide a local production and distribution site. Shorter transportation routes for hazardous chemicals or wastes may also be a consideration.

Environmental—If a product or its raw materials require special permitting (for example, air permits) or if the client company's facility is inappropriate for the process, tolling could provide a means to achieve the company's production goal.

Product or Process Development—A company can develop a new product or process as a quasi-research effort with a toller while simultaneously building the in-house production capacity. This allows problems found in the toller's intermediate scale efforts to be fixed in the large-scale process and to reduce development time and costs. It may simply be a case of a company wanting to try new raw materials in a well-known process without disrupting existing production or establishing a pilot facility. Tollers can provide a way to achieve these activities in a parallel fashion.

1.5. Advantages and Disadvantages of Tolling

There are two primary advantages of tolling that can be summarized from the previous section addressing the reasons to toll:

- Economics
- Staying Competitive

The economic advantage is typically why a client lets a toll contract and is the reason tollers exist in the first place. The economic benefit may be from overcoming the capital-intensive construction of a new process (which a toller may already have available), the simple cost per pound benefit of outsourcing, or the economics of buying the toller's expertise. The second advantage, staying competitive, is about market timing and appropriately managed risk. The ability to rapidly meet customer needs at a reasonable cost is highly valued—tolling can help achieve this. Additionally, selecting a toller based upon expertise in hazardous operations can alter production risks, making them more manageable.

The disadvantages of tolling are less clear cut. A contract is intended to limit liabilities for at least one and hopefully both parties. Tolling liability can be limited by identifying potential problems and avoiding them using techniques presented in this

guideline. Two disadvantages that may need to be considered when tolling are:

- Loss of internal manufacturing expertise or loss of the opportunity to develop it for a process.
- Loss of technology developed in-house or loss of other types of proprietary knowledge.

Some potential problems involved in tolling are listed in Table 1-1.

Examining the lists above makes it clear that a good toller–client relationship with open and honest communication of process safety information, process hazard analysis input and early recognition of issues can help avoid potential problems.

Tolling operations should be held to the same principles of public openness and communication espoused by forward thinking companies in the chemical industry. In 1988, the Chemical Manufacturers Association (CMA) initiated the Responsible Care® initiative to assist in making this possible. Its goal is to lead the chemical industry in ethical practices that increasingly benefit society, the economy and the environment.

Regulations such as the U.S. Occupational Health and Safety Administration's (OSHA) *Process Safety Management of Highly Hazardous Chemicals* and the U.S. Environmental Protection Agency (EPA) *Risk Management Program* rule complement CMA's goals. Both regulations make it very clear that government expects the chemical industry to adopt strong HS&E related management systems.

Even if tollers are not subject to these regulations, or not members of CMA or AIChE/CCPS, these are useful references in guiding operations. It is unacceptable to consider gaining an advantage by using a toller to circumvent accepted HS&E practices that would apply to in-house production.

1.6. Joint Responsibilities

This guideline emphasizes the role of both parties in fulfilling components of the relationship to achieve safe, environmentally respon-

Table 1-1. Potential Problems Encountered in the Tolling Relationship

Potential Problems for Tollers	Potential Problems for Clients
Communication breakdown with the client	Communication breakdown with the toller
Contract termination is an economic threat	Less control over the process than when it is done in-house
	Termination is a supply chain threat
Must rely on certain information provided by the client	Environmental issues due to unknown hazards from other ongoing tolls or a toller's past practices
Safety issues due to unknown or insufficient information on processing hazards by the client	Safety issues due to unforeseen operating and maintenance practices by the toller
	Agency actions or catastrophic events at the toller's facility can threaten the supply chain
For new tolls, dealing with an unknown company	For new tolls, dealing with an unknown toller
Uncertain wear and tear on equipment by unfamiliar materials or processing techniques	Uncertain management practices by the toller
Noncontractual transfer of expertise to the client	Confidentiality concerns for proprietary information
Identifying cross-contamination problems between previous and successive products and processes	Receiving product contaminated by other products and processes
Timing issues due to scheduling multiple products or batches	Timing issues due to a more complex supply chain
Late receipt of raw materials or packaging from the client	Personnel turnover can create unforeseen delays

sible performance. It provides a behind-the-scenes view of how companies assess potential tollers and can help ensure consideration from companies seeking qualified tollers. In many of the examples provided, it is clear that only tollers with high internal standards for process safety will win tolling contracts. For tollers,

this guideline should be seen as a positive way to improve their ability to gain contracts and fulfill them safely and efficiently.

There is a wide spectrum of philosophies regarding the level of participation required from the client. Some clients choose to remain at arm's length from the toll operation in an effort to establish a distinct separation of responsibilities. Such clients may audit the toller's HS&E program on a periodic basis and do little else.

At the other end of the spectrum, some clients recognize that they have much to gain by providing more substantive oversight of the production operation. While these companies don't provide day-to-day supervision of the tolled production, they may assume a greater responsibility in an effort to forestall problems associated with final product specifications, worker safety and environmental responsibility. Companies taking this posture will likely have technically oriented representatives at the toll facility on a regular basis. The responsibility of these representatives is not to supervise but rather closely monitor and guide if the need arises.

Joint OSHA/EPA investigations of past accidents in tolling operations include recommendations that emphasize the importance of communication between the toller and the client. The primary ways recommended to prevent recurrence of similar events focus on a joint understanding of the basic tenets of process safety elements.

1.7. Using Process Safety to Ensure Safety, Product Quality, and Environmental Compliance

Concepts presented in this book are a vital part of every tolling operation's vendor–client relationship.

Our objective is not to set new standards, but to encourage companies and individuals to apply existing standards and the operational discipline necessary to establish their own internal requirements that support business excellence. This guideline provides tools to help the toller and their client take a systematic approach to managing their relationship and implement applicable

portions of Responsible Care®, CCPS's process safety practices, and other industry guidance, while reaching mutual health, safety, environmental, and quality requirements.

1.8. How to Use This Guideline

The toller and the client essentially form a tolling operation team to mutually ensure that applicable regulatory, business, and societal responsibilities are met in a systematic way. This text is a guide to assure relevant issues are identified and addressed appropriately. The examples in this text are based upon samples provided by companies involved in tolling. They are offered for the reader's use. Recognizing the unique characteristics of process safety as applied to tolling, the reader should modify these examples to meet each situation's needs. A thorough safety, technical, and legal review is recommended prior to use.

The list below summarizes some of the major questions that are addressed in following chapters.

Chapter Two—The Toller Selection Process

- How are potential tollers identified?
- What methods are used to assess tollers?
- When does physical location affect consideration?
- How important is past performance history?

Chapter Three—Detailed Agreements, Obligations, and Contract Considerations

- What are the rights that might be established between the contracting parties?
- What legal obligations are typical in a tolling contract?
- Will the contract address compliance with regulations?
- How do you manage transfer of technology?

Chapter Four—Pre-Start Up and Start Up Activities

- How do you choose an effective Process Hazard Analysis (PHA) team?

- How do you identify and develop required procedures?
- Who needs training for this process and to what level of detail?
- How do you resolve pre-startup safety review issues and action items?
- What makes an effective post-startup review?

Chapter Five—Ongoing Operations: Audits and Follow-up

- What are some of the issues that can arise during the tolling process?
- How do you conduct audits based on appropriately managed risks and the nature of the product involved?
- How do you manage the consulting relationship between the two parties?
- What are the management of change considerations?
- What unforeseen regulatory elements may apply?

Chapter Six—Closure and Audit

- Which environmental, health and safety considerations affect closure and audits?
- How do companies ensure the return of proprietary documents?
- How can you analyze the operation for future reference?
- What are some checklist items to review during the closing phase of the toll?

2

THE TOLLER SELECTION PROCESS

Once a company decides to seek a toller for a project, the next step is to build a list of candidate companies. This section provides guidance for both sides of the tolling arrangement to use to enhance their abilities to

- make a discerning choice as a client or
- present information that allows thorough evaluation as a capable toller.

An example of a preliminary technology package form and other tools are provided here and in the appendices.

The flow chart on the next page graphically represents the use of concepts presented in this chapter. As each tolling project is unique, your application of the guidance can be tailored to describe the process as it applies to your company.

2.1. Potential Candidates: How to Find One—How to Be One

Investigations of incidents associated with tolling projects have identified that appropriate selection of a toller based upon proper equipment and expertise is important in reducing the likelihood of future process safety related incidents and environmental releases. It is likewise important to review toller safety, health, and environmental practices (current and past) in the selection process. This review can identify those practices that would need to be modified to be acceptable. Eliminating less qualified candidate firms at an early stage is a best practice.

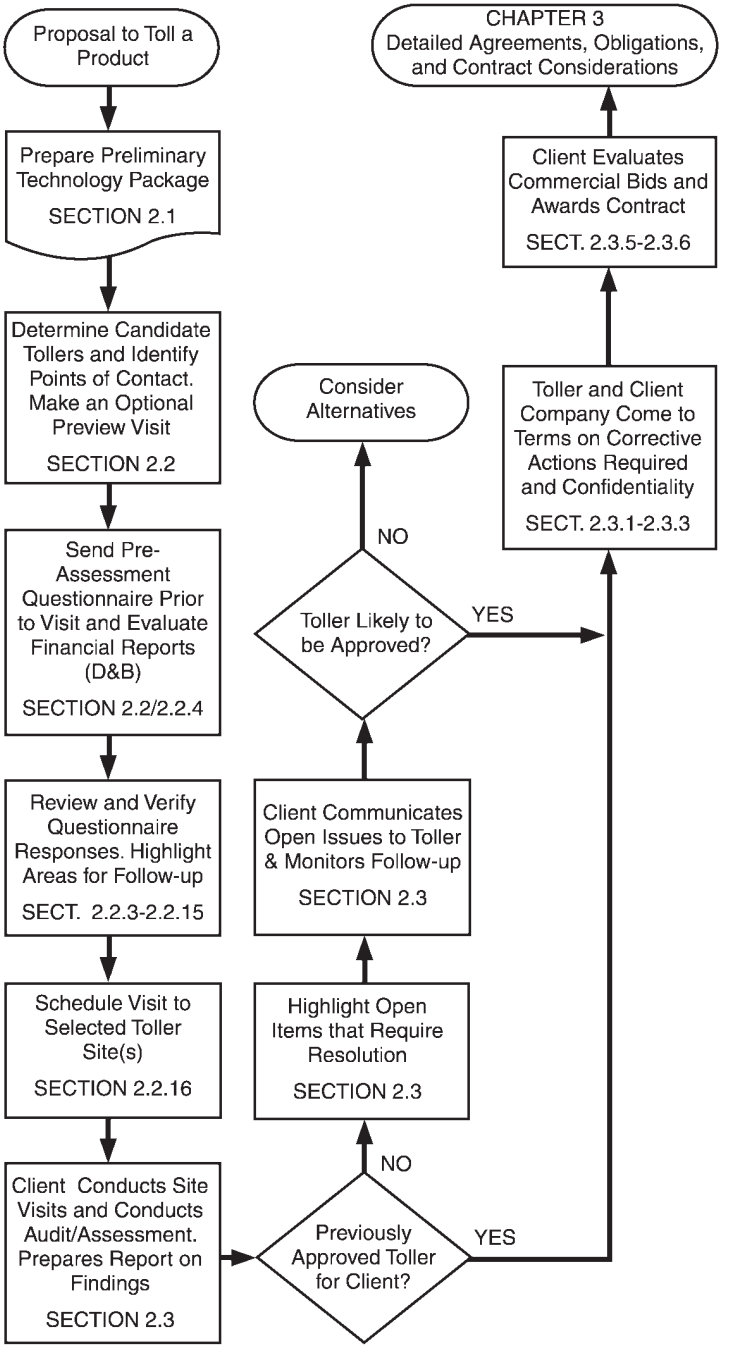

Figure 2-1. Toller selection process flowchart.

This chapter describes typical steps to consider in identifying and qualifying potential candidate tollers.

2.1.1. Identifying Technical Specialties and Expertise

The process of building a list of candidates begins with the client. By examining the specific synthesis desired or material processing and handling required, you can search for tollers that possess the skills and equipment to meet the processing scope.

The technology package for the toll should be at least partially established prior to starting the active search for a toller. This will assist you in defining the level and areas of expertise needed for the project. Some companies that frequently let toll contracts have internal service groups that assist in the toller selection process. An example of an internal questionnaire used at such a company is shown in Example 2-1. It is an excellent way to identify the expertise required for a specific tolling project.

Companies desiring to initiate a toll without the luxury of a special services group can adopt the questionnaire for their project development group to use. Candidate tollers may use this example as a preparatory tool for completing bid responses.

Example 2-1 is just a start for preparing the final technology package to be included with the contract but it provides enough information for a client to identify the special needs required of the candidate tollers. It may need to be modified to meet the specific needs of your situation.

Tolling Contract Services Group—Initial Technology Package

Following is a list of information that could be pertinent in the development of your project. You may not be able to provide information in all areas and some areas may not be applicable. Please mark N/A in areas intentionally left blank. The more information you can provide, the better we will be able to meet your needs. You can use this electronic form for filling in the information or provide information in your own format.

Example 2-1. Initial Technology Package

(Cover Letter)

Dear Internal Customer:

Subject: Tolling Contract Services Group (TCSG) Initial Technology Package Request

Attached is our businesses' Technology Package Request. This information will be helpful in allowing us to meet your needs and expectations by selecting an appropriate toller. Our department developed this list to identify issues to consider in the tolled manufacturing of your product. Any information that you are able to provide will help us considerably and expedite our evaluation process. We look forward to working with you on this opportunity.

Regards,

TCSG Manager

1. General Product Information

Introduction and background (brief project description)
Chemical and physical properties of the raw materials, intermediates, and final product
Pertinent toxicology for raw materials, intermediates, and final product
Estimate of product volume needed from toller and timing for first production

2. Process Chemistry

Chemical nomenclature
Key step definitions
Desired chemical reactions and side reactions
Reaction kinetics and thermodynamics
On what scale has this product has been made before? (for example, reactor size, throughput)
Is the toll strictly using existing technology? (If NO, please describe the changes or improvements.)

3. Material Balance

Index flow sheet
Material balance

4. Unit Operations

Block flow diagram
Technology and equipment description

5. Process Equipment

Design criteria and materials of construction (for example, vents, relief valves)

6. Environmental

Environmental treatment philosophy
Characterization of potential waste streams
Handling of potential waste streams
Environmental data (for example, material balance)
Special environmental considerations (including emergency venting, spills, or releases)

7. Physical Properties

Pure component physical properties (indicate whether liquid or solid; flashpoint; LEL; and, for powders Kst/MIE/MIT)
Mixture physical properties

8. Reactive Chemicals

Reactive chemicals test results (thermal stability, calorimetric, ARC, DSC)
Chemical compatibility chart (How do the chemicals involved react with each other if one is added in excess or the addition of one is limited; how do these chemicals react with common metals and chemicals?)
Reactive chemical considerations for each key process step (enclose data if possible)
Describe any prior reactive chemical incidents with these materials. Include previous safety studies.

9. Analytical

Raw material analysis (indicate liquid chromatography or gas chromatography)
Process stream and intermediate analysis
Byproducts analysis
Final product analysis
Analytical equipment maintenance and calibration requirements
Reference compounds and data
Special sampling requirements needed for project
How should retains be stored?
How should retains be handled?
Is a one-quart retain sufficient for needs?
How clean must equipment be prior to the start of project?
What is a good solvent for cleaning equipment used to produce your product?

10. Raw Material, Intermediate and Final Product Specifications

Raw material specifications
Supplier information
Intermediate specifications
Final product specifications

11. Packaging and Labeling for Final Products

Containers
Labeling requirements
Storage and disposal of containers
How will the final product be shipped? Fiberpak ❑ Drum ❑ Size _____ Tank Truck _____ Rail car _____ Other _____
Class shipping instructions and placard information

12. Regulatory Issues and Hazard Communications

TSCA and others
CGMP required
MSDS Please enclose MSDS for all raw materials, intermediates and final products.
Any consent orders on this product or raw materials?
Any prior process hazard analyses on this process?
Any special handling or industrial hygiene (IH) concerns not clearly indicated in the MSDS?

13. General Project Overview

Project contacts (who are the key people to contact with questions and issues?)
Overview of significant learning experiences in previous production of this material.
Process opportunities (areas to focus upon to improve cycle time or conversion)
Project volumes/production rate
Project plan and timelines
Desired start date
Desired completion date

14. Economics

Raw material costs
Target conversion cost

15. Process Research Reports and Patents

A. List of reports
B. Selected report summaries
C. List of patents, applications, and disclosures
D. Selected patent summaries

2.1.2. Prequalified Tollers—The Preferred Route

If repetitive tolls are the norm for a client, a good way to screen candidate tollers is to make use of past experience. A satisfying business relationship between a toller and a client is a prelude to the continued use of a toller and the toller's continued desire to meet a good customer's needs.

However, just asking the purchasing department for a list of companies previously used for tolling is not enough. Prior successful use of a given firm is not adequate qualification for future tolls, especially if the new toll involves a different product. At this point in the selection process the five facets mentioned in the previous chapter come into play:

- Safety
- Industrial hygiene
- Catastrophic incident prevention
- Off-site and on-site environmental consequences, and
- Quality production and packaging of contracted materials

In order to verify performance of a given toller with whom a company has worked before, it is essential to document and understand their performance history in the five areas listed above. Good documentation of prior toller performance will allow a new engineer or new manager in charge of tolling projects to base their initial selection of candidates on accurate data.

Chapter 5, *Ongoing Operations: Audits and Follow-up*, provides guidance on how to build a database of information about previous and ongoing experience with a toller. Consider using the audits to build a summary database of experience with tollers. In many companies the more difficult part of the audit process, whether internal or external audit, is tracking resolution of the findings. A ranking system may be useful to assist in building a list of candidates based upon their expertise, severity and number of findings, and their timely resolution of findings.

Communication is important to both the toller and their client company. Tollers already working on one or more active projects with a company can regularly check with their client contacts for

information about how they are doing. They can ask straightforward questions such as:

- Do you see room for improvement in the five areas?
- How can we assist in the audit process?
- Have we resolved past audit findings satisfactorily?
- Is there a technical aspect of our capabilities or equipment you would like to see strengthened?
- Do you have suggestions to help ensure consideration for future contracts?

Some approaches to quality management suggest that companies reduce the total number of suppliers for a service or material to just a few high quality entities. This allows the companies to symbiotically develop relationships. Both parties can benefit greatly by using a system designed to rank preferred tollers. However, do not let the motivation to reduce the number of suppliers inhibit the critical review of potential tollers capable of performing the toll successfully.

Another advantage of maintaining long-term relationships with a few preferred tollers is the ability to establish better communications and restrict dissemination of confidential or proprietary information.

2.1.3. Finding a New Toller—Technical and Trade Association Networking

If a tolling project demands that a company seek candidate tollers with different expertise from that required for previous tolls, or if it simply wants to expand its list of preferred tollers, other resources exist to help.

In large companies that contract tolls (those with several business groups), inquiring within the company may turn up candidate tollers of which one business group was unaware. This can often aid in evaluating the candidates if good performance data is available as described in the previous section.

When a need for fresh candidate tollers exists, the following publications represent four better-known listings and can provide

contact points that will allow a company seeking a toller to begin a dialog with the new candidates.

- The *Brandon Guide to Custom Chemical Synthesis Services: North America* is issued annually by Brandon Associates, Merrimack, New Hampshire
- The *Custom Processing Services Guide* is issued annually by the Custom Guide Company, Closter, New Jersey
- The *Commercial Guide* is issued each January by the Synthetic Organic Chemical Manufacturers Association (SOCMA), Washington, D.C.
- A *Guide to Custom Chemical Manufacturing and Processing* compiled and published by Quest Data, Inc., Nashville, Tennessee. The fourth edition is planned for publication in 2000.

These guides include information such as:

- available equipment,
- existing unit operations, and
- chemical reactions performed.

Other sources for helping identify new tollers are trade association conferences and shows. The largest U.S. gathering of tollers is the Informex exhibition presented annually by SOCMA. The Custom Manufacturing Expo sponsored by *Chemical Week* provides a similar forum for networking. Tollers typically display their capabilities in an exhibit booth, provide printed materials describing their services, and staff their exhibit with their sales manager and technical representatives (many include operating managers). This allows a company seeking new toller candidates to collect a great deal of vendor information across a wide cross-section of companies with appropriate expertise. The chance to meet with the people that you may eventually be working with is also a great benefit.

SOCMA includes a magazine version of the commercial guide free to Informex attendees. Copies of this guide are also available direct from SOCMA for a fee. The SOCMA homepage on the Internet also provides a wealth of information.

2.2. The Initial Qualification Process

At this point, a client has a list of likely candidate names. Prior to expending more effort, it is possible to screen this list for safety performance, environmental performance and financial stability. For a candidate toller to make the next cut, it should have a health, safety and environmental program with appropriate human and financial resources to implement effective programs. Safety and environmental performance (or lack of readily available information about performance) can be a telling indicator about a company's commitment to quality. A brief, optional preview visit to the site can give the client information about the toller's housekeeping habits, process safety program, and general qualifications. At times, tollers are ruled out because a preview visit can reveal a company culture that is not a good fit with that of the client.

2.2.1. Assessing the Candidates—Lines of Communication

The first step in assessing the candidate tollers is to notify the candidates they are being considered for this toll, and determine their interest in further evaluation. Pending mutual interest in further consideration, the companies must establish lines of communication with commercial representatives, technical/manufacturing representatives, and health, safety and environmental (HS&E) representatives. There may be one person in a candidate company that funnels the communication from these three groups or several, especially if the HS&E function is split. Tollers should recognize these discrete needs and be prepared to respond accurately and efficiently to enhance their merited consideration.

2.2.2. A Typical Questionnaire

Companies experienced in assessing candidate tollers typically have some type of assessment questionnaire used to collect data. The assessment questionnaire is useful because it provides a relatively inexpensive tool to collect a standard set of data.

Questionnaires can be customized for each application. Such a questionnaire is commonly used as follows:

- It is sent to candidate tollers for their staff to complete.
- The company selecting a toller evaluates the data provided from each candidate and identifies which firms are qualified for a site visit.
- The company then uses the specific toller's completed questionnaire again during the site visit to verify that accurate information was provided and resolve open issues.

Some companies have more detailed forms for the site visit. One example of an assessment questionnaire is provided in Appendix A, *Sample Toller Pre-Assessment Questionnaire*.

In the example in Appendix A, candidate tollers are asked to respond to twelve topic areas:

1. Policies, affiliations, and certifications
2. Character of area around the plant
3. Personnel
4. Environmental
5. Security and maintenance
6. Storage
7. Preparedness, prevention, and emergency response
8. Health and safety
9. Production
10. Quality assurance
11. Potential exposure
12. Addendum for existing tollers

Companies evaluating tollers should modify the examples in this book to best meet their needs. Tollers may gain insight by comparing the examples to questionnaires that they have completed previously. Additional samples of assessment forms are provided in the appendices.

2.2.3. Weighing Special Technical Competencies

Assessment questionnaires may not typically require details about technical expertise the candidate tollers may possess. It is assumed that the list of candidates who will receive the questionnaire have

the appropriate technical competency based on researched evidence. This aspect of toller selection—technical competency—requires the value judgment of experienced staff. These value judgments are often based upon impressions resulting from interpersonal communication with the tollers' staff during site visits. The site visit also allows opportunities to get a better feel for the unique technical capabilities and human resources a toller can provide. During the site visit, the technical package requirements, reaction capabilities and mechanical capabilities can be compared and assessed.

In some cases, companies with frequent or challenging toller service requirements may take on long term programs and commitments to develop one or more toll firms with skills, knowledge, and equipment appropriate for the processes in question. If successful, these long-term commitments can achieve a safe, highly efficient, symbiotic relationship.

2.2.4. Financial

A toller with a good history of HS&E performance is able to obtain advantageous insurance rates and expends less of their revenue on legal problems, thus helping with their potential for cost competitiveness in the final bid. A toller in good financial standing is more likely to expend capital to install adequate safeguards.

Companies assessing tollers have at least two tools that may help with this first screening. They are:

- D&B—Duns Financial Records Plus (DFR) service (see Table 2-1)
- Predicasts Overview of Markets and Technologies (PROMT)

Both can be accessed through the Knight-Ridder Information Services—DIALOG Services Database Catalogue.

The Duns Financial Records Plus (DFR) database provides a balance sheet, income statement, and fourteen of the more widely used business ratios for measuring solvency, efficiency, and profitability. DFR also provides industry norms and percentages that can be used to compare a toller's financial position to that of their

competitors. DFR includes a brief description of company history and operations. Many companies use DFR to evaluate potential suppliers for their financial status. It is to a toller's advantage to ensure that the data provided by the DFR service is current and accurate.

The Predicasts Overview of Markets and Technologies (PROMT) is a database that provides international coverage of companies, products, markets, and applied technologies for industries. PROMT abstracts more than 1000 worldwide business publications. PROMT derives information from:

- trade journals,
- local newspapers and regional business publications,
- national and international business newspapers,
- trade and business newsletters,
- Securities and Exchange Commission (SEC) registration statements,
- investment analyst reports,
- corporate press releases, and
- company annual reports.

Environmental and safety incidents that make the news are included in PROMT's summaries. This makes PROMT a quick tool for evaluating a toller's history of major incidents.

Again, this is a high level screening. Depending on the results of a search, it could lead to either eliminating a candidate from the list or spurring a more thorough evaluation of a candidate during the next phase.

2.2.5. Consider Location

The assessment questionnaire responses can help screen candidates for proximity to sensitive local receptors. Both parties must be made aware of and understand the nature of the substances to be used or produced during the toll and the consequence potentials of both the materials and the process. In the U.S., the toll process may be conveyed under Environmental Protection Agency (EPA) Risk Management Program (RMP) issues OSHA PSM issues, or state, local or foreign requirements depending upon the substances involved in the toll. If a regulated substance is being introduced to a toll facility at

quantities above the threshold quantity identified in the applicable regulation, the toller may become subject to the regulation. They may therefore need to implement the OSHA PSM requirements and file correct plan documents under the RMP rule or resubmit their existing risk management plan. Analogous regulations exist in many other jurisdictions. The compliance requirements, related strategy, and overall toll viability may be impacted by these regulations.

Emergency response capabilities and community involvement becomes extremely important if a toller is handling toxic substances or flammable mixtures in a populated area. What liability is involved for the client? Are the candidate tollers experienced in handling the specific hazards posed by the process? Is there a difference in the level of risk each candidate toller poses to its surrounding community? Is the local emergency infrastructure, including emergency response capacity, local emergency planning committee (LEPC) capability, mutual aid groups, local professional or volunteer fire and rescue squads, consistent with toll requirements? In some cases, the answers to questions in the assessment questionnaire can help select finalists from among the candidates.

If the toller has contracted with a private emergency response contractor, specific instructions or concerns regarding the toll materials may need to be forwarded to the contractor prior to startup.

The physical location of the toller can impact logistics, transportation and distribution issues. If you have a market need in a region of your country or a foreign location, a component to consider in selection of the successful toller is the capacity to provide support to the client distribution system or shortest supply chain.

The issues of regulatory compliance, local infrastructure, and logistic concerns cannot be readily changed to achieve vastly different requirements. These concerns need be identified early in a qualification process to assure they are adequately understood and addressed.

2.2.6. Consider the Environmental Baseline

The assessment tool shown in Appendix B, *Sample Toller HS&E Assessment* is designed to draw attention to existing HS&E problems. This example may be especially appropriate for toll contracts involving materials or processes of high hazard.

Ultimately, assurance of selecting an environmentally responsible toller relies upon research, the site visit and inspection. One on one communication with the tollers' management and technical staff can help answer detailed questions about:

- Solid waste management expertise
- Site contamination history and cleanup
- Water discharges
- Air emissions
- Site compliance history

A client can research the above topics by using publicly available data sources or commercial data collection services to obtain details about a site. The commercial data collection services can compile public records of remediation activities, citations, or fines from governmental entities and other data of interest for any property. Examples of these types of firms are Vistainfo, IAO Environmental Services and Lexis/Nexis.

2.2.7. Verifying Safety, Quality, and Contractual Obligations

It may be appropriate to request that candidate tollers provide contacts at previous client facilities to allow general inquiries about their performance. This allows a company seeking a toller to determine whether the safety, environmental and quality programs are truly implemented as written. In addition, it can reveal whether the candidates made good faith efforts to meet contractual obligations.

One way to make the importance of this clear is by including a business ethics provision in the tolling contract. The CMA Responsible Care® initiative can be called out in such a provision and applied to both parties in the contract if they have both subscribed to its code of ethics. This is discussed further in Chapter 3, *Mutual Agreements, Obligations and Contract Considerations.*

2.2.8. Process Equipment Capabilities

A quality toll can only be achieved by tollers with properly designed and reliable equipment. Companies letting a toll contract should

satisfy themselves that the right equipment is available and effective routine inspection and maintenance programs are in place to detect equipment defects before they cause accidents or breakdowns.

Preventive maintenance on vital equipment should be properly scheduled, carried out and documented. This program must be separate from the regulatory inspection.

Examining a candidate toller's records of formal reporting and follow-up on mechanical deficiencies or hazardous conditions is imperative. The assessor should verify whether such a system is in place and is effective.

The assessor should also find out whether an effective testing program is in place to help ensure the serviceability of process measurement equipment. The successful toller should have an established calibration program to address the accuracy of critical measurement equipment. Safety critical process parameters should be monitored and critical process equipment should automatically interlock when monitoring instrumentation detects safety critical deviations. Interlocks should either facilitate a remedy to the critical deviation or bring the process to the zero energy state. These instruments and interlocking devices should be routinely tested to ensure operational reliability.

2.2.9. Personnel Capabilities and Expertise

Experienced and qualified people are essential to a company's performance level. Successful tolling operations may show evidence of proper personnel selection, career planning and advancement.

The confidential nature of individual records must be respected. During the site visit, the assessor may have to rely on the assurance of the toller's personnel manager to make a selection judgment. Some questions to ask when assessing a toller's personnel capabilities follow:

- Are job criteria formalized in job descriptions for each position?
- Is there a more detailed job task analysis or profile?
- What level of formal education is required for each position?
- Is there a requirement for past experience for employment or advancement?

- Is there minimum language mastery required?
- Is there a pre-employment and follow up medical examination required?
- Is there a documented interview system?
- Is there a documented training program?

Turnover rate is a key indicator of how an employer values their employees. Employees who have a career path, are rewarded for good performance, and provide contributions to the success of their employer are less likely to leave. On the other hand, companies with high turnover rates may not provide such good working conditions and the resulting turnover results in employees who may not have much experience.

2.2.10. Capability to Scale-up Production

Depending upon why a company chose to let a toll, the ability to scale up production may be an important factor. If a toll project was designed to meet a specific, short-term need for a known quantity of material, scale-up capability may not be an issue. However if the goal was to develop a wider market and eventually increase production, a small toller that meets all other criteria for selection could be excluded based upon this factor. Planning for success is essential.

Some companies that let toll contracts have been known to work with small tollers who displayed excellent technical, safety, and quality characteristics to help them achieve the necessary higher production capacity. This is feasible if the time frame allows and a closer relationship is mutually beneficial.

2.2.11. Process Safety

If a U.S.-based toll project requires threshold quantities of feedstock, intermediate or finished product that are considered:

- highly hazardous chemicals under OSHA's Process Safety Management (PSM) regulation or
- regulated substances under the EPA Risk Management Program (RMP) rule,

a candidate toller will become subject to either or both of these rules and should demonstrate understanding and thorough implementation of these regulatory elements of process safety (termed "prevention program" under the EPA rule). The capability to achieve these regulatory requirements may be a key factor in a toller's evaluation.

When a candidate toller is not currently regulated by a governmental process safety requirement and the proposed toll project will not trigger regulation, evidence of other good process safety practices should be still be sought and evaluated. Tollers should consider the benefits to their business that come from using recognized tools available through implementing a process safety system as defined by these regulations, or similar systems as defined by CMA's Responsible Care® Codes or CCPS publications. These include key elements such as:

- Employee participation
- Process safety information
- Process hazard analysis
- Management of change
- Operating procedures
- Mechanical integrity
- Emergency planning and response
- Training
- Contractors
- Hot work permit
- Compliance audits
- Pre-startup safety review
- Incident investigation
- Trade secrets

Non–U.S.-based operations may reference the same documents or alternative local references, such as:

- European Process Safety Institute publications
- CIA Publications (United Kingdom's Chemical Industry Association)
- TNO Publications (The Netherlands Organization)
- HSE References (United Kingdom's Health & Safety Executive)

Whether or not a firm is subject to these regulatory requirements, examples of questions to ask candidate tollers at this stage of initial qualification are:

- Have there been fires, explosions or chemical release incidents? If yes, request the incident investigation data, including actions taken to prevent a reoccurrence.
- Request to examine PHA reports.
- Has the facility identified, evaluated and implemented controls to reduce the risks associated with catastrophic chemical releases or accidental releases of regulated substances? Look for evidence of the following:
  - minimization of on-site hazardous chemical inventories,
  - process controls that will prevent releases,
  - substitution of lower hazard chemicals,
  - installation of early warning systems for hazardous chemical releases, and
  - procedures and equipment to mitigate or minimize releases once occurred.
- Has the facility established an effective critical-equipment maintenance program (also termed mechanical integrity program) to prevent failures that would cause hazardous conditions?
- Are there appropriate planning, training, drills, and equipment for response to emergencies? If yes, ask to review the emergency response plan and training records. Be aware that for some facilities, an acceptable plan is to evacuate and call the fire department.

One excellent sign that a candidate toller has an understanding of process safety is the existence of a written management system that describes how each applicable requirement is met.

2.2.12. Security

High value products and proprietary information are often placed in the custody of the selected toller. This can be a major concern in the decision to work with a toller. It is sometimes essential to determine

what measures are being taken by the toller to safeguard a customer's products and information, including electronic information.

The candidate tollers' security policy should emphasize the importance of protecting people, property and the operational practices against loss by intentional destruction or theft. During the site visit, check to see if appropriate methods are taken to control entry and movement of people and vehicles as a security measure. One telltale sign is that you may be denied access to an area because of another company's confidential process. Though an interference, it affirms a sound security practice. Determine whether security inspections are being held during off-duty hours.

2.2.13. Corporate Health, Safety, and Environmental Policies

Although not as informative as past performance measures or hard evidence of good programs, the existence of a company policy stating a candidate toller's commitment to health, safety and environmental responsibility should be determined. These policies, typically signed and displayed prominently in the facility, help ensure management and company executives are fully aware of their commitment to workers and the public.

2.2.14. Housekeeping and Appearance

The general appearance of a facility speaks volumes about how the site is managed. The reviewers for a client can again make some value judgements about a candidate toller by noting the general housekeeping practices during a site visit. Housekeeping can be an indicator of the company's attitude toward health, safety, and the environment. Is trash strewn throughout the facility? Are work sites maintained in a clean and orderly fashion? Is temporary equipment properly stowed when not in use? Are tools well kept and organized? Are small spills properly cleaned and disposed of in a timely fashion? Some tollers may have policies, training, or safe work practices that address housekeeping expectations for personnel. These should be reviewed if available and compared against practice.

2.2.15. Insurance Review and Experience Modifiers

Candidate tollers should be made aware of special insurance needs the proposed toll will require as soon as possible in the initial qualification process. Clients should ask to see a toller's standard insurance certificate to verify coverage. It is common to check for:

- Workmen's compensation insurance at statutory limits and employers' liability insurance
- Comprehensive general liability insurance
- Property insurance
- Pollution and environmental impairment insurance (when applicable)

An experienced candidate toller probably carries the basic insurance required for the industry but contracts are typically dependent upon proof of adequate coverage. Depending on the anticipated contract terms and the financial assessment of both firms, other insurance or bonds may need to be evaluated. These may address business interruption, third party liability, or other identified loss potential.

Examining workers' compensation insurance modified premium will give an assessor more information about past safety performance. If the experience modification rate (EMR) factor is good (calculated by a rating bureau such as the National Council on Compensation Insurance based upon historic loss and payroll data), the toller will be an attractive risk to their insurer and will receive lower premiums. On the other hand, if there are several excess losses (any single claim over $5000) the experience modification rate factor will result in higher premiums. This signals a potential problem worthy of further investigation. Remember that the data used to calculate EMR can be over a year old depending upon how it is collected. Looking at the last three years of data is important in order to determine a trend—and to understand whether the toller is improving or not.

In general, tollers should have active insurance policies that protect themselves and to a certain extent the client from excessive loss. Make certain that the insurance coverage held by both parties works well to manage risks.

2.1.16. Conducting a Site Visit

Some of the candidate tollers' practices, records and documents can not be assessed using only a questionnaire form. A site visit to one or more of the short-listed candidate tollers is usually indicated. This is especially helpful if an unfamiliar toller is competing against a toller that is currently being used. Candidate tollers can use the information in this section to prepare for a site interview when one is requested.

If an on-site visit is required at this stage, review personnel can usually obtain the information from the client through a brief visit. It consists of six parts:

1. Opening meeting
2. Interviews
3. Facility walk-through
4. Document review
5. Closeout meeting
6. Postinspection report

At larger sites, it is sometimes more efficient for two reviewers to interview candidate toller personnel. In general, the senior site manager should be involved in the interview session unless the toller's facility is extremely large with several layers of operations management. It is assumed interviews will include the toller's technical personnel or specialists related to the proposed toll.

An essential part of the on-site visit is the physical inspection of the toller facility—the walk-through. It offers the opportunity to confirm interview responses, observe work practices, interview employees, and note general housekeeping, soil contamination and safety issues.

Field notes should be taken during the inspection to use in preparing a report on the visit. Observations should include the following:

- Facility condition/housekeeping (odors, visible emissions)
- Employee use of personal protective equipment
- Potential for exposure (proximity of residences)
- Process equipment design/operation

- Warehousing (material storage areas)
- Areas of potential contamination
- Design and condition of tank areas
- Waste storage and treatment areas
- Rail/truck transfer areas and loading racks
- Site security provisions
- Fire equipment locations
- Safety shower locations
- Potential release points
- Condition of vessels/drums (properly labeled?)

The extent to which documents are reviewed will depend upon the results of the initial questionnaire responses, the interviews, and facility walk-around. In general, documents should be reviewed to verify good practice compliance, and a sampling will usually suffice.

The following documents and records should be reviewed as appropriate, and observations noted. Some of these documents may not be available as they can contain proprietary information for other clients. Place emphasis on determining whether the toller has established procedures and a management system adequate to ensure ongoing compliance.

- MSDS files
- SARA reports
  – §.311/§.312 annual reports and §.313 annual reports
- Spill prevention control and countermeasures plan (if required)
- Emergency response plan
- Production records sufficient for TSCA
- Sample operating and maintenance procedures
- OSHA 200 Log (note incidents involving operations or materials: are they properly completed?)
- OSHA PSM/EPA RMP documentation (PHAs and incident investigations)
- Training records (OSHA, EPA, DOT)
- Hazardous waste manifests (check for returned generator copies)
- RCRA TSD permit/EPA generator number
- Air/water/waste permits (and monitoring reports)

- Container and sample labeling
- Tank inspections
- Hazardous waste storage area inspections

As a courtesy, a brief closeout meeting should be held with the key contact or parties interviewed. This provides an opportunity to resolve open issues and allows the toller's personnel to ask questions.

Post-visit activities primarily consist of preparing a report, making a recommendation regarding suitability, and communicating the results. Some basic steps recommended are:

- Review and include a summary of the financial assessment
- Review and include the summary of the newspaper/industry on-line search
- Review and include insurance certificates (if appropriate for this stage at your company)
- Identify need for follow-up reviews or commitments to be obtained, for example, a PHA or added industrial hygiene measures
- Check/confirm regulatory violations
- Review information in agency files
- Recommend special clauses or revisions to contract if needed
- Identify contractor follow-up or corrective actions
- Indicate whether these are suggestions or conditions of approval
- Prepare a draft report and transmit it to management
- Obtain management approval authority
- Issue the report as appropriate within your company
- Communicate appropriate findings to the toller

As follow up, document the implementation of corrective actions taken by the toller. Keep this documentation with the initial inspection report that lists the deficiencies for which actions were taken.

2.2.17. Compatibility with Ongoing Operations

One easily overlooked question to ask when selecting a toller is, "What other materials will be handled and what other processes will be operated concurrently with our proposed toll?" The answers may

impact raw material shipping and storage, finished product handling, or effective cleaning of equipment between production runs. A construction or expansion project at the tolling facility may be incompatible with the planned tolling operation. While full disclosure of other processes at the toller facility may be precluded by business interests or confidentiality agreements, these processes may impact the evaluation of the toller. Prior experience with a related process or similar products will generally support knowledge and skills to perform the proposed toll. However, they may also present conflict of business interests or proprietary technology confidentiality concerns.

Consider common scrubbers, vents, sumps, drains, off-gas treatment and other opportunities for inadvertently mixing process materials. Cross-contamination potential at transfer stations should not be overlooked.

Occasionally, an otherwise good candidate toller may need to be rejected or conditionally approved until assurance can be made that contamination, improper storage facilities, confidentiality and other issues are properly managed.

2.2.18. Initial Qualification of International Tollers

When assessing potential tollers for a project where an international presence is prescribed or simply expanding your selection of available tollers, the same basic approach presented here can be used. However, some elements may need to be implemented differently, expanded, or combined to accurately depict a toller's capabilities when crossing national and cultural boundaries. A client should still seek the same ethics regarding safety, environmental responsibility, quality and contractual obligations as described previously.

Building the initial list of candidates for tolling outside the client company's home borders can create some unique problems in regard to their fair assessment. The list may include several good candidate companies that may unfortunately each be located in a different country or region. Each of them may be capable of meeting the distribution or marketing need that initially drove the international toll project.

This situation will require the reviewers to weigh additional aspects such as:

- language barriers
- tax advantages and disadvantages
- cultural differences
- international regulations
- local regulatory requirements
- trade status

The company seeking to toll internationally in this case will benefit from selecting an experienced team of reviewers with international experience. Tollers seeking business from foreign companies would benefit by recognizing these new aspects may present difficulties when their capabilities are being assessed. The candidate tollers could prepare information in advance that helps respond to these potential concerns.

Differences in each country's regulatory requirements may, in turn, cause differences in operating philosophies. It is important to clearly review expectations with regard to health, safety and environmental matters during initial assessments of foreign tollers.

2.3. Making the Final Selection

In this phase of the toller selection process, we assume the "long list" became a "short list" and now one or more candidate tollers from the "short list" will be given an opportunity to prepare a commercial bid. This by no means indicates the short listed tollers are perfect. There may be deficiencies that need to be corrected in concert with the client. With proper effort, one will be successful and be engaged for the toll. Sometimes it is appropriate to decide on a backup toller, as complications can develop that prevent the primary candidate from executing the project as originally planned, due to an incident in their plant, departure of key personnel, or unexpected production demands on the toller.

2.3.1. Comparing and Ranking the Initial Qualification Information

If a standard form was used in the qualification phase, a system should exist to rank the respondents that are being considered. Such a system can be as simple as the reviewers making a written recommendation summarizing the strong points of their selections. Some companies have developed forms that allow the final scores to be quantified. Appendix C, *Sample Toller Assessment—Quantitative Format* contains such an example. With either method, the client should consider having two or more reviewers discuss the candidates and agree on the recommended finalists.

2.3.2. Audit and Verification Process

Data collected for the finalist tollers should be audited and verified once more to ensure no misrepresentation has occurred. Often a more detailed analysis of financial data is undertaken. The guidelines shown in Table 2-1 are rules of thumb to use when interpreting a Dunn & Bradstreet (D&B) report.

2.3.3. Confidentiality Agreements

A confidentiality agreement is frequently required prior to the final selection process. Depending on the process technology, a confidentiality agreement may be required during initial discussions with the toller. Alternately, it may be included in the request for bid or when the final contract is executed.

Some companies that let toll contracts do not visit a site until this last phase in the toller selection process and would need a signed agreement to make the visit and discuss proprietary aspects of the project.

A typical confidentiality disclosure agreement or secrecy agreement addresses:

- The fact that the parties acknowledge that in the course of performing work they may have access to or acquire information that is confidential and proprietary.

Table 2-1. Sample Toller D&B Review Guidelines

ABC CO. TOLLER D&B REVIEW GUIDELINES

- The D&B report is considered confidential and must not be copied or shared with the company under review or outside parties.
- Keep in mind that the information in the D&B report comes from the company itself, therefore it may be subjective. It is in the toller's interest to keep the information supplied to D&B up to date.
- Financial condition of the toller will be rated as Poor (P), Fair (F), Good (G) or Excellent (EXC). For ABC Co. selection, the company should have a condition of Fair or better.
- The asset to liability ratio should be greater than or equal to 1.
- Check that the toller's bills are paid in a timely fashion. The PAYDEX index should be greater than or equal to 65.
- Check to see that the amount of credit they will have extended for a single vendor on our behalf is within the range of amounts they have had extended to them from other vendors in the past.
- Look for trend statements in the report and ask the toller to explain their expected trend if it is potentially relative to ABC Co. interests.
- Check to see whether there are lawsuits, liens or judgements, which may be material to ABC Co.'s interests, for example, product liability.
- Check longevity, for example, that the toller under review has been incorporated for greater than five years.
- If ABC Co.'s stake with the toller may be potentially great, look at relationships between the company and any of its affiliates.
- If there is concern of environmental action against the toller or its site, request a D&B Environmental EPA Federal/State report.

- How the disclosed material may be identified (typically marked PROPRIETARY or CONFIDENTIAL) along with a clause that states that the failure to mark such information does not mean it is not of confidential nature.
- The fact that disclosures made orally or by visual inspection may be considered confidential information.
- An agreement that the parties will hold such information in strict confidence, not disclose such information to third parties and not to use such information for purposes other than in connection with the tolling contract.

- Information that is not considered confidential.
- A time frame for the confidentiality agreement. If included in a contract, it typically extends beyond the term of the contract.

A toller may need to use resources outside their company to measure physical properties, conduct safety or other testing, engineer changes to piping or other facilities and equipment. This need frequently occurs for products in the initial development or commercialization stage. The toller should maintain confidentiality agreements with their suppliers and subcontractors commensurate with the proprietary nature of their client companies' processes. Provision to allow disclosure of information to third parties should be addressed in the contract between the toller and the client. It may be structured so that the client must approve the toller's release of information to third parties.

2.3.4. Finalizing the Technology Package

If a preliminary technology package was completed in the style of Example 2-1, *Initial Technology Package,* it should now be expanded and approved within the client company. The technology package is the single most important tool in ensuring the efficient, accurate transfer of information between the parties. Effective technology transfer to a new toller relies upon a well-constructed, complete technology package.

Typical items to consider for inclusion in the package are:

- A synthesis flow diagram
- A detailed process description
- A capacity model
- Detailed sequencing of processing steps with material balance and processing times
- Past operating records (if the material has been processed in a pilot plant or another facility)
- Any pre-existing process hazards analysis from the pilot development or other tolling efforts
- Reactivity information

- A detailed description of the hazards associated with the raw materials / component products (including MSDSs)
- Documentation of appropriate materials of construction and observed or anticipated corrosion rates
- A list of required and suggested personal protective equipment
- Any special equipment requirements, including that needed for charging or handling highly hazardous materials
- Details on special processing requirements, including emergency situations
- Analytical methods and specifications for the component materials, intermediates, and the final product
- Any required in-process checks
- Equipment cleaning and validation methods
- Environmental monitoring methods required
- Identification of exceptional regulatory requirements (SARA §.311/ §.313 lists status; FDA controlled substance list; NORM or other radiation issues, chemical-specific registration or license requirements)
- Material safety data sheets (MSDSs) for the intermediates and final product
- Waste disposal procedures
- Special packaging requirements
- Required product-storage conditions
- Technical project reports (if available) or previous experience of running the same process in-house

Engineering staff, HS&E representatives, chemists, and others should participate in the development of the technology package as demanded by the risk involved with the specific toll. The technology package, plus the operating procedures, equipment drawings, and other process safety information, become the basis of the process hazard analysis. Thoroughness will help ensure an accurate assessment of the risks associated with the tolling project.

2.3.5. Evaluating Proposals

Each company seeking tollers has its own approach to how they bid toll contracts. In some cases, the candidate tollers have been ranked

and the company begins technical and commercial negotiations with the top rated candidate toller. If terms that meet safety, environmental, technical and cost considerations cannot be agreed to, the client company continues negotiating with the next toller on the ranked list or assists the first toller in correcting deficiencies. Eventually a qualified toller provides an economical bid (or an alternative course is chosen). Opting to drop the toll project completely is sometimes the appropriate choice from a process safety standpoint.

A company selecting a toller will be well served if they ensure candidates received a clear set of proposal requirements. When qualified finalists are given a project scope based upon an accurate technology package, they can produce a bid that is easily evaluated.

Some guidance for evaluating toll project proposals follows:

- Assign a technical review team and a commercial review team.
- Use a checklist to ensure bidders responded to each specific item in the request for proposal. Eliminate or resolve incomplete proposals.
- The technical review team should compare the thoroughness of each scope of work related response between the candidate toller proposals.
- The technical review team should compare the overall response related to process safety, environmental, health, and quality capability-related items to the data gathered through questionnaires or visits. Does their practice match their policy?
- The technical review team should rank each proposal for total responsiveness, quality and completeness without cost consideration. Can deficiencies be corrected?
- The commercial review team should rank the proposals based upon their commercial attractiveness.
- The two teams should meet, compare rankings and select the candidate with the best overall ranking.
- Prior to making the award, it is important to determine whether a company has a philosophy of excellence and corresponding technical capacity to achieve process safety and

environmental responsibility commensurate with the risk posed by the toll processes and chemicals.

2.3.6. Contract Award and Negotiation

Once the successful bidder is selected, it is still possible to request corrective actions and additional terms through contract negotiation. There are occasionally situations where a contractual term cannot be negotiated with the first selection and the next candidate is offered the toll contract. Chapter 3, *Mutual Agreements, Obligations, and Contract Considerations* addresses this topic in more detail.

3

MUTUAL AGREEMENTS, OBLIGATIONS, AND CONTRACT CONSIDERATIONS

Once a toller has been selected and any required preliminary confidentiality protection is in place, the client typically shares more detailed information. The toller can then make an informed decision about the economic, technical, and safety aspects involved in bidding the work. If the two parties decide the project will be mutually beneficial, agreements and obligations are negotiated and then formalized in a written contract. Both parties—the client and the toller—have roles in fulfilling the contract and in carrying out their responsibilities to the workers and the public. The purpose of the written contract is to clarify and document those roles and responsibilities to effectively execute, maintain and eventually terminate the project.

Figure 3-1 provides a flowchart depicting the process described in this chapter.

3.1. Defining the Rights and Expectations of the Parties

A successful tolling project depends upon defining the project objectives at the outset and clearly communicating those objectives. The objectives take into account the rights and expectations of both the toller and the client. Specifics such as ownership, specifications, timing, regulatory requirements, product quality, and documentation are considered. Each project or process is unique and consequently the agreements reached between the parties and the

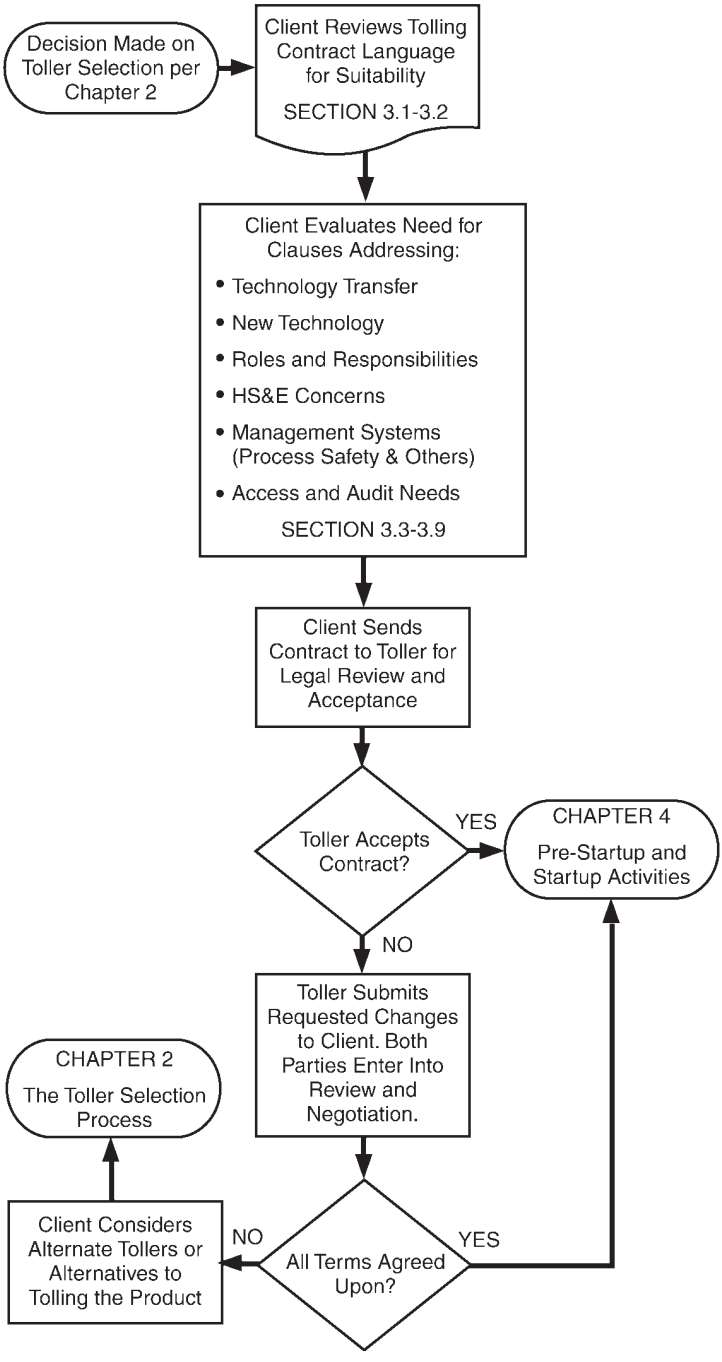

Figure 3-1. Mutual agreements, obligations, and considerations flowchart

ensuing contract will also be unique. Some points you may want to consider are

1. What confidentiality and/or secrecy agreements are needed to protect both parties?
   - Does access to production area need to be restricted?
2. Are points of contact identified for all concerned parties?
   - Who are the technical points of contact?
   - Who are the commercial points of contact?
   - Who issues the purchase orders and invoices?
   - Who is the emergency contact?
3. Ownership
   - Who supplies which raw materials?
   - What is the value of supplied materials at any given time under the toller's control?
   - Who supplies packaging and labeling?
   - Who owns process technology?
   - Who owns product specifications?
   - Who owns products while they are transported?
   - When does title to product change hands?
   - Who owns raw materials while they are transported?
   - Who owns leftover materials?
   - Who owns process waste?
   - Who has liability for process waste disposal? (That is, who generates the hazardous waste manifest and under what owner/shipper name?)
4. Product Quality
   - Should the toller or their client be responsible for final product qualification? (that is, certificates of analysis)
   - Which party will be responsible for handling product returned from customer which does not meet product specifications?
5. Will the client's personnel participate in process set-up and/or manufacturing process? Why?
6. What is the anticipated time frame (or term) for the Agreement?
7. What are the anticipated production rates?

- Will the quantities fluctuate over the term of the agreement?
- What is the mechanism for dealing with fluctuations?
- Negotiation?
- Formula?
- Other issues?

8. Which manufacturing facilities and equipment will be used?
9. Specify the yield ratio or method of determining the yield ratio.
   - How will the client be compensated for reduced yield?
   - Should the client share in the cost savings of improved yield?
   - Is off-spec material considered in calculating the yield?
10. Manufacturing Fee
    - Specify the fee. How will the fee be calculated?
    - Will it be adjusted? If so, when and on what basis:
      – Off-spec material
      – CPI or other index
      – Negotiated increases
      – Increase in raw material/labor costs
    - Will the client pay or reimburse toller for disposal costs? Other costs?
11. Forecasting/Ordering/Delivery
    - How will product manufacturing and delivery be handled?
    - Who sets delivery schedules?
    - When are firm orders placed?
12. Transportation and Storage
    - Who is responsible for shipping/delivery to client or end user?
    - Who pays for shipping client material to toller and who pays for shipment of finished product from toller?
    - Will storage of finished product be required from toller?
    - Are dedicated shipping vessels required for bulk material transport?
    - Which party will select the carriers used for shipments?
    - Will any of the supplied material be imported from another country?
    - Will the finished product be exported to another country? Which party will handle the required export shipping documentation?

13. Packaging
    - Who is responsible for labeling and packaging product?
    - How is the material to be packaged?
    - Who purchases packaging materials?
    - Are there special packaging specifications? If so, specify.
14. Reports: Identify necessary documentation and reporting requirements.
15. Equipment
    - Should equipment be dedicated to the client's exclusive use?
    - Will new equipment be purchased?
    - Who will own the equipment?
    - Who specifies and designs the equipment and installation?
    - Who is responsible for installation?
    - Will the client pay for or reimburse the toller for new equipment?
    - How will the client reimburse the toller?
16. Is time of the essence? How will timing be addressed?

3.2. Legal Obligations, Defining Boundaries, Contract Topics

In addition to the laws and regulations that govern the handling of the substances involved in the process, the parties have legal obligations to one another as stated in the contract. Contract topics that specify boundaries may include:

- ***Premise:*** recitation of the relationship between the parties and history
- ***Manufacturing service:*** lays out the basic arrangement between the parties
- ***Term:*** time frame with expiration date
  – *Early termination:* list of possible reasons and procedures
  – *Proration:* provision for prorating if the contract is ended early
- ***Production:*** quantities to be manufactured for fixed term (monthly, quarterly, periodically, as ordered)
  – Minimum quantities to be purchased
  – Quantity of supplied materials (raw materials)

- ***Manufacturing Facility:*** location where work will be performed
- ***Yield:*** definition of the quantity of product to be produced from a given quantity of raw materials
- ***Manufacturing Fees, Hazardous and Nonhazardous Waste Disposal Costs, and Invoicing***
  - *Statement* of the fee formula
  - *Disposal Fees:* definition of who pays the disposal fees
  - *Invoices:* statement of procedure for submitting invoices
- ***Quality Control:*** explanation of responsibilities for analysis of supplied materials, finished product, and work in progress; consequences of off-spec materials; procedure for rework
- ***Process Ownership:*** specification of who owns the process, degree of liability for remediation, procedure for review and approval of process changes
- ***Forecasting; Orders; Shipping:*** definition of client needs and toller capacity; logistics for labels, bills of lading, delivery modes, and packaging
- ***Reports:*** listing of necessary reports: for example, production status inventories of supplied materials and product, mass balances
- ***Dedication of equipment:*** stipulations concerning the installation of special equipment, equipment decontamination and cross contamination
- ***Schedule:*** limitations on performance dates, consequences of delay
- ***Other terms and conditions:*** provisions for payment terms, freight, taxes, packaging and operational difficulties, and insurance
  - Limitations on liability
  - Compliance with laws and permits
  - Disposal of waste
  - Improvements
  - Title and risk of loss
  - Inspections and auditing
  - Termination; disposition of property
  - Confidentiality
  - Assignment

– Taxes
– Insurance
– Equipment purchases
– Force majeure

Compliance with regulations is not only a legal necessity and an ethical duty, but can also help ensure a successful tolling project. For tolls that invoke special regulations not normally required for an industrial facility, the contract and its referenced documents should mention them. Even though the regulatory burden may initially rest with the toller, the toll would benefit by spelling out these requirements and obtaining agreement on the responsibilities each party has in complying with them. Chapter 5: *Ongoing Operations,* Section 5.3.5, *Regulatory Issues* contains a more detailed list of regulations that may apply.

3.3. Technology Transfer

Technology transfer is a critical step in ensuring project success. The client must recognize that each toller is different in regard to how they progress from the laboratory to a test run to production. The toller selection step should have revealed that each candidate company possessed different levels of skill, experience and management culture.

While a complete technology package is essential, the transfer of technology can be enhanced by:

- Data on past experience with the process
- Data on mistakes that were made in the past and how to avoid them in the future

One method that can be used to enhance the efficiency of technology transfer presents itself when a client has a laboratory or pilot plant producing the materials. When this is so, the toller's personnel can visit the site, observe the processing and ask questions of the research and development team. Conversely, the research and development team or chemists and engineers from the client can witness any test runs taking place at the toller's plant. These options allow both companies to ask questions, give advice on process and

safety improvements, and reassure themselves that the technology is implemented properly.

3.4. Technology Developed during Tolling Operations

What happens to technology improvements developed during tolling operations? Regardless of ownership, process changes should involve mutual notice and consent and may trigger process safety related activities. The parties need to come to agreement as to who owns and has patent rights on improvements to the process. Clients do not want to be put in the position of having their manufacturing rights blocked by a patent for which a toller may apply that is based on an improvement to the existing process. Conversely, tollers may want to use improvements of general applicability to their own business. If this is acceptable to both parties and does not rise to the level of disclosure of confidential information, the client may wish to license the right to the toller to allow use of such improvements.

3.5. Knowledge Enhancement for Both Parties

A tolling project is an opportunity for knowledge enhancement for both parties. It is not only an opportunity, but it is a responsibility.

- The toller is obliged to learn about the process so that it can be performed safely and in an environmentally sound manner while producing quality product.
- The client should learn about the toller's planned operation, and as part of their product stewardship responsibilities, audit the toller regarding HS&E practices.

The client may have the specific objective to use the toll operation to pilot or develop scale up information on the process, including evaluation of equipment and process variables.

3.5.1. New Learning about Processing Hazards and Production Efficiency

Tolling situations can arise at various stages in a product's development. For example, a company may choose to issue a tolling con-

tract for a product that has been fully developed and produced many times in the past. Conversely, some tolling situations involve a product in the early stages of research and development. The development of the process may address many issues, including quality, yield, and production efficiencies. Depending on the prior knowledge of the process, there may be only limited knowledge of safe or effective operating conditions. Development beyond the initial operating conditions requires agreed controls and effective communication between the parties.

3.6. Roles and Responsibilities

The roles and responsibilities of the toller and their client are spelled out in the contract. For example, some of the toller's responsibilities may be:

- unloading, handling, and storing raw materials and packaging materials at the toller's facility;
- manufacturing products;
- collecting, analyzing, and retaining samples of the products for a specified period;
- assuring quality;
- packaging products;
- handling and storing bulk and packaged products;
- preparing products for shipment;
- making the products available to a common carrier;
- keeping records and reporting to the client and applicable governmental agencies;
- handling, storing, treating, and disposing of wastes generated by the toller in connection with the toller's performance of the agreement.

The responsibilities of the client may be:

- providing technology relating to the manufacture of the products;
- providing supply and operations planning;
- ordering and supplying key raw materials;
- providing HS&E and process safety information;

- providing on-site support with the company's technical resources to assist the toller in producing products.

While these responsibilities seem straightforward, there are numerous responsibilities that are intertwined and discrete. Both parties need to understand their individual responsibilities especially regarding process hazards, environmental concerns, communication, and technology/knowledge transfer.

3.6.1. What Is Contained in a Detailed Technology Package?

The success of the tolling experience is directly related to the quality of the technology package. Chapter 2, Example 2-1, *Initial Technology Package*, presented a sample of the contents of a technology package that could be expanded and attached as an addendum to the contract. A detailed technical package is as unique as each project, however, the items included in the example as well as in Section 2.3.4 "Finalizing the Technology Package" may assist tollers and client companies in formulating a complete technical package to guide the tolling operation.

Adequate time and resources spent preparing the technology package help ensure an efficient and comprehensive transfer of information and knowledge, and therefore, play an important part in carrying out a safe project.

The client generally supplies processing technology and specific operating parameters related to safe operating condition. The Technical Package may include, but not be limited to, the following:

- Table of Contents
- Product Formulations Summary Sheet
- Chemistry
- Process Conditions
- Forecasted Volumes Summary Sheet
- Manufacturing Procedures
- Product Controls
- Raw Material Specifications
- Packout/Container Requirements
- Packaging Requirements
- List of Analytical Equipment Required
- Analytical Test Methods

- Health, Safety and Environmental Information
- MSDS for Raw Materials and Product
- Previous Process Hazard Analyses
- Responsible Care® Commitment for Contract Processors
- Copy of Contract or Agreement
- Copy of Secrecy Agreement
- Process Safety Information (if available)

3.6.2. Scale Up Technology

A client may choose to develop a toller who is qualified, but will need additional or improved equipment and technology to meet the eventual production levels required later in the life of the toll contract. The client may require the toller to make changes or modifications at their plant in order to effectively manufacture a particular product in increasing quantity. Some areas of concern applicable to scale up were listed in *Various Points to Consider*, Section 3.1. Additional considerations to address in the contract may include:

- Responsibility for new equipment selection, design and installation
- Responsibility for the performance of the new equipment or new technology
- Responsibility for maintenance of new equipment
- Responsibility for determining if the new equipment or technology is suitable for the intended purpose
- Payment for equipment or R&D
- Ownership of the equipment or technology after project completion

3.6.3. Emergency Response Considerations

The toller is generally responsible for emergency response at the site, as required by local authorities and applicable regulations. Some of these include:

- Hazardous Waste Operations and Emergency Response (HAZWOPER)—29 CFR 1910.120
- Employee Emergency Plans and Fire Prevention Plans—29 CFR 1910.38

U.S. regulations that may be applicable during a new toll due to types and quantities of chemicals introduced are listed below:

- Process Safety Management of Highly Hazardous Chemicals (PSM): OSHA 29 CFR 1910.119
- Guidelines for the Preparation and Implementation of a Spill Prevention Control and Countermeasure Plan (SPCC): EPA 40 CFR part 112.7
- Oil Pollution Act (OPA) Facility Response Plans (FRP): EPA 40 CFR part 112.20
- Risk Management Program Rule (RMP)—Emergency Response Program: EPA 40 CFR part 68.95
- Resource Conservation and Recovery Act (RCRA)—Contingency Plan and Emergency Procedures: EPA 40 CFR part 264 or part 265, Subpart D
- Resource Conservation and Recovery Act (RCRA)—Preparedness and Prevention: EPA 40 CFR part 264 or part 265, Subpart C

The toller and client should evaluate any special emergency response needs for the toll and determine whether these need to be addressed in the contract.

3.6.4. Wastes and Emissions

Both the client and the toller should have an interest in ensuring the toller's compliance with environmental requirements, including the appropriate storage, treatment and disposal of waste from the tolling operation. Under some environmental statutes, penalties—civil and criminal—may be assessed against one or both parties and even their officers. Although the details of the agreement and course of conduct between the client and the toller will greatly affect the outcome, liability for investigative and remedial costs incurred by other parties are an additional concern. Therefore, the party contracting the toll is urged to review and approve the toller's waste handling and disposal, assure that the agreement reflects these activities and then monitor them to ensure compliance. This is the best protection that the client can achieve to minimize the potential liability for the toller's noncompliance with environmental laws.

For "hazardous" and other regulated waste streams, these contract terms should address at a minimum:

- Ownership and responsibility for each waste stream
- Responsibility for short term storage and consolidation of waste streams
- Agreement or prohibition of commingling waste streams from various processes, or between processes associated with more than one client
- The responsible party and associated regulatory responsibility to generate a hazardous waste manifest.

Similar issues should be reviewed for nonregulated wastes.

3.6.5. Establishing and Maintaining Communication

The lines of communication that were established in the toller selection phase can be formalized in the contract stage. The contract should spell out the persons to contact and under which circumstances they *must* be contacted. Detailed and continuing exchange of information is necessary in order to optimize the administration and performance of the tolling contract. The parties may want to come to agreement and include the following in the contract or supporting documentation to enhance communication:

- Who are the technical points of contact and how can they be reached?
- How often should the parties meet and who should be included?
- What reports are needed to ensure the smooth flow of necessary information?
- What is the process for resolving issues?
- How will changes in personnel be managed?
- How will process changes be managed?
- How will emergencies be managed?

As with any relationship involving two or more parties, communication is key to a successful tolling relationship.

3.6.6. Participation in PHAs: Resolving the Issues

In order to understand the chemical and process hazards, a Process Hazard Analysis (PHA) should be conducted. For tolls involving

regulated substances present above the threshold quantities per 29 CFR 1910.119 (OSHA Process Safety Management Standard) and 40 CFR part 68 (EPA Risk Management Program Rule), a PHA is a regulatory requirement. Both parties need to stipulate their areas of responsibility and participation with respect to:

- Assignment of the PHA leader
- Provision of PHA team members
- Type(s) of PHA methodology acceptable for the toll
- Process safety information update and preparation
- Resolution of PHA action items
- Reports on progress of action item resolution

Details concerning such responsibilities could be provided in the contract or in project correspondence. Chapter 4, *Pre-startup and Startup Activities,* provides more guidance to consider when performing the PHA.

3.6.7. Training Requirements

The contract or other agreements can establish responsibility for the necessary training. This can range from basic safety training at the toller's site to the toll specific process overview and job specific procedure training.

The client may be expert on the process and therefore in the best position to supply engineering and technical personnel to assist with training the toller's staff. This may be a cost-effective way to bring the toller's staff up to speed. If the toller is supplying the technical expertise, this may not be necessary. The client will want to ensure that the training program at the toller's facility is valid and meets process safety and environmental risk management training recommendations and requirements.

3.7. Health, Safety, and Environmental Considerations

It is essential that health, safety, and environmental data be shared between the parties. This can be mentioned in the contract or a sup-

plementary document or referenced policy. Any techniques, information or experience learned by the toller in execution of the contract should be shared with the client.

The toller needs to be familiar with all raw materials, intermediate materials, products and wastes, used, produced or generated, respectively, while operating the process. Tollers in the U.S. should comply with the Federal OSHA "Hazard Communication Standard," codified as 29 CFR. 1910.1200 and any similar state "right-to-know" laws that are currently in force or may be enacted during the term of the contract. This is often stated in the contract. The contract may require the toller to inform its employees of the chemical hazards associated with products or chemicals and may also be responsible for training its employees in the proper handling methods. The toller has an obligation when in doubt about a product or chemical, to seek further information from the product's manufacturer.

While material safety data sheets (MSDS) provide important information they may not provide information on all hazards that may be encountered during processing. A review of the MSDS is not a substitute for conducting a process hazards analysis. Additional information to consider should include:

- Characterization of potential waste streams
- Waste treatment and disposal
- Environmental data
- Reactive chemicals test results
- Chemical compatibility chart
- How the chemicals react with one another if added in wrong amounts
- How the chemicals react with common metals and chemicals. (Note materials to be avoided when working with the chemicals.)
- Thermal and chemical stability data
- Hazards of shipping and storing container quantities, hazards of larger quantities
- Powder and dust testing data
- The history of reactive incidents with these chemicals
- Protocols for employee exposure monitoring

3.8. Management Systems

It is incumbent upon the toller to develop and follow internal management systems as appropriate to support business needs, production needs, process safety, environmental responsibility, and worker health. The selection process should have considered whether or not satisfactory systems are in place. Nevertheless, the contract or auxiliary documents may be the vehicle used to help ensure that the system reviewed is the system actually used for completing the toll in question. Within the process safety management system, the management of change and training elements are essential subsystems.

3.8.1. Management of Change, Including Change of Personnel

In the United States, the post-OSHA PSM/EPA RMP view of management of change (MOC) has come to mean managing a change in equipment, chemicals, technology or procedure. There should be agreement between the client and the toller on how change is to be managed for a toll. For more detail, see Section 5.3.1 "Management of Change Issues."

Change of personnel can also impact safety. Evaluate if changes in the number and duties of personnel benefit from management of change. For example, such changes could affect operating procedures and emergency response capabilities. There may be an additional benefit in addressing how a toller will provide the information turnover and maintenance of skills necessary to ensure continuity of operations in the event that key personnel change. Consider aspects such as what kind of personnel change may activate MOC.

3.8.2. Defining and Executing Training Requirements

Another management system that may need to be defined in the contract or associated documentation is the training management system. Regulatory training requirements for workers in the plant are important and there are other groups to consider from a business and efficiency standpoint. The responsibility for developing procedures and training for operators and maintenance crews may be denoted in the contract.

In addition to the plant workers, others may benefit from some special training related to the toll. It may be advantageous or required to consider laboratory personnel, technical support staff, management and others when planning training. Again, the contract may be the way to define this and document responsibility.

3.9. Access and Right to Audit

The client will want to ensure that it has access to and the right to audit the tolling facility. Factors that may be negotiated and formalized in the contract include:

- Who will pay for audits and inspections?
- May audits be conducted outside of normal working hours?
- What is considered by both parties to be reasonable notice prior to an inspection or audit?
- What records relating to manufacturing, processing, storage, packaging, transportation and disposal of products or waste are subject to inspection?
- How long after the agreement is terminated might the client need access to records (or will the records be turned over to them on completion of the toll)?
- Under what circumstances might the toller be asked to assume the cost of an inspection or audit?
- Will the client conduct audits to assure that regulatory requirements are being met?
- Will audits be conducted by the client or an agreed upon third party auditor?
- How will audit findings be resolved?

3.10. Requalification: The Time Frame Issue

Even when dealing with a familiar toller, the client may choose to reevaluate the toller when there is a change in the process, a change at the tolling facility, a change in personnel, or a change in equipment. Additionally, as new information becomes available, both parties may choose to reassess the relationship. The schedule for requalification

when there are no known changes is largely dependent upon the complexity of the process, the size of the project, and the hazard of the materials. Chapter 5, *Ongoing Operations: Audits and Follow-up,* provides guidance on requalification of the tolling arrangement.

3.11. Equipment Selection, Preparation, and Decontamination

Both parties need to identify responsibilities for choosing the right equipment for the process, preparing equipment for the process, and decontaminating equipment. Consider whether chemical and process hazards have been addressed in the selection, preparation, and decontamination of equipment. Examine the need to contractually address containment and disposal of residual process fluids and decontamination materials. If food products or pharmaceuticals are involved, cleaning methods may also be an issue to address in the contract.

3.12. Performance Clauses and Bonuses

If the toller improves the yield, or produces more product than expected from the quantity of raw materials used, it may be appropriate to share in the cost savings on some basis. Performance clauses and bonuses for production can be part of the formal agreement negotiated between the parties.

3.13. Insurance Requirements

Insurance requirements are stipulated in contracts between tollers and client companies. Often, the toller is required to show proof that it obtains and maintains specified insurance coverage. Minimum amounts may be set for:

- Workers' compensation insurance as required by laws and regulations applicable to and covering employees of the toller engaged in the performance of the manufacturing services.

- Employers' liability insurance protecting the toller against common law liability, in the absence of statutory liability, for employee injury arising out of the master-servant relationship with a specified limit per occurrence.
  - Commercial general liability insurance including products/completed operations with limits of liability
  - Personal injury
  - Property damage
- Automobile liability insurance including nonowned and hired vehicles
- Bodily injury
- Excess liability insurance over commercial general liability and comprehensive automobile liability coverages afforded by the primary policies
- Environmental impairment liability insurance for non-sudden and accidental occurrences
- Business interruption

The toller may be required to furnish certificates of insurance or copies of policies showing specific coverages and provide the client with at least thirty days notice of cancellation or modifications. As appropriate, the client should be named as an additional insured party on insurance certificates.

3.14. Permit Requirements: Required Filings

The responsibility for obtaining permits, required filings, and rights to review permits should be noted in the contract. Both parties are expected to be in compliance with all laws and permits applicable to the tolling operation.

3.15. Escape and Termination Clauses

Contracts usually contain clauses to govern the termination of projects upon completion at a specified renewal period or early termination for various reasons. Termination normally requires written notice with a specified time frame for conclusion and removal of

property. Possible reasons for termination prior to the normal conclusion of the project include:

- Adverse change in financial condition of one of the parties such as insolvency, reorganization, debt arrangement, assignment for the benefit of creditors or any other granting of relief from creditors; or dissolution, liquidation, or bankruptcy proceedings
- The discovery of a condition causing or amounting to imminent danger to health, safety or the environment
- Commercial considerations
- A material breach of the contract

The contract can specify the amount of time the client needs to remove its materials from the toller's facility and lays out notification procedures for dissolving the contract. Chapter 6, *Closure and Audit*, Example 6-1 is a sample contract termination checklist. It is an illustration of one company's inventory list for closing out a tolling project. It addresses material, financial, legal and environmental considerations.

3.16. Notification of Accidents, Incidents, Releases and Agency Inspections

Contracts or associated documents normally specify that the toller will report accidents, incidents, releases and agency inspections to the client as soon as practicable or within a specified time frame. This is particularly important if these involve injuries, offsite consequences, or damage to property resulting from work performed for the client. The toller should also be requested to provide their client with copies of any reports sent to regulatory agencies for these occurrences.

3.17. Right to Assist in Investigation

The client may want to reserve the right to participate in investigations of incidents or releases resulting from production, packaging,

or transporting of its product. The contract can state the terms and methods for participation. Some questions to resolve may be:

- Who investigates accidents? (The toller, the client, both parties, third party, other specific site positions?)
- What are the rights and responsibilities of each party with regard to regulatory inspections?
- What are the rights and responsibilities regarding interviewing parties, requiring drug testing, medical review of people involved in the accident, as well as policies associated with these areas?

3.18. Pre-startup Safety Review (PSSR)

The contract or associated documents may address a requirement for a pre-startup safety review (PSSR). In the case of toll operations, the PSSR may also provide a 'final check' that all agreed issues have been addressed and conditions met to assure the toll operation is ready for start-up. The contract may specify remedies if either party has failed to perform, resulting in delay or cancellation. Like the PHA, a PSSR may be a regulatory requirement in the U.S. under the OSHA PSM and EPA RMP regulations. Chapter 4, *Pre-startup and Startup Activities,* provides some considerations for performing a PSSR that may assist in determining this obligation or agreement.

3.19. Formalizing Agreements, Obligations, and Other Considerations

The following example is a portion of an actual agreement for a tolling operation. As all tolling operations are unique, so are the resulting written contracts or agreements that govern them. Attachments to this example might include the technology package, PHA findings, MOC methods, training plans and procedure development plans.

Example 3-1. Sample Purchase and Sale Agreement

This Purchase and Sale Agreement ("Agreement") is between
THE SELLER [INSERT TOLLER COMPANY NAME AND ADDRESS]

_____

and

THE PURCHASER [INSERT CLIENT COMPANY NAME AND ADDRESS]

_____

In consideration of the mutual covenants set forth herein, Seller and [insert company name] agree as follows:

1. TERM OF AGREEMENT.

This Agreement will be for an initial term of _____ beginning on _____ and ending on _____. This agreement may be renewed for additional (X) year periods upon mutual written agreement.

2. PURCHASES AND SALES.

a. [insert company name] agrees to buy from Seller and Seller agrees to sell to [insert company name] the following product meeting the specifications set forth in [attach addendum with product specifications]:

Product Name	Estimated Quantity	Minima1 Annual Quantity	Maximum Annual Quantity	Price (U.S. Currency)

b. In addition to the purchase price for Product, [insert company name] will deliver to Seller, at (no charge) _____ pounds of _____ meeting the specifications set forth in [attach addendum with material specifications] for each pound of Product supplied under this Agreement.

3. PRODUCT ORDERS.

[Insert company name] will issue orders for Product at least ____ days before the delivery date which specify the quantity, time, and place for delivery of Product. Seller will timely manufacture and deliver Product as directed in [insert company name]'s orders for Product. Product will be

shipped in mutually acceptable types and sizes of drums, bins, cartons or other shipping containers.

4. PRODUCT SPECIFICATION, CERTIFICATIONS AND CHANGES.

a. Seller will certify conformance of Product to the specifications with each delivery. [insert company name] is not required to inspect Product for conformance to specifications.

b. From time to time, [insert company name] may request changes to the Product specifications which will not be effective unless agreed to in writing by Seller. If more than (X) days pass following the receipt of [insert company name]'s request and Seller and [insert company name] have not agreed upon mutually acceptable terms and conditions for delivering Product meeting the revised specifications, then [insert company name] may, at any time thereafter, terminate this Agreement or wholly or partially cancel its remaining purchase obligations by sending (X) days' prior written notice and may purchase such quantity of Product from other sources.

5. DELIVERY; TITLE; RISK OF LOSS.

a. All Product will be shipped FOB destination point, to the location specified in [insert company name]'s order for the Product. Title to Product and all legal responsibilities associated therewith will remain with Seller until the Product is delivered to the FOB point. [insert company name] may select the carriers and the routes.

b. Materials will be shipped, FOB shipping point, to Seller's facility at _____. Title to Materials and all legal responsibilities associated therewith will transfer to Seller when the Materials are delivered to the FOB point. [insert company name] will pay freight for Materials to Seller's facility. Seller will use the Materials exclusively to manufacture Product for [insert company name]. Upon delivery of Materials to the FOB point, Seller will be solely responsible for the receiving, handling, storing, safekeeping, and disposal of Materials and will be liable for any loss or damage thereof. [insert company name] may select the carriers and the routes. The parties shall mutually agree on the delivery dates for delivery of Material to Seller.

c. Upon the expiration or termination of this Agreement, if [insert company name] so requests, Seller will, according to such request, deliver and convey title to [insert company name] remaining Product at the prices set

forth in this Agreement and Materials which Seller has not earned. The parties will then settle any remaining imbalances according to the terms contained in paragraph 8. Title and any responsibility for handling such Product or Materials shall not be deemed to have been conveyed or transferred to [insert company name] until such Product or Materials have been delivered to [insert company name] pursuant to the terms in paragraph 5(a) above, except [insert company name] will pay freight for Materials.

6. PAYMENT AND PAYMENT TERMS.

Seller will invoice [insert company name] each month for Product delivered the preceding month. Payment terms are net (X) days from the date of receipt by [insert company name] of Seller's invoice. Seller's charges under this Agreement include all applicable taxes, costs and expenses.

7. COMPETITIVE OFFERS.

If [insert company name] can obtain comparable Product at a lower delivered cost from another party, then [insert company name] may request Seller to meet such cost within (X) days of Seller's receipt of written notice from [insert company name]. If Seller is unwilling to meet such cost within such notice period, then, at the expiration of such notice period, [insert company name] may obtain the Product from such party and the quantity of such Product will be deducted from [insert company name]'s and Seller's obligations hereunder.

8. IMBALANCES.

Each party will, as soon as practical, following the end of each month, provide the other with a report stating the quantities delivered and received during the month and the calendar year pursuant to this Agreement, as well as exchange balance for such periods. The reports will be sent to [insert company name and address] and to Seller to the attention of _____ at _____. If quantities of Materials delivered by [insert company name] are not in proportionate balance with the amount of Product delivered by Seller at the end of any calendar quarter, then within (X) days Seller will itemize and document the difference to [insert company name]. [Insert company name] will then, at [insert company name]'s option, (1) deliver Materials to Seller as necessary to correct the imbalance, or (2) take delivery of Product from Seller as necessary to correct the imbalance, or (3) either invoice or pay Seller, as applicable, for the price of Materials (i.e., the price of Mate-

rials as reported in the then most current *Chemical Marketing Reporter*) to correct the imbalance.

9. FACILITIES AND OPERATIONS.

a. Seller warrants that the facilities it will utilize in the performance of this Agreement will comply with all laws, regulations and ordinances governing construction and operation of such manufacturing facilities, including, without limitation, all environmental, health and safety laws. Seller has the responsibility to properly engineer, construct, maintain and operate such facilities. Seller will maintain all facilities and equipment used to perform its obligations pursuant to this Agreement in a good and serviceable condition.

b. Seller warrants to perform the following activities safely, properly and in conformance with all applicable laws, regulations and ordinances: manufacturing, receiving of Materials and raw materials, storing, blending, packaging, cleaning, performing analytical work, lot control marking, shipping, completing paperwork, and all other operations related to Seller's performance of this Agreement. Seller shall be deemed the generator and owner of any "Wastes" [which term, as used in this Agreement, includes the meaning of "hazardous substance" and/or "hazardous materials" which is "disposed or released" as provided in the Federal Comprehensive Environmental Response, Compensation and Liability Act ("CERCLA"), 42 U.S.C. 6901 *et seq*., the meaning of "waste" as provided in the Federal Resource Conservation and Recovery Act ("RCRA"), 42 U.S.C. 6901 *et seq*. and includes waste of any kind including, without limitation, routine process waste and by-products which are disposed] generated in connection with Seller's performance under this Agreement, and as such shall be solely and independently responsible for any liabilities caused by such wastes and shall safely, properly and in compliance with applicable laws, regulations and ordinances dispose of or arrange for the disposal of the same. On an annual basis, Seller will certify to [insert company name] that all Wastes have been properly disposed of in compliance with applicable laws, regulations and ordinances. Seller's failure to fulfill the obligations of this paragraph 9 will be construed as a material breach of this Agreement.

c. The Seller will maintain a written Management of Change (MOC) procedure to ensure that both the safety of plant operations and product quality. Changes to all plant operations must be thoroughly evaluated by the Seller to assess the potential to affect employee health, personnel and equipment safety, the environment, and product quality. The MOC procedure should

include adequate evaluation of changes to equipment (except for "replacement in kind"), piping, control systems, process interlocks, raw material and process chemical suppliers, technology, operating conditions, analytical procedures, and key personnel. The MOC procedure will apply to both temporary and permanent changes and address effects on existing Hazards Reviews conducted for this project. The Seller is responsible for managing change, including appropriate review by technically qualified personnel. When changes impact product quality or have H&SE implications, Seller will obtain obtaining [insert company name] pre-approval for these types of change or when this is not possible, the Seller will advise [insert company name] of these changes within (X) business days.

10. SAFETY, SECURITY AND HYGIENE.

Seller will become familiar with all raw materials and Materials, Products and Wastes, used, produced or generated, respectively, while manufacturing Product. Seller will comply with the Federal OSHA "Hazard Communication Standard," codified as 29 C.F.R. 1910.1200, *et seq.*, and any similar state "right-to-know" laws which are currently in force or may be enacted in the future. Seller is solely responsible for informing its employees of the chemical hazards associated with any products or chemicals handled pursuant to this Agreement and is also responsible for training its employees in the proper methods of handling such products and chemicals. Seller has an affirmative obligation, when in doubt about a product or chemical, to seek further information from [insert company name]. Seller's failure to fulfill the obligations of this paragraph 10 will be construed as a material breach of this Agreement.

11. PRODUCT WARRANTY.

Seller warrants that Product delivered to [insert company name] will (1) conform to the descriptions and specifications as set forth in this Agreement; (2) be of good quality and workmanship and free from defects, latent or patent; and (3) be merchantable and fit and sufficient for [insert company name]'s intended purpose. Payment, inspection, acceptance or use of Product will not affect Seller's obligation under this warranty.

12. INDEMNIFICATION.

Seller will indemnify, defend and hold [insert company name] (including [insert company name]'s officers, directors, employees, servants, affiliates, agents, successors, and assigns) harmless from any and all liability, expense

(including actual attorneys fees and internal costs associated with internal attorney work), cost, loss or damage [insert company name] may suffer as a result of claims, demands, costs, suits or actions (whether based on facts now known or later discovered) against [insert company name] arising out of the following:

(A) The failure of Seller or those acting under or for Seller to comply with all federal, state and local laws, regulations and ordinances (including, without limitation, those related to the environment, health and safety) in connection with Seller's performance of this Agreement (including, without limitation, Seller's ownership or operation of its business and facilities);

(B) Any contamination of the environment or damage to natural resources at a facility owned or operated by Seller or a facility/location chosen by Seller for its disposal of Wastes or any other facility at which Seller's Wastes may be released or threatened to be released, including any liability imposed by federal, state and local laws, regulations and ordinances, including, but not limited to, the Federal Comprehensive Environmental Response Compensation and Liability Act (CERCLA), 42 USC 9601 *et seq*., the Federal Resource Conservation and Recovery Act (RCRA), 42 USC 6901 *et seq*., or comparable and applicable state legal requirements or any extension or revision thereof; or

(C) Any damage to any property, including damage to any environmental medium (air, water, groundwater, soil), or damage to natural resources, or death or injury of persons (including Seller's employees) arising out of (1) Seller's performance or nonperformance of this Agreement, (2) The Materials delivered or the Products ordered pursuant to this Agreement unless caused by the sole negligence of [insert company name], or (3) any design or manufacturing defect in the Product, whether latent or patent.

This paragraph 12 will apply regardless of the type of assertion being made including, without limitation, any legal, equitable, or admiralty causes of action or rights (including, without limitation, negligence, strict liability in tort, other tort, express or implied warranty, indemnity, contract, contribution or subrogation), whether the assertion is made by a party to this Agreement or any third party, and will apply to all types of damages (including, without limitation, direct, compensatory, incidental, consequential, exemplary, punitive, or special). In the event of a claim, [insert company name] shall select the legal counsel and Co-ordinate the defense. This paragraph 12 will survive the expiration or termination of this Agreement, and will be binding upon Seller's successors, assigns and trustees.

13. INSURANCE COVERAGE.

Seller will procure and maintain insurance in the following amounts, at its own expense, at all times while the Agreement is in effect:

(A) Workmen's Compensation insurance at statutory limits and Employers' Liability Insurance at not less than $ (X) aggregate; and

(B) Comprehensive General Liability Insurance (including contractual liability, products, and completed operations) with a bodily injury, death, and property damage combined single limit of $(X) per occurrence; and

(C) Pollution and Environmental Impairment Insurance with a limit of $(X) per occurrence and $(X) aggregate.

Seller will furnish [insert company name] a certificate(s) from an insurance carrier showing all insurance set forth above. The certificate(s) will include the following statement: "The insurance certified hereunder is applicable to all contracts between the [insert company name] and the Insured. This insurance may be canceled or altered only after (X) days' written notice to [insert company name]." The insurance, and the certificate(s), will (1) name [insert company name] (including [insert company name]'s officers, directors, employees, servants, affiliates, agents, successors, and assigns) as additional insureds with respect to Seller's performance under this Agreement, (2) provide that such insurance is primary to any liability insurance carried by [insert company name], and (3) provide that underwriters and insurance companies of Seller may not have any right of subrogation against [insert company name] (including [insert company name]'s officers, directors, employees, servants, affiliates, agents, successors, and assigns). The insurance will contain an ordinary deductible. Failure of any of the terms and conditions of this paragraph 13 will be considered a material breach under this Agreement.

14. TERMINATION.

Either party may terminate this Agreement at any time, without further liability, by providing the other party with (X) days written notice upon the occurrence of any of the following events:

(A) The filing of bankruptcy for or on the part of the other party (or its parent organization or affiliate organizations);

(B) The appointment of a receiver, trustee or liquidator for all or substantially all of the assets of the other party (or its parent organization or affiliate organizations);

(C) An assignment by the other party (or its parent organization or affiliate organizations) for the benefit of its creditors;

(D) The filing of any petition by or against the other party (or its parent organization or any affiliate organizations) asking for a reorganization under any state insolvency law or under the Federal Bankruptcy Act;

(E) The failure of the other party to cure a material breach within (X) days after having received written notice specifying the breach.

15. LIENS, SETOFF, AND UCC FILINGS.

a. Seller will keep Materials and Product free and clear of all liens, encumbrances, security interests and charges of any kind and character. Seller will indemnify, defend, and hold harmless [insert company name] for all liens, encumbrances, security interests and charges that [insert company name] may be compelled to pay in discharging such, including all costs and reasonable attorneys' fees.

b. The parties shall have the right to setoff of any amounts due hereunder. The Parties acknowledge that the obligations to setoff are mutual under this Agreement.

c. Upon passage of title in Materials to Seller [insert company name] shall have, and Seller hereby grants to [insert company name] a purchase money security interest ("PMSI") in the Materials and its proceeds and products. Seller shall, at the request of [insert company name], execute such documents in connection with the Materials supplied pursuant to this Agreement as [insert company name] may reasonably deem necessary, including but not limited to, the execution of any uniform commercial code (UCC) statements. Seller further agrees, at the request of [insert company name], to disclose the names and addresses of its existing secured creditors. [insert company name] may, at its expense, send a notice of its PMSI in the Materials to all such creditors.

16. INDEPENDENT CONTRACTOR.

Seller is an independent contractor, with all the attendant rights and liabilities, and not an agent or employee of [insert company name]. Any provision in this Agreement, or any action by [insert company name], which may appear to give [insert company name] the right to direct or control Seller in providing Product means Seller will follow the desires of [insert company name] in results only.

17. **FORCE MAJEURE.**

a. In the event of war, fire, flood, strike, labor trouble**,** breakage of equipment, accident, riot, action of governmental authority and laws, rules, ordinances and regulations (including, but not limited to, those dealing with pollution, health, ecology, or environmental matters), act of God, or contingencies beyond the reasonable control of Seller or [insert company name], interfering with the production, supply, transportation, or consumption practice of the party at the time respecting the Product or Materials covered by this Agreement, or in the event of inability to obtain on reasonable terms (other than price) any raw material (including energy source or power) used in connection therewith, delivery of quantities so affected may be delayed without liability during the duration of such occurrence only, but the Agreement will otherwise remain unaffected. The affected party will promptly notify the other party in writing after the commencement of such force majeure occurrence, setting forth the full particulars of such force majeure occurrence. The affected party will remedy such force majeure occurrence with all reasonable dispatch consistent with this paragraph and will promptly give written notice to the other party at the cessation of such force majeure occurrence.

b. Notwithstanding the above, if the estimated duration of a force majeure occurrence which will interrupt, delay or decrease Seller's supply of Product to [insert company name] is for more than (X) days, then [insert company name] may, at its option, elect either to terminate the quantities of Product so affected from the Agreement altogether or terminate this Agreement by giving (X) days written notice thereof to Seller.

18. RIGHT TO INSPECT.

[insert company name] will have the right, but not the obligation, to inspect and test all Materials and Product during the period of manufacture and at all other times, at any place where the Materials, Products or Wastes may be located. The fact that [insert company name] may have inspected, tested or failed to inspect or test Materials or Products will not affect any rights of [insert company name] at law or at equity under this Agreement. This right will arise only upon the giving of reasonable notice to Seller and may occur only during the normal business hours of Seller.

19. RIGHT TO AUDIT.

[insert company name] will have the right but not the obligation to have the records of the Seller, insofar as such records relate to this Agreement, examined by an independent third party for the purpose of determining

compliance with this Agreement. Such third party will be mutually acceptable to the parties. This right will arise only upon the giving of reasonable notice to the Seller and the records may be examined only during the normal business hours. If the examination reveals a breach, Seller will bear the cost of the examination; otherwise, [insert company name] will bear such cost.

20. ASSIGNMENT.

None of the rights, duties, or obligations under this Agreement may be assigned, delegated or transferred by either party without the other's written consent. All the processes associated with the manufacture of Product under this Agreement will take place only at Seller's facility located at _____; the work performed under this Agreement will not take place at any other facility without [insert company name]'s written consent. Seller will not subcontract any portion of this Agreement without [insert company name]'s written consent.

21. WAIVER.

Waiver by either party of any breach, or failure to enforce any of the terms and conditions of the Agreement at any time, will not in any way affect, limit or waive the right of that party thereafter to enforce the Agreement and compel strict compliance with every term and condition of it.

22. SEVERABILITY.

If any provision of this Agreement or the application thereof to any person or circumstance will, for any reason, and to any extent, be held to be invalid or unenforceable under applicable law, such provision will be deemed limited or modified to the extent necessary to make the same valid and enforceable under applicable law. If such invalidity becomes known or apparent to [insert company name] and to Seller, [insert company name] and Seller agree to negotiate promptly in good faith in an attempt to make appropriate changes and adjustments to achieve as closely as possible, consistent with applicable law, the intent and spirit of such invalid provision.

23. NOTICES.

All notices, request, demands and other communication under this Agreement will be in writing and will be deemed to have been duly given on the date of the service if served personally on the party to whom notice is to be given, or on the date of receipt if mailed to the party to whom notice is to be given by first class mail, registered or certified, postage prepaid or by over-

night courier service (i.e., Federal Express or equivalent) and unless either party should notify the other of a change of address properly addressed as follows, or on the date of receipt where the intended recipient has acknowledged receipt:

To Seller:	To [insert company name]:
Toller Company	Client company
Attn:	Attn:
_____	_____
_____	_____
_____	_____

24. APPLICABLE LAW.

The validity, interpretation and performance of these terms and conditions will be governed by [insert appropriate state and federal laws].

25. TRADEMARKS.

Seller shall not obtain any rights in or to the use of the trademark _____, the [insert company name], the trade name [insert company name], or any other trademarks or service marks of [insert company name] as a result of performing pursuant to this Agreement.

26. NONDISCLOSURE.

The Confidentiality Agreement executed by [insert company name] and Seller, effective _____ as set forth in [attach addendum with Confidentiality Agreement] to this Agreement is incorporated herein by reference; however, such Confidentiality Agreement shall be governed by its own terms and conditions.

27. ENTIRE AGREEMENT.

This Agreement (with its addenda) constitutes the full understanding of the parties, and is a final, complete and exclusive statement of the terms and conditions of their agreement. All representations, offers, and undertakings of the parties made prior to the effective date of this Agreement are merged herein. All modifications to this Agreement must be in writing and

signed by an authorized representative of each party. The parties have caused this Agreement to be executed by their duly authorized representatives as of the date corresponding to their respective signatures, but effective as of the date first written above.

TOLLER OR SELLER COMPANY	NAME OF CLIENT COMPANY
By:_____	By:_____
Name:_____	Name:_____
Title:_____	Title:_____
Date:_____	Date:_____

4

PRE-STARTUP AND STARTUP ACTIVITIES

4.1. The Path to a Successful Toll

The activities related to the startup of a new tolling situation can help ensure safe and efficient process runs. It is essential that communication between the company letting the tolling contract and the toller is extensive and accurate during this stage in the toll process. This chapter focuses on the following ten activities involving preparation for startup, during, and shortly after startup:

1. Establish specifications and analytical techniques
2. Verify accurate procedures are in place
3. Analyze the hazards
4. Mitigate the risks
5. Train the workers
6. Implement the management of change system for the toll
7. Consider other process safety elements that may be called for by the toll
8. Evaluate raw material control and qualification
9. Consider a test run
10. Perform a post-startup review

The flowchart on the next page shows an overview of steps for the pre-startup and startup phases of a typical tolling process.

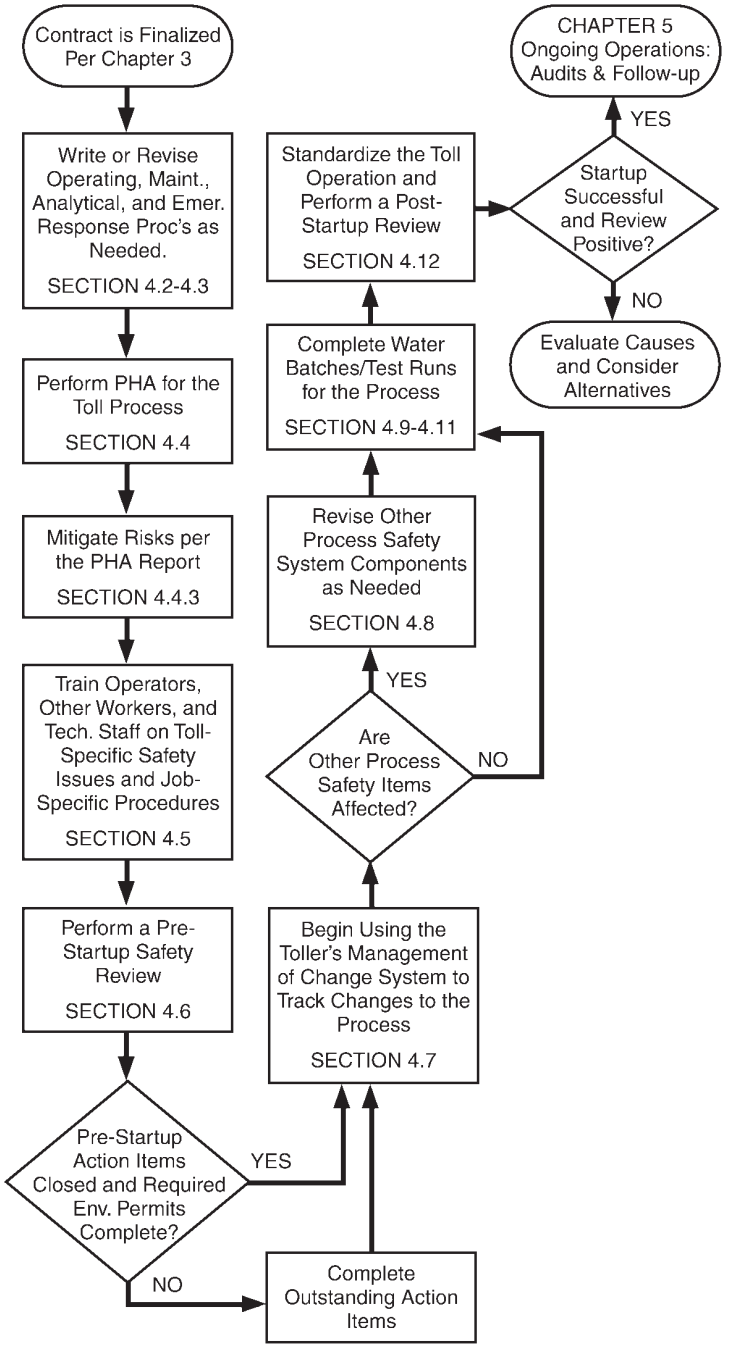

Figure 4-1. Pre-startup and startup activities flowchart

4.2. Establishing Specifications and Analytical Techniques

Process specifications will typically be set forth in the process technology package. However, a process hazard analysis (PHA) in preparation for startup may reveal additional useful measurements or sample points. These may be analyses or measurements for the startup period or for the life of the toll.

If the technical staff from the client company recognizes that a toller may be asked to perform new analyses and make operating decisions based upon the results, the client may help the toller develop the needed procedures and skills required to make these decisions. Typically a "round robin" laboratory qualification exercise will be performed. Samples of known standards and unknown concentrations of the materials to be analyzed for the toll will be prepared and sent to both laboratories. This can help ensure that equipment calibration is synchronized and that the toller is capable of performing accurate measurements. In some cases, the toller may be the party with the chemical, process, or synthesis specific expertise.

4.3. Developing or Revising Required Procedures

The task of developing or revising procedures varies in complexity for each tolling situation. In some cases, the toll may involve only slight changes to the raw materials for an existing, well-known batch or continuous process. In other cases, both parties may be operating and maintaining a completely new process with less familiar equipment or materials. Usually, the effort involved in the procedure development task for a new toll is somewhere between these two extremes.

The review and approval process for procedures for the toll needs to be clearly understood between the toller and their client. This can be addressed in the management of change system. A preliminary process or batch procedure may be written or proposed as part of the toller selection process or may be included in the initial

technology package. As additional process details are identified, these initial procedures are revised to reflect the actual process and mechanical conditions.

The individuals and firm most familiar with the technology should review the intermediate and final procedures to assure both safety and commercial interests are satisfied. In many batch operations the procedure(s) can be a substantial portion of the process technology package. The procedures represent both a major safety system as well as a propriety technology. The pre-startup review should assure both PHA related and other changes proposed to the procedures have been approved and implemented.

The types of procedures to be developed or revised for a new toll can be organized into the following major categories:

- Operations
- Maintenance
- Emergency response plan
- Safe work practices
- Laboratory and sampling

4.3.1. Operating Procedures

The standard operating procedures demand great attention as they reflect personnel safety issues, safe operating limits and quality considerations. They should be written simply and clearly. The level of detail is determined by the training and experience of the operations staff but should also take into account the hazards inherent in the process.

The major category—operating procedures—can be broken into subcategories by operating phase. Continuous process tolls will have four basic types of subcategories each representing one phase of operation:

- **Startup**: This includes procedures addressing pre-startup operations, initial startup, startup following turnaround and startup after emergency shutdown.
- **Normal Operations**: This includes all procedures describing activities performed after startup, before a planned shut-

down, or activities independent of operating phase (such as sampling, routine monitoring, product rework, or filter changes as performed by operations personnel).

- **Shutdown**: This includes all procedures preparing for, completing and following up a planned normal shutdown.
- **Emergency Operations**: This includes all procedures that direct operators' process related actions in emergencies and could lead to a shutdown, back to normal operations, or to the emergency response plan. These include chemical releases, loss of utilities, and operating actions to take in the event of fire or explosion. Emergency procedures should include the conditions under which emergency shutdown is required, and the assignment of shutdown responsibility to qualified operators to ensure that emergency shutdown is executed in a safe and timely manner.

Within each subcategory are any specially designated temporary procedures required for equipment operating in one of the four operating phases. These procedures are typically short lived due to a terminating condition or expiration date. They describe special tests or temporary changes in operating steps. These temporary procedures can be archived when they are not active.

Specific titles within each of the operating phases can be determined using a job task analysis in concert with the technology package and process safety information. Appendix D, *ISD Model and Job Task Analysis Techniques,* provides basic guidance in this useful method.

An example of procedures found by performing a job task analysis would be rework procedures. Occasionally, out of specification product is produced which can be reworked in the process. This subcategory of normal operations phase procedures may require special consideration. While rework can be a straightforward operation, it could have safety consequences if done improperly.

Operators with previous experience in similar tolls teamed with engineers using the process safety information can identify the specific procedures needed within each subcategory. Whenever possible, try to use experience from duplicate tolls or similar processes.

Tolls for batch processes introduce a twist to this basic approach to procedures. The equipment, which could include a reactor,

vacuum compressor, dryer, mixer, mill or heat exchanger (and associated pumps and piping) may each have their own startup, shutdown, normal and emergency operating procedures. However, the equipment configuration may be different for different product tolls. Batch processes also add a new subcategory of operating procedure, the batch instruction (sometimes termed a "batch recipe" or "processing instruction").

The batch instruction procedure should be written to mesh with the equipment procedure(s) that may already exist. The batch instruction may need to address steps in subsections such as:

- Configuring process equipment
- Staging the materials
- Charging the materials
- Monitoring the process
- Sampling and analysis
- Transferring the product
- Cleaning and equipment decontamination
- Toll-specific emergency operations

If operating procedures need to be developed from scratch, this could account for a considerable portion of the pre-startup work. If current, valid standard operating procedures exist, and the toll is only introducing a new set of batch instructions, the task becomes simpler. However, it is recommended that the new batch instructions are reviewed simultaneously with the existing startup, shutdown, normal and emergency operating procedures for the equipment to help ensure potential process deviations are examined and addressed.

4.3.2. Maintenance Procedures

Existing maintenance procedures must be reviewed for several reasons. Typically, these are established based upon manufacturers recommended practices for stock equipment such as pumps, centrifuges and some reactors. However, a new toll can introduce special cleaning and preparation steps as well as possible material of construction incompatibilities. If the toller is using new equipment, special maintenance practices and tools may also be required.

If special materials of construction are needed, provisions need to be in maintenance procedures to make sure these materials are used. If there are prohibitions on certain materials of construction, the procedures need to have provisions to make sure that they are not used. These considerations are especially true if there are multiple operations involved in the tolling unit. Answering the questions below can help determine which maintenance procedures need to be written and the level of detail required:

- Is equipment currently installed, operated, and maintained as designed?
- What are the equipment manufacturer's recommendations for use of the equipment and is it reflected in procedures?
- Does the toller maintain and review updated equipment manufacturer information?
- If use is different than that specified by the equipment manufacturer or designer, has the appropriate person been consulted concerning suitability for use and does a procedure exist describing it?
- Has the equipment manufacturer or designer been consulted about modifications to design?
- Are liquids used to cool or purge seals compatible with materials processed in the equipment? If so, are temperature, pressures, and materials appropriate for the seal components and reflected in procedures?
- What is the maintenance history of the equipment?
- Is corrosion monitoring appropriate for the process?

4.3.3. Material Control/Purchasing Procedures

Material control and purchasing procedures may also need to be written and training implemented for the users, especially if there are special materials of construction considerations. There may need to be procedures and training for stockroom personnel in receiving, segregating, storing and dispensing maintenance parts and materials for the tolling unit when there are special materials of construction considerations.

4.3.4. Emergency Response Plan Procedures

Emergency response plan procedures may need to be evaluated against new material hazards introduced by the toll. This is primarily a concern when the toller is handling a feedstock or product that introduces hazards that may not have been present previously at that facility. Most emergency response plan procedures are written at a high enough level of detail that they will be unaffected, but it is necessary to evaluate the plan's adequacy.

4.3.5. Safe Work Practice Procedures

As discussed in Chapter 2, *The Toller Selection Process*, evaluating the site's safe work practice procedures should have been a part of the review during the toller selection process. Still, new materials may indicate a need to revise or develop special procedures to address unique chemical and physical hazards. New hazards such as vacuum, cryogenics, ultra-high pressure, or new rotating equipment could be introduced. Medical monitoring requirements or special handling and spill response procedures for the toll's raw materials and products may indicate a need to write or revise safe work practices.

4.3.6. Laboratory Procedures

Laboratory procedures may need to be evaluated against the sampling techniques and materials involved in the toll. There may be new laboratory chemicals and hazards to be considered. This work may have been identified in the evaluation of special analytical techniques required for the process. A good practice is to ensure that the lab technicians have the necessary guidance and types of equipment on hand to monitor the process and waste streams accurately and safely.

A resource for assisting in developing, revising and managing the procedures needed for the tolling process is the AIChE/CCPS text *Guidelines for Writing Effective Operating and Maintenance Procedures*. It provides checklists for assisting in ensuring the procedures are written clearly and accurately as well as formatting examples

and guidance for revising procedures. The process hazard analysis will benefit if the team reviews well written operating procedures along with the other process safety information.

4.4. Process Hazard Analysis

Process Hazard Analysis (PHA) can be defined as the application of a systematic method to a process design in order to identify potential hazards and operating problems. It determines the causes and consequences of abnormal process conditions that arise from equipment failure, human error or other events. The goal is to determine whether opportunities exist to reduce the risks of the toll's hazards and then to implement warranted action items. The AIChE CCPS guideline *Guidelines for Hazard Evaluation Procedures, Second Edition with Worked Examples* is a good resource for fully detailed approaches to process hazard analysis. It provides an introduction to hazard evaluation as well as guidance on:

- How to prepare for hazard evaluation studies.
- Typical results from the various types of hazard evaluation techniques.
- How to select and use a hazard evaluation technique for your process.
- How to analyze recommendations and follow-up on implementation.

PHAs are performed primarily to reduce losses resulting from incidents that can injure plant personnel or the public, or damage or destroy buildings, equipment, and material. There are other less measurable losses that occur after incidents. Companies' reputations, the industry's reputation and the effect on customers and the public are all at stake.

For every new tolling situation a process hazard analysis should be conducted using one of several acceptable methodologies in common use. The goal is to select a methodology appropriate to evaluate the hazards of the toll process in question.

When the analysis is complete, the PHA team leader will issue a report with action items. Items required to be done before start-up

must be identified. The toller should submit a written plan to modify the equipment or its operation in response to the PHA findings. The plan should be approved by both parties and implemented prior to the start of the toll process. Any later modifications to the equipment should be performed using the toller's management of change system, which was reviewed and evaluated during the selection process.

4.4.1. Defining the PHA Team

The objective is to have as much firsthand experience on the team as possible. Again, the importance of communication and teamwork between the toller and their client must be emphasized.

All types of PHAs benefit from a multidisciplinary approach. This ensures appropriate technical expertise is available to evaluate each deviation discussed during the sessions. While it is not essential that all team members have had formal training in the PHA method selected, it is important that the team leader has experience. The participation techniques can be learned when a new participant is included as a part of a team in which some members have already gained PHA experience.

Two members selected from the team act in supportive roles during the PHA. These roles are the leader and the scribe. A team leader is always needed for a PHA and should double as the scribe only for extremely simple hazard evaluations. For more complex analyses or the HAZOP study method, a separate person should always be assigned to scribe.

The team **leader** is responsible for managing the analysis sessions and keeping the discussions on track and productive. The team leader should be experienced in the selected PHA method through attending training and participating as a team member in at least one previous PHA. This individual is not necessarily expected to make major technical input into the analysis; it is more important that he or she guides the questioning in such a way that all team members contribute within their area of expertise.

The **scribe** is responsible for accurately recording the hazards and recommendations as the team identifies them. The individual

chosen to be the scribe does not need previous PHA experience and does not require extensive experience with the specific process under study but his or her performance may benefit from both. The prime responsibility is to ensure that team findings are recorded accurately. If time allows, each entry should be reviewed with the team to obtain agreement as to its accuracy. A summary of each session could be distributed to the members for review.

The **experts** are the members providing the technical expertise for completing the study. Depending upon the process, a process hazard analysis could include any or all of the following types of experts. Some can be brought in on an as needed basis:

chemical engineer
chemist
civil engineer
construction representative
corporate safety manager
electrical engineer
environmental engineer
expert from another plant
fire protection engineer
hazard evaluation expert/leader
human factors specialist
industrial hygienist
inspection engineer/technician
instrument engineer/technician
interpreter
maintenance supervisor
maintenance planner
mechanic, pipefitter, electrician
mechanical engineer
medical doctor/nurse
metallurgist
operations supervisor
operator/technician
outside consultant
process engineer
process control programmer

project engineer
recorder, secretary, clerk
R&D engineer
safety engineer
shift foreman
toxicologist
transportation specialist
vendor representative

Though occasionally a time consuming exercise, a well-performed PHA can be a source of satisfaction and may be required by the OSHA Process Safety Management Standard or the EPA Risk Management Program Rule. It is important members actively participate and lively interaction is promoted during the sessions.

4.4.2. Selecting the PHA Method

Each type of PHA has its own purpose and limitations so selecting the proper methodology for a toll process is important. When conducting a PHA on a process covered under the U.S. OSHA Process Safety Management regulation or the EPA Risk Management Program rule, various types of PHAs may be used. The following list identifies some common methods for performing PHAs:

- What-If
- Checklist
- What If/Checklist
- Hazard and Operability Study (HAZOP)
- Failure Mode and Effects Analysis (FMEA)
- Fault Tree Analysis
- Any appropriate equivalent methodology

When selecting the type of PHA to perform, consider the following criteria:

- What is the motivation for the PHA?
- What types of results are needed?
- Is process safety information complete?
- What are the characteristics of the process or problem?
- What is the perceived risk?

- What is the level of experience to date?
- What resources are available?
- What preferences does the company have in regard to PHA type?

The toller and their client can work together to identify the appropriate method and detail required for the process hazard analysis. Consider adding a brief statement in the final PHA report documenting why the method was selected.

4.4.3. Performing the PHA

Gathering process safety information in preparation for the PHA is the foundation of performing a high quality hazard analysis. A thorough final process technology package combined with the toller's equipment information (P&IDs, vendor manuals, mechanical integrity data, and management of change files) become the raw materials for the analysis and the resulting PHA report and recommendations. It is particularly important that the P&IDs are current and accurately depict the process control systems, alarms, interlock levels, as well as process equipment and piping.

Other information may also benefit the PHA. Standard operating procedures for processing equipment, safe work practices, maintenance or job safety analyses, emergency response plans could be appropriate review items for some PHAs depending upon the toll.

With the PHA methodology selected, the team assembled and the process safety information gathered, the analysis of chemical and process hazards, and the consequences and deviations associated with those hazards are identified.

Investigations of incidents involving tolling operations have found that the PHA can be the most important pre-startup activity for preventing problems while providing an opportunity to share information. When representatives from both parties are focused on the PHA, they may discover special procedures not previously identified. For example, decision points and emergency steps for shutting down a toll can be decided upon and agreed to by both the toller and the client.

Investigations have also shown that relying solely on MSDSs provided by third parties can be problematic. The information for raw materials may not have considered all hazards that could be encountered when mixing or blending with other materials. Additionally, MSDSs for the final mixture may specifically address the hazards of small quantities, but may not apply to the larger quantities present during processing. One joint investigation of a tolling related incident by U.S. OSHA and EPA stated "the (process hazard) analysis should include a cautious review of chemical hazards, incompatibilities and a thorough examination of all mechanical equipment. Standard operating procedures should be developed and the consequences of deviation ought to be identified."

After the PHA documentation is complete, each action item to be implemented before startup is given an estimated completion date and an assigned individual with responsibility to carry it out. Regular follow-up to ensure these action items are completed is essential to a timely startup. These responsibilities should be documented.

4.5. Training the Startup Team

The question to answer for this pre-startup task is "Who needs training for this process and to what level of detail?" One method to analyze training needs is offered by the Instructional Systems Design (ISD) technical training model. It points to the job task analysis method mentioned previously (Appendix D, *ISD Model and Job Task Analysis Techniques*) to identify procedure titles as a first step for determining which job positions require specific knowledge and skills.

The toller selection process allows companies letting tolls to evaluate the candidates' training records to check that a potential toller understands this basic approach to industrial training. Electronic training records management systems common in the industry enable a quick report showing whether or not an individual is qualified for a given position or set of tasks by comparing an up-to-date curriculum with training documentation.

Tolling presents a special consideration that can make the training step easier. Typically a toller's technical staff, operators and mechanics are knowledgeable in the basic operations and tasks related to the toller's specialty. For example, experienced operators may know operations of the reactors, columns, exchangers, and packaging equipment quite well. The mechanical personnel may be very familiar with the required safe work practices, equipment cleaning procedures and maintenance tasks for standard vessels and piping.

In this case the training focus can be on the special needs of the process in question. The new or revised operating, maintenance, and emergency response procedures should always be reviewed with the workers expected to perform them. Each employee should have an opportunity to ask questions, familiarize himself or herself with the sequence and assure they understand the steps.

If a toller has a contract to perform the same toll repeatedly, but on an infrequent basis, training should not be overlooked in preparation for restarting the repetitive toll. It is a good practice to provide refresher-training sessions to assure that the personnel have received current training. One company has picked a six-month period between campaigns as the indicator that the operations team needs refresher training.

If there is one special need in the area of procedure training, it is emphasis on emergency operations—especially emergency shutdown of the toll. This is dependent upon the inherent hazards and associated risks for any given toll. Operators, management and technical staff should all understand the decision points in the emergency procedures that would lead to an emergency shutdown for a toll involving hazardous materials or conditions. It should also be very clear within the emergency operating procedures when an operator should initiate the site emergency response plan.

Tollers may have an emergency response plan that requires their personnel to respond in an emergency such as a fire, explosion or release. Other tollers may call upon local responders and evacuate. It is essential that training for responders on the emergency response plan procedures should be up-to-date prior to startup of the new toll. For companies in the U.S. that are required to register

under the Risk Management Program rule or whose process is regulated by the OSHA PSM standard, training on relevant emergency response plan procedures is required.

Effective procedure training not only affects process safety, it also affects quality. Process yields, batch turnaround time, and equipment cleaning are all enhanced when the procedures are technically accurate and fully understood by the crews.

Maintaining good records of employee training will benefit both the toller and the client. A toller is more likely to be selected if they can show a history of high quality, appropriately designed training. The client benefits by having the training portion of the pre-startup activities well managed.

If a toll process falls under the U.S. PSM or RMP regulations, it is a requirement to document "the identity of the employee, the date of the training, and the means used to verify that the employee understood the training." Even when not required by regulations, this documentation will enable the toller to demonstrate a commitment to maintaining competent operating personnel.

4.6. Performing a Pre-startup Safety Review

A Pre-startup Safety Review (PSSR) is a method to confirm that the startup team and process equipment are prepared for chemicals to be introduced into the system. It is a final check to confirm that a new or modified process or facility has been built as designed, all procedures are in place, training is complete and all action items from the process hazard analysis have been resolved. A PSSR for U.S. OSHA PSM and EPA RMP compliance is required when any change modifies the Process Safety Information. For a minor change to a facility, one person can perform a PSSR. However, if a toll's preparation involves extensive construction, re-piping, procedure development and training, the PSSR should involve a team and several meetings over an extended period of time during construction.

As a good practice, a PSSR team could be formed as a part of new facility construction. It is recommended every PSSR involve at

least one member besides the PSSR leader although this is not required for U.S. OSHA PSM and EPA RMP compliance.

If a PSSR is extensive, the PSSR team should include a toller company engineer and an engineer from the client. In addition, an operations supervisory representative and operations personnel with appropriate knowledge and skills along with a maintenance and safety representative may also be included on the team. The PSSR leader must ensure enough manpower and expertise is available on the team to review the new facilities and major modifications thoroughly.

The PSSR team will confirm that the following requirements have been met before materials are introduced into the new or modified toll process.

- **Construction and equipment meet the design specifications.** Obtaining field verification or performing document review for the new or modified process can validate design specifications for construction and equipment. If a change is not "physical" (such as a setpoint for an interlock shutdown), the method for the change and its anticipated effects should be reviewed.
- **Safety, operating, maintenance and emergency procedures are in place and adequate.** Examine the process management of change system documentation package for entries that indicate any operating, maintenance or emergency procedures that were developed or revised for a modification. The management of change documentation package (as defined in the toller's management of change system) and referenced documents should be reviewed. Existing site safety procedures should be checked to ensure they exist and are adequate.
- **A PHA has been performed for new facilities.** The management of change documentation packages and referenced documents should indicate when a process hazard analysis was performed for the modification or new facility. The PSSR Team should verify all of the PHA recommendations have been implemented or otherwise resolved before the toll process can be judged ready to operate.

- **Training of each employee involved in the operating process is complete.** Typically, the management of change documentation package indicates when training of each employee involved in the startup of a new or modified process is complete. Training of other employees not directly involved with startup should be planned to occur before the first shift in which they would be required to operate the new or changed toll process. The PSSR team may consider training complete for introduction of chemicals into the new facility or modification when this training information is verified.

4.6.1. Resolving PSSR Issues and Action Items

An overall review of the management of change documentation package should be performed to ensure documentation update items (including material safety data sheets) are addressed and that PHA action items are complete. This can be done by one person but is often best achieved by a PSSR Team. The process needs to account for:

- Assignment and follow-up of action items—responsibilities of each party
- Acceptance or rejection of action items—right of review by each party, resolution of disagreements
- Timing—pre- or post-startup
- Final close-out

It is necessary for the PSSR team to perform a detailed physical inspection of the new or changed process. This can help find items like physical obstructions, potential for unintended mixing, siphoning, and other issues prior to the testing phase.

4.6.2. Considerations for Restart after Extended Downtime

If a product has not been tolled for an extended period (some companies use six months), it is essential to check the management of change documentation packages for all of the equipment involved. This review should focus on ensuring changes made between the new request to toll and the last time the product was tolled do not

affect personnel safety, process safety, the environment or quality. It may be necessary to verify that the PHA, management of change, and training are valid and up to date. The result of this review may indicate that a PSSR needs to be performed.

4.6.3. Defining When the Process Is Ready for Startup

Once the PSSR team is satisfied with their review, a form such as Example 4-1, *Pre-startup Safety Review Completion Form* can be used to capture their approval for startup. For simple changes, this one-page form may be all that is required. In the case of extensive modifications, a detailed checklist of items examined by the team may accompany this form. It could include unsatisfactory findings as well as respective recommendations. If recommendations were made, these must be prioritized. Some may need to be resolved before startup; others may be appropriately addressed after processing has begun. Some items reviewed by one company for extensive modifications and logged in addition to the one-page form are:

- **Facility inspection:** safety, ergonomics, and mechanical completion
- **Response and follow-up of PHA action items:** action items resolved and documented
- **Operating procedures:** written, complete, meeting requirements of PSM Standard or RMP Rule, if covered
- **Training:** completed and documented
- **Mechanical integrity**: equipment reviewed and classified
- **Emergency response plan:** new or modified unit included in the facility plan, maps and emergency plan procedures updated, training performed
- **Industrial hygiene:** potential hazards identified, baseline monitoring needs fulfilled, any special equipment obtained, PPE hazards assessments in progress
- **Laboratory support:** adequately staffed, equipment/supplies in place
- **Computer control checkout:** provisions for backups, training performed
- **Regulatory:** permits obtained, regulatory requirements met

Example 4-1. Pre-startup safety review completion form

TOLLER CO. SPECIALTY CHEMICALS	**Pre-startup Safety Review Form** Form No.: PSMADM09.501 Rev. 2

Date:	PSSR Team Leader:
Facility/Process Equipment Reviewed:	

Type of Startup (Check one)	New Construction: ❒	Modified Process: ❒

Recommendations: (Check Pre S/U box if item must be done prior to startup. Attach relevant documents to this form.)

Item No.	Description	Pre S/U	Initials	Date Resolved

PSSR Completion Summary: The following issues have been resolved and the undersigned believe the process/facility is ready for startup.

1. The construction and equipment meet design specifications.
2. Safety, operating, maintenance, and emergency procedures are in place and are adequate.
3. For new facilities, the initial process hazard analysis (PHA) has been performed and recommendations have been resolved.
4. Training of each employee involved in the operating process is complete.
5. Changes made to modify the process/facility have been reviewed and authorized by the ABC Co. Management of Change program.

Confirmation by PSSR Team Members

Title	Signature	Date

- **Process safety information:** information identified and complete
- **Startup and commissioning plans:** plans complete and comprehensive.

4.6.4. Confirming Permits Are Complete

For tolls involving regulated raw materials or waste streams, application for required permits may be a vital part of the pre-startup activities. Startup cannot happen until the official permits or other interim government approvals are obtained. For such tolls, the staff from both parties should work together to ensure responsibilities are assigned for making the applications and communicating with the appropriate governmental representatives.

4.7. Management of Change Considerations

Having a defined system for assessing the effects of any change is a good business practice. This is true whether or not the materials involved in the toll are specifically covered under a regulation requiring management of change. The quality of the toller's management of change (MOC) system should have been a key indicator used during the toller selection process. An efficient MOC system indicates the toller's dedication to process safety.

The toller should include the primary contact from the client in their management of change process prior to making any changes identified during the PHA or PSSR. The toller's management of change process should include this provision for notification. This client contact person or group, with support from appropriate manufacturing or technical staff, should review and dually approve the changes with the toller staff.

4.8. Other Process Safety Elements That May Affect Startup

This chapter has touched on the application and importance of nine basic elements of process safety and how they are interwoven in actual practice:

- Process Hazard Analysis
- Process Safety Information
- Operating Procedures
- Training
- Mechanical Integrity
- Safe Work Practices including Hot Work Permits
- Management of Change
- Pre-Startup Safety Review
- Emergency Planning and Response

Additional considerations may need to be given to other elements depending on the tolling situation.

- **Employee Participation**: Preparation for startup is an excellent opportunity to document employee participation. If a toller is covered under the OSHA PSM regulation, they must record PHA participants, procedure writers and reviewers, PSSR team members and test run team members. All these roles reflect the true intent of this element of process safety. Everyone benefits from intimate involvement in the management system used to protect life and health.
- **Contractors**: If contractors are working at a toller's site, this element of process safety demands that they be informed of any hazards the new toll could present. If contractors are specifically involved with the toll in question and the company is subject to PSM compliance, other aspects of this element must be met.
- **Incident Investigation**: Previous incidents related to the chemicals or equipment involved in the new toll should be considered during the PHA and must be considered if subject to PSM/RMP compliance. In addition, procedures should be in place to describe how the client will be informed and involved in the investigation. It is very important to ensure that action plans addressing the root cause of past incidents were implemented.
- **Compliance Audits**: If a new toll process causes a toller's first experience with OSHA PSM or EPA RMP compliance, this

element will come into play. If the toll exceeds the three-year period during which a self-evaluation and certification of PSM compliance is required, a system must be in place to perform and document compliance audits.

- **Trade Secrets**: When a toll involves proprietary information, a system must exist to ensure that employees have the process safety related knowledge needed to meet the intent of the process safety management system.

4.9. Test Runs for the Process

Some toll processes lend themselves to test runs in the pre-startup phase. Actual materials for the toll may be used in the test or substitute materials, typically with low hazard potential, are often used to simulate the charging, reaction, and physical changes to be accomplished in the toll. Flow control, temperature control, pressure control, mixing and transferring efficiency can be measured. Mechanical integrity can be verified in regard to pumps, seals, vessels, heat exchangers, and safety devices.

Test run steps can frequently be incorporated into process startup procedures. Two examples would be: pulling a vacuum on vessels and verifying it holds, or distilling a solvent and checking for the presence of water to verify the mechanical integrity of the heating and cooling equipment.

4.9.1. Value of Performing Test Runs

When a test run is performed using the actual materials for the toll, it is a prime opportunity for the toller and the client to document the capability of the equipment, instrumentation, and process steps. During such a test, frequency of sampling may be increased, additional analyses performed and yield capabilities checked to find the optimum setpoints and timing for the toll process. Health, safety and environmental staff may choose to provide close coverage of the test run to evaluate areas for improvement during the actual startup and long term operation.

Many tollers use the term "water batching" or "water run" for a test run substituting water for the liquid components of a toll. At a minimum, the liquid handling system can be checked for leaks, pressure or vacuum containment and heat transfer. Pumps can be "run in" during the test run if they are new or recently overhauled. Water batching can also assist in flushing newly constructed piping or vessels. Personnel can monitor the flushed water by checking screens or filters to determine whether the cleaning was effective.

In an analogous manner, when powders are being formulated, tollers will substitute clay granules or other inexpensive inert materials to test the systems.

In either type of test run, an opportunity exists to ensure the utilities for the process are capable of performing their function.

Test runs also allow the primary steps of operating procedures to be validated and checked for logic or human factors aspects.

Some tolled products can be reworked if they fail quality assurance tests. In these cases the production cost may go up, but the product is not a complete loss. However, other tolled products, some pharmaceuticals for example, could be completely ruined by similar processing mishaps. Losses in these cases can be quite extensive. Test runs and approved rework procedures for such products may help avoid these losses.

4.9.2. Guidelines for Performing a Test Run

There are some considerations and planning that can assist in performing a successful test run.

- Assign a test run team and select a leader.
- Have the team set clear goals for the test run. Ensure they are measurable.
- Identify additional sampling and monitoring to be performed during the test.
- If a design limit test is included in the test run (such as a hydrostatic test) and it exceeds safe operating limits, consider writing a special procedure for this part of the test.
- If substitute materials are used in the test run ensure they are compatible with the toll's raw materials, products, materials

of construction (including gaskets/seals), or ensure that they are completely removed from the equipment prior to startup.
- Check the results of the test against the team's goals.
- Record any warranted recommendations for improvement and use the toller's management of change system to control their implementation.

A test run involving the actual raw materials for the toll or the initial startup that follows a water batch and PSSR is an appropriate time to evaluate any planned changes necessary for increasing production later in the toll.

Examining the feasibility of increasing the charging amounts or shortening turnaround times for batches might be the reason for testing. Both of these items can raise issues that potentially affect process safety.

Increasing the volume of the raw materials may mean altering mixing times, reaction times, and catalyst weights and possibly resizing equipment. One batch plant's operators were forced to make a midnight run on the warehouse's stock of empty 55-gallon drums in just such a situation. They realized a little too late that the new batch instruction procedure had them charging 6000 gallons of materials into a 5000-gallon-capacity reactor. Luckily this scenario involved a low hazard process, although it undoubtedly resulted in a more lively morning turnover meeting.

Some of the pre-startup activities may need to be revisited when physical increases in volume and changes to equipment are planned. A PHA may need to be revalidated prior to implementing such a change to evaluate any secondary issues it could cause.

Some tolls start up with the intent of manning only one shift until business demand increases. Eventually, the same equipment may be used for two and then three shifts, attaining higher and higher batch numbers per day. This scenario raises the issue of adequate training for the operators and maintenance crews assigned to work the toll. Have the new people involved had the training and experience necessary? Is enough time left between batches to properly clean and prepare the equipment? Do the operators have skills to lead and document efficient "shift turnover" meetings? These kinds of production changes can also benefit from revisiting the pre-startup activities described in this chapter.

4.10. Qualifying and Controlling Raw Materials

The technology package for the toll should have established minimum standards for the raw materials that are used in the process. In some tolling arrangements, the company letting the toll supplies some or all of the materials. Others may detail the suppliers the toller must use.

It would be very disappointing to complete a successful pre-startup phase only to see quality drop off or safety problems arise due to uncontrolled raw materials later in the toll. This could be from something as innocuous as fluctuations in water quality from the toller's supply system or improper storage/shipping conditions for purchased materials. Required material control systems should be identified early in process, and in place prior to start-up including agreement for testing or documenting raw material quality.

4.11. Starting the Process

The tolling team has analyzed the hazards, addressed the risks and modifications using a management of change system, revised and written procedures, trained the workers, performed a PSSR, and completed any required test runs. The pre-startup phase is complete at this point.

These startup precautions should determine if a startup advisor or team from the client should be present for the initial startup and shake down operations. This is especially helpful if part of the toll involves technology or chemicals new to the toller's staff. Having someone nearby who may have prepared the technology package and run a pilot of the toll process can be very useful to the startup crew.

4.12. Post-Startup Review

The first process review should be conducted shortly after startup to verify that the tolling operations are within the scope of the final technology package. The post-startup process review can be

requested and scheduled by the client. A team composed of the personnel involved in selecting the toller and in developing the technology package is best for this review. Some companies may have special auditing groups skilled at this type of activity.

This post-startup review team should report the results of their review to the management of the business unit responsible for the final tolled product. If operating parameters or equipment configurations different from those approved in the technology package, management should promptly assess any risk associated from the variances and either:

- terminate processing immediately, or
- after consultation with appropriate internal engineering safety and technology groups, establish a timely, written program to correct or accept the variances.

4.13. Monitoring Scale-up Concerns

A toller may be operating the first scale-up of a process that has previously only been produced in pilot quantities. This pre-startup situation benefits when special concerns related to a scale-up are monitored.

Some process characteristics designed and observed during pilot operation must be observed more closely during scale-up to take into account the order of magnitude changes in vessel size and quantity of materials that may have been engineered into the new process design. Scale-up may involve significant production increases that introduce new process safety concerns such as bulk storage and new material handling technology. When scaling up exothermic or high temperature processes, heat removal capability must be considered. The pilot or bench process design may be compromised by a lower surface to volume ratio. This may be a key factor during equipment selection for the scale-up.

Simple mixing of raw materials and intermediates may present special problems when processing significantly larger quantities in comparison to the pilot process or laboratory bench amounts. All aspects of the toll should be considered while performing the PHA to identify potential problems caused by the scale-up.

5

ONGOING OPERATIONS: AUDITS AND FOLLOW-UP

After implementing or participating in a well thought-out selection process, negotiating a mutually beneficial contract, and teaming to ensure thorough pre-startup and startup activities, the toller and their client company should be experiencing a generally successful tolling operation. However, as always, changes or problems may arise on a day-to-day basis. These could be related to external events, quality, process safety, environmental issues, or contract requirements. Both parties must be prepared to participate in three primary activities that will help minimize or avoid these occurrences. These are:

- Auditing
- Consulting
- Managing Issues

The following sections provide guidance and some examples for addressing these ongoing activities. The flowchart on the next page shows a typical sequence of ongoing operations and audits.

5.1. Audit as Appropriate for the Process and Product

Depending upon the specifics of the toll, the primary control activity performed by the client during ongoing operations will be auditing the toller. This assures operations are going as planned and

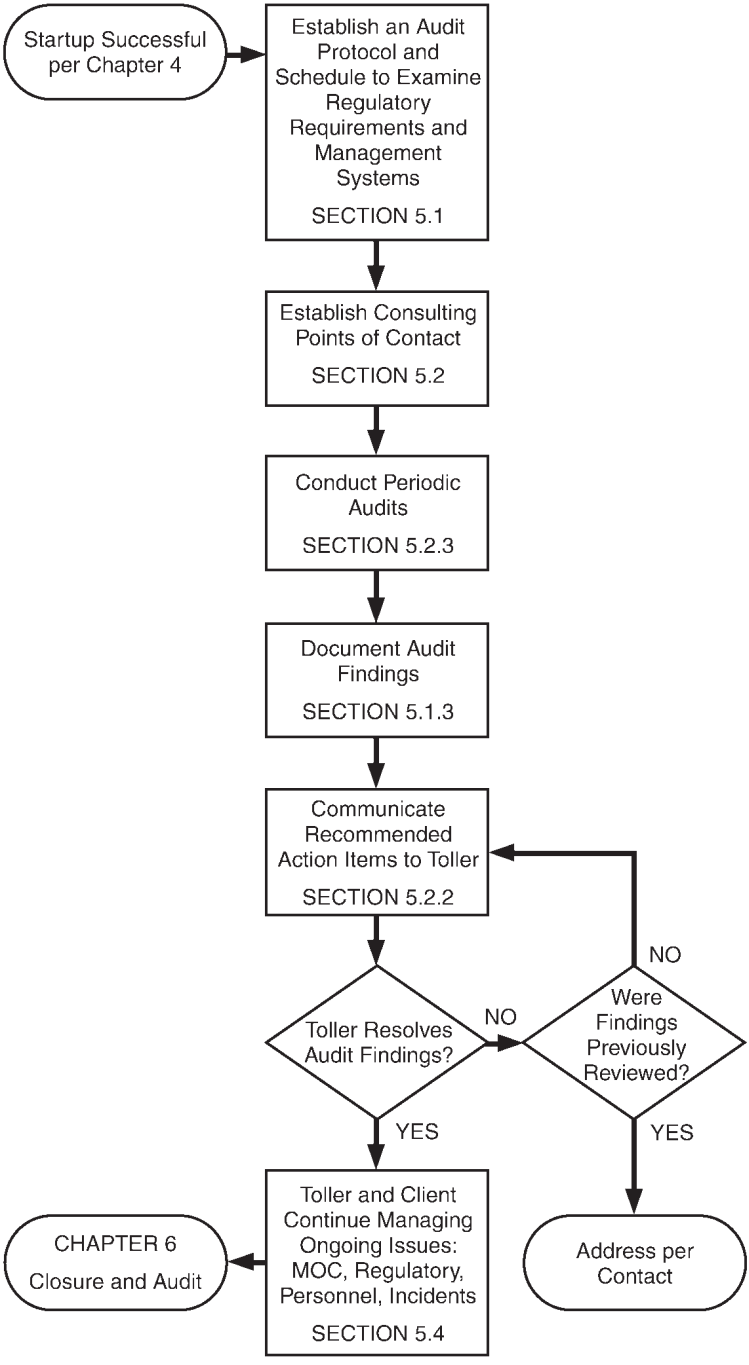

Figure 5-1. Ongoing operations: audits and follow-up flowchart

obligations are being met. For less hazardous tolls, audits may primarily be scheduled to monitor production levels, quality, and personnel safety issues. For more hazardous tolls, a more frequent and rigorous audit schedule may need to be implemented. The three primary questions to be answered by the toller and client are:

- What is the purpose and scope of the audit?
- Who performs the audit?
- How will the results of the audit be used?

5.1.1. Regulatory Requirements: PSM, RMP, and Others

In addition to assuring that any internal auditing needs of the client and toller are met, there may be laws requiring audits of a specific nature. Two U.S. regulations that may require regular audits relating to process safety are OSHA's Process Safety Management (PSM) of Highly Hazardous Chemicals (29 CFR 1910.119) and EPA's Risk Management Program (RMP) rule (40 CFR part 68). Both have a three-year compliance audit schedule to help ensure that covered facilities keep their management system up to date. Even if not covered under one of these two regulations, a facility is subject to the general duty clause from the Clean Air Act (CAA) 112(r) amendments of 1990. It is the toller's responsibility to perform required audits (or have them performed by a third party). In some cases, it may be appropriate for the client to participate in the compliance audit. When applicable, these audits should be a key reference to the toller's client with respect to process safety performance.

The United States is signatory to a treaty known as the Chemical Weapons Convention (CWC). It is aimed at stopping the proliferation of chemical weapons. Under CWC, plants that synthesize threshold quantities of unscheduled discrete organic compounds (UDOCS) are obligated to report the quantities of material produced and provide contacts for arranging inspection by a CWC Team. To prevent any repercussions that might affect the toll, the client should confirm that the toller has met this obligation, even if the client's product is not involved.

5.1.2. Management Systems

There is a movement in the chemical processing industry to view recent safety, environmental and quality management systems in a more holistic way. A company can guide and document their overall operational discipline through the use of a single management system. Such a system can simply reference the various regulations, industry initiatives or certification programs to which they adhere.

With well-designed management systems in place, the process of auditing and follow-up for ongoing tolls can be simplified. Regardless of whether or not a toller's facility is covered under PSM or RMP, a review of their work processes and management systems against basic process safety techniques may be beneficial during ongoing operations. A company may be ISO 9000 certified for their quality management system or certified under ISO 14000 for their environmental management system, or they may simply have an in-house management system that reflects their overall philosophy of operation and methods to fulfill it. The option to audit facets of these systems for items of process safety interest can be spelled out ahead of time in the contract if desired.

5.1.3. Documenting the Audits

Toller audits may be categorized into the following three types:

1. **Pre-contractual:** To establish conditions during qualification and contract development for the purposes discussed in Chapter 2, *The Toller Selection Process*.
2. **Pre-amendment:** To establish capacity to perform substantially changed tasks, sometimes needed if the contract, as discussed in Chapter 3, *Mutual Agreements, Obligations, and Contract Considerations* is undergoing revision.
3. **Follow-up or Periodic:** To establish the current status of operations, at a frequency implied by the hazard level or quality sensitivity for a specific process or general type of processing and otherwise agreed to by both parties.

The ongoing production phase involves the last two types, pre-amendment audits and periodic audits. The differences in docu-

mentation between a pre-contractual audit and one performed during production vary from company to company. Some client companies use the same audit protocol form used in the selection process as guidance for all three types of audits. Others have developed a separate approach once the toller has satisfactorily passed earlier audits.

An example of an audit guide that focuses on environmental, health, and safety inspections during the toll-processing phase is included as Appendix B, *Sample Toller HS&E Assessment*. This example should be customized to meet specific needs by adding quality concerns or other processing related items.

In addition to these paper tools, there are several commercially available health, safety, and environmental audit software programs that can be customized to meet specific needs.

The general purpose of an audit may be to determine if the toller has management systems and documented procedures in place to ensure process safety, environmental responsibility, product quality and traceability of materials. The need to audit could be to evaluate compliance with regulations or accordance with client requirements related to specific performance elements. A subjective rating system for ranking management systems audit results is often used. An example of one that might be appropriate is shown below:

> **Good:** The management systems audited provided reasonable protection against significant loss or noncompliance with regulations and directives. Any deficiencies found were deemed minor. Relevant management systems are documented and routinely followed. Some corrective action may be necessary.
>
> **Adequate:** The management systems audited provided reasonable protection from significant loss or noncompliance. Most of the required management systems are documented, but not necessarily followed every time. Some corrective action is required.
>
> **Needs Improvement:** The management systems audited provided limited protection from significant loss or noncompliance. Some required management systems may be

documented, but are not routinely followed. Prompt corrective action is required. Additional auditing/investigation may be necessary.

Needs Significant Improvement: There are no management systems or those audited provided little or no protection from significant loss or noncompliance. Urgent corrective action is required. Additional auditing/investigation is required.

At the conclusion of the audit, the auditor should review findings with the toller. It is not necessarily the role of the auditors to prescribe specific toller activities that will alleviate audit findings. The auditors may discuss potential responses or implementation activity, however the audit subjects should be given adequate time to determine a complete and integrated response to the audit findings. Typically, the toller responds to the specific findings with action plans that are discussed with their client company and mutually agreed upon at some period after conclusion of the audit. The action plan should include a timeline for completion and a method of tracking individual action item progress. This action plan is a statement of agreement to specific elements to achieve the agreed performance specified in the toll contract. Progress against the elements of this action plan should be reviewed as part of an overall review of the toller contract performance. Audit subjects receiving low performance ratings may need more aggressive review of performance against action plans.

5.1.4. Auditing as Specified in the Technical Package

The technical package may specify a scope and frequency for periodic audits and performance criteria that could lead to changing the audit frequency. It may be a general safety and environmental performance audit or a special audit for items such as raw material storage and handling, quality control methods and documentation. The proprietary nature of a process or product or the complexity of the toll could be a reason to establish a more frequent audit schedule for certain tolls. Audits can also be conducted to follow-up on previously identified shortcomings to document that they were addressed properly.

5.2. Consulting

Throughout the life of the toll, it is important to maintain the communications emphasized in earlier chapters. The client often has process or product specific expertise. This places them in the position of a consultant to the toller on issues regarding the specific product or process. For tollers with specialized skills, the role of consultant may be reversed. Tips for becoming a successful internal tolling consultant follow:

- Help "clients" define the problem. All parties should agree to a complete picture of the problem or situation before selecting a path for action.
- Know what resources are available and how to access them. Human resources, data resources, and technical expertise may be available in both companies. Someone in a consultant's organization may have seen a similar situation that can provide insight. Networking is essential.
- Practice a high level of operational discipline. Maintain good communications and a positive outlook.

Considering the merchant nature of the tolling business, these informal communications must still respect the confidentiality concerns and restrictions on both parties. While specific experience in allied technologies often may not be disclosed, it is incumbent on both parties to establish means to convey critical safety issues without disclosure of otherwise confidential information.

5.2.1. Points of Contact

It is essential to develop contacts within both companies to create an atmosphere of two-way communication. The toller should feel comfortable in asking for advice or assistance and this is best achieved by building rapport with their primary contacts from their client company. After an audit, the points of contact can be assigned responsibility for ensuring completion of individual action items.

Establishing specific points of contact for the following disciplines may be useful:

- Process safety
- Risk management
- Occupational safety and health
- Environmental compliance
- Process engineering
- Quality systems/statistical process control
- Toll chemistry
- Management of change
- Logistics
- Invoicing

Within the client company, a person could be designated the overall "toll manager." This person can act as an overseer to make sure resources are available and issues are not inadvertently dropped.

5.2.2. Communication

Regular communications through telephone, e-mail or memoranda offer opportunities to communicate off-hand issues that might not be asked during a scheduled audit or required report. A regular report from the toller to the client "Toll Manager" or designated point of contact within the client company is an opportunity to discuss the day-to-day processing. The "Toll Manager" should consider meeting or calling to discuss the report even if just to note good progress. In case of emergency or unexpected occurrences during ongoing operations, this role can be essential for ensuring rapid response.

5.2.3. Periodic Visits

Consider the value of periodic visits outside of those slated strictly for audit purposes. One or two persons may arrange a day at the toller's site observing operations and making themselves available for questions. A good practice is to make it clear to the toller that such visits can be arranged at their request for technical, environmental or process safety support. Periodic visits to the tolling site may be helpful particularly in complex or hazardous tolling situations and in laying the groundwork for processing improvements.

Acting as a consultant can result in new methods, techniques or tools producing more efficient or safer processing of the toll. In some cases, the toller may be the expert in the process or equipment thus consulting to their client company to help them gain expertise for contracting future tolls.

5.3. Managing Issues: Guidelines and Suggestions

Certain issues present themselves regularly in the tolling situation. This segment provides options and suggestions for addressing changes in personnel, the process, and ownership, as well as for issues like incident investigations, handling and storage of materials and waste, regulations, new hazards, and performance monitoring.

5.3.1. Management of Change Issues

Whether or not a toller site or a specific ongoing toll process is covered under a regulatory mandate to manage changes, there is always a question of when to involve the client in day-to-day management of change (MOC) activities.

As noted in the consulting segment of this chapter, tollers should identify a point of contact in their client company that can review and approve MOC activities when related to the client's toll. Identifying a point of contact and establishing some ground rules for approval of changes is fundamental to assure good business relationships, appropriate product quality control, and enhances the communication essential for a safe tolling operation. These ground rules are a starting point for a system that encourages review of change by persons with appropriate expertise. The merits extend beyond HS&E issues related to the change. Most products have very strict specifications and process changes can influence product characteristics and change conformance to the specifications in various degrees. Failure to monitor process changes can easily lead to product that fails to meet specifications. Consequently, it is important to assure persons from both companies with the appropriate expertise review all changes. This helps ensure that HS&E issues and off-spec product do not result from the changes.

The issue that must be managed is the appropriate threshold to communicate the change and initiate appropriate approval processes. Tolls subject to regulatory requirements may use the regulatory guidance as the threshold for management of change processes; other tolls must establish the threshold appropriate to process risks, quality systems, and business concerns.

Both companies, the toller and their client, should mutually agree upon a definition for "change" that is encompassing enough to address the hazards and risk associated with their toll. If covered under U.S. PSM or RMP regulations, any deviation from the original design specification is considered a change. However, parties may agree to establish a conservative definition that goes beyond the regulatory definition of a change in order to ensure proper review by experts.

Example 5-1, *Sample Toller Management of Change Form*, can be modified to meet the needs and staffing of the toller and client. Note that this form is to be used in concert with the company's management system procedure. Each part of the two-page form is explained in detail in the associated management system procedure to clearly denote the requirements for performing reviews, what responsibility each person's signature entails, and what signifies completion of training, procedure revision, P&ID updates, and other items. The procedure could also give specific examples of changes and non-changes in accordance with the agreed upon definition.

Remember, once a complete process safety system is in place, the management of change element is the engine that drives the other elements of process safety. It serves to keep them current and provides an opportunity for the toller to perform a mini-audit of other PSM elements each time a well designed management of change system is used. Client companies can learn about the nature of changes at a toller by examining the management of change files for the facility during audits.

5.3.2. Process Issues

If properly established, the management of change mutual-review agreement and designated points of contact should preclude most

Example 5-1. Sample toller management of change form, page 1

TOLLER CO. SPECIALTY CHEMICALS	**Change Approval Form (CAF)** Form No.: PSMADM11.501 Rev. 3	PSM ADMIN. ASST. USE ONLY PAGE 1 OF 2

PART 1 – INITIATE CAF	**CAF INITIATOR NAME:**		
Completed by CAF Initiator – This form should be used with procedure PSM-ADM-11, *Management of Change*			
Applicable Cost Codes for Affected Equipment/Area:			
Title of request:			
Brief description:			
Technical Basis: (Check all that apply)	❍ Production Rates	❍ Envir. Control	❍ Experimentation
	❍ New Equipment	❍ Equip. Unavailable	❍ Yield/Quality Improv.
	❍ New Product Dev.	❍ Chemical Change	❍ Other:
Reason for the Change:	❍ Improved Safety	❍ Envir. Control	❍ Essential to Operation
	❍ Profitability	❍ Other:	
Work Order Number: (if applicable)			
Temporary Installation?: ❍ NO ❍YES If yes, state Expiration date/Condition:			

PART 2 – ASSIGNED CAF SEQUENCE NUMBER:

PART 3 – TYPE OF HAZARD REVIEW (determined by CAF Coordinator)
CAF COORDINATOR – SIGN:

PART 4 – DISCIPLINE REVIEWS (check one for each) Reviewers - Attach documentation of findings		Reviewer Signature/Date Complete
HS&E Review Initials of Assignee:	❍ Assigned ❍ Not Applicable	
Client Company Review Initials of Assignee:	❍ Assigned ❍ Not Applicable	
Process Engineer Review Initials of Assignee:	❍ Assigned ❍ Not Applicable	
Mechanical Engineer Review Initials of Assignee:	❍ Assigned ❍ Not Applicable	
Mechanical Integrity Review Initials of Assignee:	❍ Assigned ❍ Not Applicable	
Process Cont. Engineer Review Initials of Assignee:	❍ Assigned ❍ Not Applicable	
Instrumentation Eng. Review Initials of Assignee:	❍ Assigned ❍ Not Applicable	

Example 5-1. Sample toller management of change form, page 2

PART 5 – CHANGE HAZARD REVIEW COMPLETE	PAGE 2 OF 2
CAF COORDINATOR SIGNATURE:	
UPDATES REQUIRED:	Signing Indicates Complete (or mark N/A) with Date Signed
Items must be completed: 1) Prior to Commissioning/Startup 2) Prior to Project Closure	
1) Operating Procedures	
1) Material Safety Data Sheets *	
1) PHA/Checklist Recommendations	
1) Process Overview Training	
1) Process Technology Package *	
2) Maintenance Procedures	
2) Contractor Training materials	
2) Mechanical Integrity Information	
2) Safe Work Practices	
2) Emergency Response Plan	
2) Process Control Documents	
Other (attach pages if needed):	
Did the Process Safety Information Change? ❍ YES ❍ NO (* items indicates PSI) (If YES, initiate PSM-ADM-08, *Pre-Startup Safety Review)*	

PART 6 – INFORM AND TRAIN Sign to indicate training and/or information requirements are complete for startup. Attach Documentation	
OPERATIONS SUPERVISOR:	Date:
MECHANICAL SUPERVISOR:	Date:

PART 7 - APPROVAL Signature indicates the change is approved for startup upon completion of any required PSSR	
MANAGER	Date:

PART 8 - CLOSURE	
CAF COORDINATOR:	Date:

PART 9 - ARCHIVE	
PSM ADMINISTRATIVE ASST:	Date:

PART 10 - ❍ CAF Cancelled (if applicable)	Date:	Initials:
Explanation for cancellation:		

processing issues from becoming problems. However, when issues do arise outside of management of change items, it is incumbent upon the party finding the issues to communicate them immediately. Most commonly, questions arise at the toller's site. These often regard unexpected yields, less than satisfactory quality control capability, changes in details of raw material supply, product packaging or shipping instructions, equipment liability or performance concerns, production schedules, or issues concerning safety and chemical compatibility.

Client contacts should be notified of issues in a timely manner. Depending upon the nature and gravity of the issue, tolling may be stopped completely for a period of time or continue in limited production mode until the situation is fully diagnosed and corrective action can be implemented.

5.3.3. Personnel Issues

The importance of the capabilities and qualifications of technical and operations staff at the toller site was emphasized in Chapter 2, *The Toller Selection Process*. It may have been a key factor in the selection of a toller. The expertise of the client personnel is equally important during this phase of the tolling effort.

Should either set of personnel change in any meaningful way, the two parties should consider openly discussing the impact on the tolling operations and take whatever action is needed. Some issues and responses are listed in Table 5-1.

5.3.4. Acquisition of a Toller by Another Company

If another company purchases a toller company in the midst of an ongoing contract, several questions need to be asked. Foremost for the client company is the question of how the acquisition will affect process safety and environmental concerns.

Other questions include:

- What contract terms apply in this case?
- Is the new owner a competitor?
- Will the new company be removing or replacing key staff members at the purchased toller's site?

Table 5-1. Personnel Issues and Possible Responses

Personnel Issues	Possible Responses
Experienced operators at the toller site leave due to retirement, downsizing or other factors.	Both parties can work together to revisit and implement appropriate overview and procedure training for less experienced operators. Revisit the operating procedures to ensure they are written to the appropriate level of detail for the new operators.
In-house maintenance services at the toller site become an outsourced function.	The client company must determine if their toll will be impacted. If so, work with the toller to evaluate the compatibility of the new contract maintenance personnel.
Key technical staff become unavailable for the toll or leave the company.	Attempt to interview and extract key information from the persons prior to their departure. Arrange for an overlap period for the key person and their replacement. Train the replacement. Ensure the replacement person is given access to the historical records of the toll: contract, technology package, MOC packages, and incident investigations.
Experienced Safety, Health and Environmental staff personnel depart.	The toller may request more involvement from the client for these services until replacements are in place.
Toller management personnel change.	The "toll manager" for the client company should make efforts to build a relationship with new toller management to determine any impact on operations.
Key points of contact at the client company are reassigned or leave the company.	Both parties should communicate extensively to arrange replacement points of contact.

- What is the buyer's history in regard to process safety and environmental compliance?
- What is the financial condition of the new company? Is there a greater debt load?
- Will the new entity improve or detract from the original deciding factors important in selecting the toller?
- Does the acquisition create a conflict of interest?

A toller should be open and communicative as early as possible during the process of changing ownership. Both parties should evaluate their relationship and resolve resulting issues.

5.3.5. Regulatory Issues

Regulatory issues may arise throughout the duration of a tolling process. The type of issues experienced is dependent upon the mechanical aspects of the process, chemical makeup and quantity of the specific raw materials, intermediates, products, emissions and wastes.

To evaluate the potential for unforeseen regulatory burdens, obtain and review MSDSs for raw materials, intermediates, products, emissions and wastes along with associated process hazard analysis documentation. The following questions may be considered during the review. These are not all encompassing. They focus on regulatory issues that may be overlooked if not explicitly delineated in the technology package or contract.

Are materials subject to the requirements of the OSHA Process Safety Management Rule (29 CFR 1910.119) or the EPA Risk Management Program Rule (40 CFR 68)?

Statistical summaries of audit reports from past U.S. OSHA PSM citations have shown that, in general, companies' process safety management systems may need improvement in the following key elements. Note that these weaknesses were found at facilities that were subject to an OSHA inspection in regard to the process safety management regulation. Many of the inspections were scheduled or resulted from a referral from another agency; however, often inspections were the result of an incident or an employee reporting

a possible problem related to process safety. (Contact US OSHA for additional information.)

- **Operating Procedures**
  - Did not address all steps for each operating phase.
  - Operating procedures did not have clear instructions for covered processes consistent with PSI.
  - Were missing annual certification that operating procedures were current and accurate.
  - Did not address operating limits.
- **Process Hazard Analysis (PHA)**
  - Did not perform an initial PHA appropriate to the level of complexity of the process.
  - A system to address the team's findings, schedule and complete actions was not established.
- **Process Safety Information (PSI)**
  - Did not provide adequate information on the equipment in the process.
  - Did not provide adequate information on the technology of the process.
  - Did not compile PSI on hazards of regulated substances, technology of process and equipment in process prior to conducting the PHA.
- **Mechanical Integrity**
  - Did not establish and implement written procedures to maintain mechanical integrity of process equipment.
- **Employee Participation**
  - Lack of a written employee participation plan for covered facilities.
- **Training**
  - Failure to conduct or document initial training for operators. (This is especially important for new operators or when an operator moves to a new area of the facility.)
  - Did not provide documentation that training had been conducted.

Are there any specific, high profile environmental, safety, or health issues or concerns with materials?

- Identify potential key "risk" issues for "on-site" review.
- Identify "hazardous" or regulated raw materials, intermediates, products and wastes that fall under OSHA, resource conservation and recovery act (RCRA), Department of Transportation (DOT) pipeline safety regulations or other impacting regulations.

Are there any specific, high profile HS&E issues or concerns with any materials?

Are any of the toll products sold under Food and Drug Administration (FDA) regulations as "direct" or "indirect" food additives?

If yes, additional review of good manufacturing practice and product quality requirements may be necessary.

Are any of the materials subject to a Toxic Substances Control Act (TSCA) Section 5 Consent Order or Significant New Use Regulation (SNUR)?

Are any materials subject to the provisions of the Chemical Diversion and Trafficking Act of 1988?

If yes, then product accounting audits should be sufficient to ensure that there are no unexplained losses.

Are any materials listed under the United Nations Chemical Weapons Convention Precursors list ("Australian List")?

If yes, then product accounting audits must be sufficient to ensure that there are no unexplained losses.

If not evaluated completely during the toller selection phase, the following documents may become applicable during the toll. Consider reviewing those that are applicable (and raise the issue if one is applicable but not found).

- MSDS files
- SARA reports
- Spill prevention control and countermeasures plan (SPCC plan)

- Emergency response plan
- Production records sufficient for TSCA 5.8(a)
- OSHA 200 Log
- Training records (OSHA, EPA, DOT)
- Hazardous waste manifests
- RCRA TSD permit/EPA generator number
- Air/water/waste permits and monitoring reports
- Container and sample labeling
- Tank inspections

5.3.6. Handling, Transporting, and Storing Materials and Waste

Day-to-day movement and storage of materials and waste can sometimes present more vulnerability to spills and exposure than the tolling process itself. As the toll progresses, regular attention should be paid to any applicable regulated waste generated by the process in question. The environmental point of contact should be aware of the answers to any of the applicable questions that follow. Some of the questions may not apply to the specific tolling activity in question but violations (past, present or future) could impact production during the toll's life cycle. Note that these questions and issues should have been part of the toller selection process and need to be clear from the onset of the toll operation. However, during the audit of ongoing manufacturing, the client should continue to look for changes in these areas that have compromised original agreements.

- **Solid Waste Management**
  - Have all wastes been properly characterized?
  - Is the site classified as a generator or a transportation, storage, and disposal facility (TSDF)?
  - Can they provide a list of solid wastes generated from operations within the past year?
  - Are wastes from this process mingled with any other wastes?
  - How are wastes analyzed and at what frequency?
  - Is a list of TSDFs used for waste managment available?
  - Have these TSDFs been reviewed or inspected? By whom?

- What are the known or potential problems/concerns with above TSDF sites or transporters?
- For on-site solid waste storage locations, what is the number of satellite storage locations? Number of 90/180 day storage locations?
- Is any waste treatment conducted on-site?
- Has any waste material been buried or disposed of on-site (at any time)?
- Are manifests maintained for wastes? Where?
- Are any recycling processes used for wastes?

- **Site Contamination**
  - Has any soil contamination been reported to regulatory agencies?
  - Is the toller site being required to remediate soil or ground water under federal or state supervision?
  - Has a geological survey been made?
  - Is there a groundwater assessment report?
  - Is there a written groundwater protection plan?
  - Are there groundwater monitoring wells?
  - Are drums stored at storage areas on-site? On concrete? Covered? Diked?
  - Are any waste storage tanks registered with the regulatory agencies?

- **Loading/Unloading Facilities**
  - Are there truck facilities and do they have spill containment systems?
  - Are there rail car facilities and do they have spill containment systems?
  - Is vapor recovery a regulatory requirement?
  - Is there any evidence of soil contamination at these facilities?

- **Water Discharges**
  - Is a list of water discharge permitting agencies, permit numbers and expiration dates available?
  - Are all permits current?

- Is a list of required parameters sampled (including frequency of reporting) available?
- Are all water discharge outfalls, sources, discharge sites and sample frequencies known?
- Are there any current or potential problems with meeting discharge requirements?
- Are there any impoundments or lagoons on-site?
- Is any water treatment performed on-site?
- What reports are sent to agencies? (analysis done, frequency)
- Were there any violations during the past three years?

• **Air Emissions**
- Is the toller site a major source for any air pollutant (that is, actually emits, or has the potential to emit more than 100 tons/yr)?
- If in an ozone nonattainment area, does the toller facility actually emit, or have the potential to emit, VOC or NOx in excess of the threshold limit value?
- Does the facility emit, or have the potential to emit, more than 10 tons/yr of any single hazardous air pollutant (HAP), or more than 25 tons/yr of total HAPs?
- Has or will the facility apply for a Title V air permit?
- What is the application date for the facility?
- Is the facility subject to a New Source Performance Standard? (Explain.)
- Is the facility subject to any NESHAP rule? (Identify.)
- Does the facility have a prevention of significant deterioration (PSD) permit?
- Will the facility be subject to the marine vapor loading MACT rule? (Explain.)
- Has toxic release inventory (TRI) been completed for the site?

5.3.7. Incident Investigations

Tolling companies should promptly notify clients of incidents that potentially question the safety of the process, or impact the capacity

of the toller to fulfill the subject contract requirements. The client cannot respond to the issue unless they are aware it has occurred.

In the event of an incident, including a near miss, the toller should consider inviting affected client companies to participate in the incident investigation. Participation from client companies may range from actually assisting in the investigation (suggested if the incident involved their process) to receiving a copy of the final incident investigation report. Participation may be required by the contract.

The initial incident report is very important. This document captures the initiator's firsthand knowledge of what occurred in the moments after the specific event. Example 5-2, *Sample Toller Initial Incident Report,* is an example of the data that should be documented as soon as possible. Note that it should be modified using the company's management system procedure and incident investigation procedure, which should describe the type of data needed, and level of detail desired.

The final incident investigation report written by the assigned incident investigation team (which may include members from the client) can be written in a less structured way depending on the extent of the incident. A detailed discussion of how and why to conduct incident investigations can be found in the AIChE publication, *Guidelines for Investigating Process Safety Incidents,* Second Edition.

5.3.8. Analysis of New Hazards

Whenever a new hazard potential is recognized – whether from new knowledge, information, or analysis, the parties involved in the toll should consider if a revised process hazard analysis (PHA) is necessary. In general, the discovery of process hazards not known at the time of the original PHA would suggest the need for revision or revalidation of all or part of the prior PHA. New or discovered hazards related to the general workplace or equipment are typically addressed by management of change systems. Some factors to consider are given below.

- Does a new or existing process that is being run simultaneously or in series with the toll in question present the new hazard?

Example 5-2. Sample toller initial incident report

TOLLER CO. SPECIALTY CHEMICALS	**Initial Incident Report** This form should be used with procedure SWP-041, *Incident Investigation Guidelines*. Attach additional pages as needed.

PART 1 - INITIATION - Completed by a person involved in the incident			
Name of Initiator (print):			
Employer:			
Date This Report Started:		Time Report Started:	AM/PM
Date of Incident:		Time of Incident:	AM/PM

PART 2 - INCIDENT DETAILS - Completed by the initiator			
Type of Incident (✓ all applicable)	❍ Fire	❍ Vapor Release	❍ Solid Spill
❍ Near Miss	❍ Injury	❍ Liquid Spill	❍ **Other (give details)**
Location Details: - Unit/Area:			
Known Injuries: (List name, employer and nature of injury):			
Witnesses: (List the name, employer for each witness)			
Medical Attention (✓ all applicable)	❍ None	❍ First Aid	
	❍ Doctor Visit	❍ Hospital Admission	
Incident Details: Describe in your own words; circumstances leading to the incident, what happened during the incident, what happened after the incident, personal sensations such as what you saw, heard, tasted, or smelled.			
Signature of Initiator:			

PART 3 - SUPERVISORY REVIEW - Completed by the initiator's supervisor.	
Signature of Supervisor:	
Date Initial Incident Report Received:	Time Initial Incident Report Received:
Description of steps taken to preserve evidence (if required):	
Description of Initial Actions taken to prevent recurrence of the incident:	

PART 4 - LEVEL OF INVESTIGATION - Completed by Site Manager		
Indicate the Type of Investigation:	❍ **Cause and Effect**	❍ **Root Cause Failure Analysis**
Date Initial Incident Report Received:	Time Initial Incident Report Received:	
Site Manager Signature:		

- Is the new hazard due to shared or auxiliary equipment associated with the toll?
- Is the new hazard due to potential inadvertent mixing in the staging areas or raw material and intermediates storage areas?
- Are production interruptions causing a new hazard?
- Is the new hazard a result of production changeovers to different products?

The effort and time that is required for a process hazard analysis for these examples should not be an issue. A thorough management of change system will call for the change coordinator to make a decision as to what type of review is appropriate for the change.

5.4. Performance Monitoring

A prime directive for the toll manager at the client company during an ongoing tolling contract is monitoring the overall performance of the toller. Recall the quality aspects presented in Chapter 1, *Introduction*. Measuring performance is more than just meeting a quota for the quantity of product leaving the toller's gate. It is the total picture of operational discipline associated with the innate hazards and risks for the toll in question.

The audit forms presented in this book are but one tool that can be used to monitor performance. Accounting records, regular reports from the toller, and end-user satisfaction can be used as a metric to determine the success of a tolling operation. The quality of the toll often depends on the toller's understanding of the client company's requirements and the toller's compliance to those requirements. Careful auditing, consulting, and management of change help ensure that the client company's requirements are fully understood and successfully implemented in on-going tolling operations.

6

CLOSURE AND AUDIT

For whatever reason a toll contract is ending, there are environmental, health, safety, and commercial aspects to address. Both toller and client have roles to play in the tolling project's safe shutdown and completion. As with other components of tolling, the opportunity for success is enhanced by thoughtful planning and determination of responsibilities. Each company may have designated a "toll manager" who was the primary person to oversee the toll's success but now has the duty to ensure that the toll is brought to a safe conclusion. Ultimately, the individuals designated as the toll managers should oversee closure and audit activities until the process is satisfactorily shutdown and the contract is terminated. Some basic considerations for toll processing termination include:

- **Removal of Unprocessed Materials**: This would include raw materials, packaging materials, labels and other such items. The toller can either retain the materials at no cost, purchase the materials from their client (if offered), dispose of the materials for the client, ship all unprocessed material back to an indicated client site, or a combination of these options. Compensation must be agreed upon for any client-owned material that the toller retains. Unused packaging materials, labels and other items bearing the client's identity should be strictly managed. They should either be recovered by the client or destroyed in a manner approved by the client.
- **Removal of Processed Materials**: Materials such as product, off-spec material inventory, retained samples, and process

waste should be removed from the toller's facility unless other arrangements are made. If the toller manages removal of these materials under the contract, it is suggested that title of all materials be transferred as appropriate.

- **Recovery of Technology**: All confidential information or equipment provided by the client or toller to the other party should be returned.
- **Final Transactional Closure and Reconciliation of Materials and Costs**: Termination procedures should outline who will have responsibility for assuring residual activities, material shipments, and processing has ceased. It is wise for both parties to confirm that this last step is complete. Normally, residual service activities and material supply ceases once the final invoice has been generated.

Contractual arrangements may have been made for terminating the toll earlier than anticipated. Some reasons may be market shifts that slow the need for high production levels, the development of in-house production within the client company, or performance problems with a given toller. Regardless of the cause, the notification period as stated in the contract governs.

Three aspects of the toll must be taken into account once the toll terminates:

1. the health, safety, and environmental considerations,
2. the commercial aspects of the materials and contractual arrangements, and
3. cancellation of permits and site cleanup if applicable.

Figure 6.1 is a flowchart that shows a typical progression for closing a tolling process.

6.1. Health, Safety, and Environmental Considerations

Health, safety, and environmental concerns may be elevated during this phase of some tolls. Nonroutine physical operations such as bag

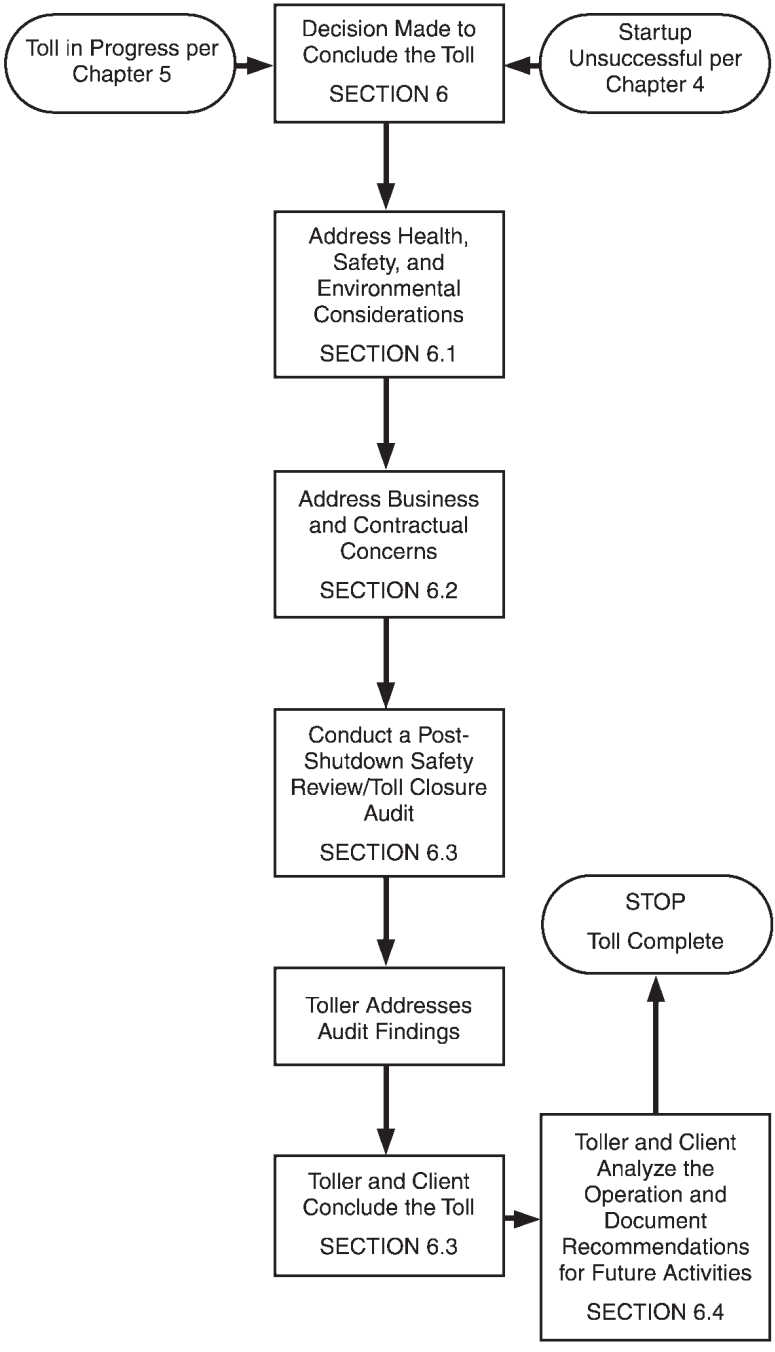

Figure 6-1. Closure and audit flowchart

house or vessel entry, line breaking, hot work, and other such activities present inherent hazards and may be performed with greater frequency than during normal operations. It is important to emphasize continued adherence to current safe work practices, especially when ending the toll. Additional protective equipment and personnel monitoring may be needed.

6.1.1. Decommissioning and Clean Up

Careful attention should be paid to processing and storage equipment to assure that certain future uses will not be contraindicated based upon the nature of the products. For example, it would not be wise to allow storage of food or food chain materials in vessels that once contained agricultural chemicals, even if the vessels were first cleaned. In the event the toller will not assure appropriate future use of the equipment, the client may consider purchasing the equipment for future use elsewhere.

In cases where the materials handled are reactive, toxic, or pose potential long-lived impact on the environment, decontamination of the equipment is a crucial step to closing the tolling effort. Efficient and thorough decontamination practices should reduce the potential for future chemical incompatibility, cross contamination or environmental impact. These practices and procedures should have been identified in the process technology package and formalized as needed during the pre-startup and operational phases. In some cases, the client may wish to specify criteria for thorough decontamination and verify through their own sampling and analysis.

Clean up includes identifying, gathering, storing (when appropriate), and classifying materials associated with a specific toll. Decisions can then be made as to which raw materials, intermediates, and product will be shipped back to the client or kept by the toller. Some off-spec product, retained samples, or unused intermediates may be considered waste materials at this point. Equipment clean up can be extremely important to preserving quality and process safety integrity prior to the next production run of a new product.

If the toller was using process equipment loaned to them by their client company or leased from a third party, whether for pro-

prietary reasons or simple economics, it generally should be thoroughly cleaned and decontaminated prior to being returned. The client company may, at times, request a different process than the standard decontamination methods or perhaps none at all.

Items to consider during decommissioning and clean up are:

- Is a decommissioning phase hazard evaluation needed? The AIChE/CCPS text, *Guidelines for Hazard Evaluation Procedures,* Second Edition, offers direction for addressing this type of evaluation.
- Material returned to the client or sent to treatment disposal should have documented chain of custody.
- Decontamination, clean up and disposal activities should be documented.
- Special considerations need to be evaluated for decontamination and clean up of difficult materials. For example,
  - pyrophoric materials or materials that can undergo decomposition, especially if there is a potential for exposure to air (pyrophorics),
  - cleaning chemicals (reactives),
  - materials affected by sitting for a period of time (unstable, explosive decomposition), or in close contact with residual materials (reactives).
- Special industrial hygiene considerations associated with clean up and decontamination activities may need to be implemented.

6.1.2. Proper Waste Disposal

Like decontamination, directions for proper waste disposal should be indicated in the initial technology package. In some cases, the client company should be very involved in how certain wastes are handled and disposed of, and may even maintain control over this part of the toll. Both parties have vested interest in assuring waste disposal is properly completed and adequately documented prior to termination of contract.

6.2. Business and Contractual Concerns

6.2.1. Return of Proprietary Documents

Most tolls involve the transfer of proprietary information from one party to the other, typically from the client company to the toller. Each party should have maintained a log of transferred documents or software code to make the return of proprietary documents a simple matter. An initial list of the documents should have been referenced in the contract or as part of the technology package. Keeping records of additional documents transferred during the course of the toll will help eliminate confusion at the end of the project. The toller may need to retain documents appropriate for their process safety system needs.

6.2.2. Governmental Notification

When tolling certain materials, the end of the toll may indicate the need to notify governmental agencies. Notification may be required to end any issued registrations for raw materials, intermediates, product or wastes or to let an agency know that a process is no longer covered under a previously applicable regulation.

6.2.3. Sample Retention and Record Retention

For some products, a decision may need to be made whether samples of product lots produced by a toller will be maintained at their site or returned to the client company. Certain samples may become hazardous waste, with associated disposal costs, when the sample retention time expires. When samples are held on behalf of the other party, ultimate disposal agreements should be in place.

Process hazard analyses, waste manifests, bills of lading, employee exposure data and other records may need to be maintained beyond the life of the toll. It is typically the toller's responsibility to maintain records of activities that occurred at their site although the client company may choose to keep duplicate records when deemed appropriate. Some of these documents may be proprietary and should be maintained as such.

It is a good practice to ensure that both the toller and client have records of the complete incident and accident history for the toll. This information can be vital to the industry as a database of experience with the tolled process. Process safety concerns for future tolls of the product or related materials can benefit from this practice.

6.3. Closure Review Checklist

It may be appropriate, based upon the hazards of the materials processed, for the client company to make a final site visit during the toll shutdown activities to review the toller's methods and completeness of process termination. This review could include termination status such as removal of all hazardous wastes and verification of associated documentation, and the adequate cleanup of equipment and the process area.

The toll manager for the client company may prepare a customized checklist as a guide for the closure. Example 6-1, *Sample Closure Review Checklist,* which begins on the next page, shows a typical list used for contract termination. This example can be used as a template to help companies prepare their own checklist by adding or deleting items as necessary.

Example 6-1. Sample Closure Review Checklist

ABC Co. Toll Process Termination Checklist

Toller Company Name: _____

Address: _____

_____

_____

Description of Services Performed: _____

_____

_____

Reason for Termination: _____

_____

_____

_____

_____

APPROVALS/NOTIFICATION

Management: _____ Date: _____

Toll Manager: _____ Date: _____

Purchasing: _____ Date: _____

Legal Counsel: _____ Date: _____

(*continued on next page*)

A	Removal of Physical Equipment and Supplies Owned or Supplied by ABC Co.	Process/ Department	Employee Initials Certifying Completion	Date
	1. Products			
	2. Raw materials			
	3. Empty containers (such as drums, bags, boxes)			
	4. Unused labels			
	5. All copies of manufacturing procedures including software			
	6. All technical literature			
	7. ABC Co. signs and identification			
	8. Underground tank contents			
	9. Personal protective equipment			
	10. Storage tanks			

B	Financial Considerations	Process/ Department	Employee Initials Certifying Completion	Date
	1. Physically count inventories and settle inventory adjustments with the toller.			
	2. Determine status of all open customer orders and ensure that all shipments have been billed.			
	3. Determine the status of open accounts payable and whether billing for all materials and services is complete.			
	4. Prepare a listing of all ABC Co. fixed assets at the location so that designated personnel can remove these from the site.			

(*continued on next page*)

B	Financial Considerations	Process/ Department	Employee Initials Certifying Completion	Date
	5. If applicable, determine that all accounts or sundry receivables have been collected from the toller.			

C	Legal Considerations	Department	Employee Initials Certifying Completion	Date
	1. Notify governmental agencies.			
	2. Give notice to terminate custom manufacturing agreement.			
	3. Document all closure efforts (using logbook, photographs, or other means).			
	4. Determine need for health, safety, and environmental review.			

D	Environmental Considerations	Department	Employee Initials Certifying Completion	Date
	1. All equipment should be cleaned and decontaminated (such as, pumps, tank loading areas, storage areas).			
	2. All wastes generated, as a result of manufacture of the ABC Co. product should be disposed of properly.			
	3. Assure all waste intended for offsite disposal has been shipped and waste manifest records are complete.			

(*continued on next page*)

D	Environmental Considerations	Department	Employee Initials Certifying Completion	Date
	4. All empty, used containers should be disposed of properly.			
	5. The site should be inspected for evidence of prior spills. If found, the area should be cleaned and decontaminated and there may be a reporting requirement.			
	6. The state environmental agency should be notified that production has stopped if permits were required to manufacture the ABC Co. product.			
	7. If ABC Co. materials were stored in an underground tank, the tank should be cleaned and examined for possible leakage. If leakage is indicated, the area must be decontaminated.			

E	ABC Co. Computer System Changes	Department	Employee Initials Certifying Completion	Date
	1. Inactivate inventory segments.			
	2. Inactivate blanket order.			
	3. Withdraw manufacturing status.			
	4. Change product status.			

6.4. Analysis of the Operation

The client's personnel who had close involvement in the toll can best determine the toller's future status. A recommendation to use the toller again can be based upon the total experience including audit results and the toller's action item follow-up. A safe, responsive, conscientious toller that met the commercial requirements of the toll contract will most likely be given consideration on future tolls. As discussed in Chapter 2, *The Toller Selection Process* this recommendation can ease any future selection process for both parties when the toller in question is known to be technically capable.

Information sources that can help the team make a supportable recommendation whether to use or not use a toller again are:

- Pre-qualification questionnaires
- Initial site visit reports
- Pre-startup audits
- Management of change system documentation
- Audits of ongoing operations
- Incident reports
- Quality assurance reports
- Post-shutdown safety review documentation

6.5. Tolling Operation: Final Evaluation

After the tolling operation has been completed, both the client and the toller may conduct an evaluation of the operation. Though mentioned here as a closure item, this evaluation could be visited throughout the life of the toll to keep it current. For the client this will allow them to determine necessary improvements in future tolling ventures. It also enables others within the client company to determine if the toller is suitable for their tolling needs. For the toller it can pinpoint areas they want to address more closely in future tolling operations. They may even determine that they no longer want to participate in this type of tolling operation. This feedback on the relationship can be of great value to both parties. Example formats for these evaluations are shown in Examples 6-2 and 6-3.

Example 6-2. Sample Toller Evaluation

ABC COMPANY—TOLLER EVALUATION	
Tollers Name:	Location:
Product Tolled:	Quantity Produced:
Duration of Toll:	
Toller Contacts/Titles:	
Evaluators/Titles:	
Job Performance:	
	Yes/No
A. Product	
1. Was the toll contract completed in a satisfactory manner?	
• Was the quantity produced sufficient for needs?	
• Did the material produced meet quality specifications?	
• Was the material delivered in a timely manner?	
B. Safety and Health	
1. Incident History	
• Were there any incidents (explosions, fires, releases, etc.) on the toll process or which affected the toll process.* * If yes, for each incident, attach the incident report or give the following information: Description of the incident, chronology of verifiable events, other pertinent facts, root causes and contributing factors, and proposals for corrective action.	
2. Accident History	
• Did any accidents occur during the course of the toll contract?	
– Number of OSHA recordable injuries related to the toll:	
– What was the Rate?:	
– Number of *days away from work* injuries:	
• Were all injuries investigated? If no, attach explanation.	

(*continued on next page*)

	Yes/No
3. Personal Protective Equipment (PPE)	
• Did personnel wear the required PPE? If no, attach explanation.	
• Were personnel trained in the use of PPE?	
4. Personnel Monitoring	
• Was any exposure monitoring for personnel conducted on site?	
– If so, what type?:	
• Were any overexposures observed?	
– If so, what was done to rectify the situation?:	
C. Environmental	
• Were there problems in obtaining any air/water/waste permits in a timely manner to avoid project delay? If yes, attach explanation.	
• Did the toller have the expertise and take the lead in obtaining these permits? If no, attach explanation.	
• Were there any permit exceedances? If yes, attach explanation	
• If there were exceedances, did they result in fines?	
D. Operations	
1. Training	
• Was training conducted for all affected personnel prior to startup? If no, attach explanation.	
• Was this training adequate (via observation of personnel)?	
2. Technical	
• Did the toller have technical expertise to adequately support the project?	
3. Operating Procedures	
• Were complete operating procedures available prior to startup?	
• If procedures were revised, were the revisions reviewed and	
• Personnel informed of the changes prior to implementation?	

(*continued on next page*)

	Yes/No
E. Management of Change (MOC)	
1. Did the toller implement and use a management of change procedure?	
2. Did the ABC Company participate in this procedure? If no, were you made aware of the changes?:_____	
3. Have all changes been documented?	
4. Have appropriate revisions been made to process safety information, P&IDs, and operating procedures?	
5. Have training plans been revised as necessary?	
F. Process Hazard Analysis (PHA)	
1. Was a PHA conducted prior to startup?	
2. Did personnel from both ABC Company and the toller participate in the PHA?	
3. Were all PHA recommendations resolved prior to startup?	
G. Information Exchange	
4. Was information shared freely between ABC Company and the toller?	
5. Did this information sharing go both ways?	
6. What was done to facilitate information sharing?	
H. Recommendation for Future Tolling Projects	
Would you consider future tolling projects with this company?	
If yes, are there any additional considerations for future contracts? If no, can changes be made to overcome these obstacles?	

Example 6-3. Sample Client Evaluation

TOLLER COMPANY CLIENT EVALUATION	
Client Name:	Home Location:
Product Tolled:	Quantity Produced:
Duration of Toll:	
Client Contacts/Titles:	
Evaluators/Titles:	
Project Information:	

	Yes/No
A. Information Exchange	
1. **Technical**	
• Did ABC Company provide sufficient technical information on the process prior to the toll?	
• Was additional technical information or assistance available/ provided during the course of the toll?	
2. **Safety and Health**	
• Was information on the process sufficient to develop appropriate safeguards?	
• Were there any unique safety considerations in the process? If yes, was information provided by ABC Company adequate to ensure safe operations? _____	
• Did any chemical used/produced in the process require use of special personal protective equipment (PPE) when handling?	
– Did ABC Company provide information on this requirement?	
– Was any special training required to utilize the PPE?	
• Was any personnel exposure monitoring required?	
– If so, what type?	
– Did ABC Company do the monitoring or assist in setting up the protocols?	

(*continued on next page*)

	Yes/No
3. **Environmental**	
• Were any additional permits required for handling the materials used/produced in this tolling operation?	
– If so, did ABC Company provide assistance in getting the required permits?	
– Was initiation of the toll delayed because permits were not ready?	
4. Management of Change (MOC)	
• Was a MOC process implemented?	
• Did ABC Company participate in the MOC process?	
• Were all MOCs documented?	
• Were appropriate changes made to PSI, P&IDs, and operating procedures?	
• Was operator training revised to incorporate these changes?	
5. **Process Hazard Analysis (PHA)**	
• Was a PHA conducted on the toll process?	
• Did ABC Company participate in the PHA?	
• Were PHA recommendations resolved prior to startup?	
B. Cooperation	
1. Was ABC Company willing to work together to resolve problems? If no, explain.	
2. Did ABC Company devote sufficient resources to ensure project success?	
C. Project	
1. Was the project executed successfully?	
2. Did ABC Company fulfill their contractual obligations?	
D. Recommendation for Future Tolling Projects	
Would you consider future tolling projects with this company?	

(*continued on next page*)

If yes, are there any additional considerations for future contracts? If no, can changes be made to overcome these obstacles?

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GLOSSARY

Accidental release: An unintended or sudden release of chemical(s) from manufacturing, processing, handling, or on-site storage facilities to the air, water, or land.

Audit (Process Safety Audit): An inspection of a plant or process unit, drawings, procedures, emergency plans, and/or management systems, etc., usually by an independent, impartial team.

Batch sheet: Sometimes called batch instruction. The operating procedure for making a batch product. Primarily focuses on material quantities, as well as instructions for any mixing, reaction, heating, cooling, drying required for the process

Block flow diagram: A simplified drawing representing a process. It typically shows major equipment and piping and can include major valves.

Catastrophic release: Under OSHA PSM and EPA RMP, it means a major uncontrolled emission, fire, or explosion, involving one or more highly hazardous chemical substances (per OSHA) or regulated substances (per EPA) that presents serious danger to employees in the workplace (per OSHA) or imminent and substantial endangerment to public health and the environment (per EPA).

Certificate of Insurance: A document verifying that a company maintains insurance at a specific coverage level.

Client: The term used in this text to identify the company issuing the tolling contract to the toller. The toller's client.

Confidentiality agreement: A written agreement between a toller and their client to outline the extent of security required in the handling of the information, equipment or product.

Confidentiality disclosure agreement: An agreement that allows a toller to release information to a third party that would ordinarily be considered proprietary.

Critical Equipment: Equipment, instrumentation, controls, or systems whose malfunction or failure would likely result in a catastrophic release of highly hazardous chemicals, or whose proper operation is required to mitigate the consequences of such release. (Examples are: most safety systems, such as area LEL monitors, fire protection systems such as deluge or underground systems, and key operational equipment usually handling high pressures or large volumes.)

Cross-contamination: Mixing chemicals unintentionally, typically through the use of the same process equipment or support systems for concurrent or successive tolls.

Emergency operations: Process changes initiated by the operations staff to place the process into a safe condition (back to normal operations or shutdown) in response to any abnormal situation that could cause a release, explosion, or other significant event.

Emergency response plan: A written plan which addresses actions to take in case of plant fire, explosion or accidental chemical release.

Flash point: The lowest temperature at which vapors above a volatile combustible substance ignite in air when exposed to a source of ignition.

Force majeure: An event or effect that cannot reasonably be anticipated or controlled.

Incident investigation: The management process by which underlying causes of undesirable events are uncovered and necessary steps are taken to prevent similar occurrences.

Intermediates: Materials from a process that are not yet completely finished product. They may be a mixture or compound.

ISO 14000 / ISO 9000: Standards published by the International Organization for Standardization. ISO 14000 standards are for companies establishing an environmental management system. ISO 9000 standards are for companies establishing a quality management system.

Management of change: A system to identify, review and approve all modifications to equipment, procedures, raw materials and processing conditions, other than "replacement in kind," prior to implementation.

Mechanical integrity: An element of process safety focused on ensuring that equipment is designed, installed, and maintained to perform the desired function.

Normal operations: Any process operations intended to be performed between startup and shutdown to support continued operation within safe upper and lower operating limits.

Operating procedures: Written, step-by-step instructions and associated information (cautions, notes, warnings) for safely performing a task within operating limits.

Operational reliability: Also known as equipment reliability. The probability that, when operating under stated design conditions, process equipment will perform its intended function adequately for a specified exposure period.

Outsourced Manufacturing: Providing manufacturing services for a fee by a contractor, to a company issuing a contract for those services. Services can include reaction processes, formulation, blending, mixing or size reduction, separation, agglomeration, packaging/repackaging, and others or combination of the above. (*See* Tolling.)

Pilot: To produce a small quantity of a product as a test prior to full-scale commercial production.

Pre-assessment questionnaire: A screening tool to collect information that potential clients need to begin the selection processes.

Preventive maintenance: Inspection or testing conducted on equipment to detect impending or minor failures and restore the equipment to its proper condition.

Process Capability (Cp): The ratio of the specification range to six standard deviations of the process.

Process Hazard Analysis (PHA): An organized effort to identify and evaluate hazards associated with chemical processes and operations to enable their control. This review normally involves the use of qualitative techniques to identify and assess the significance of hazards. Conclusions and appropriate rec-

ommendations are developed. Occasionally, quantitative methods are used to help prioritized risk reduction.

Process safety: A discipline that focuses on the prevention of fires, explosions, and accidental chemical releases at chemical process facilities.

Process Safety Information: Physical, chemical, and toxicological information related to the chemicals, process, and equipment. It is used to document the configuration of a process, its characteristics, its limitations, and as data for process hazard analyses.

Process Safety Management (PSM): A program or activity involving the application of management principles and analytical techniques to ensure the safety of chemical process facilities. Sometimes called process hazard management. Each principle is often termed an "element" or "component" of process safety.

Product stewardship: The management practice supporting a philosophy of service to customers and minimizing effects on health and the environment throughout the complete life cycle of a product.

Responsible Care®: An initiative implemented by the Chemical Manufacturers Association (CMA) in 1988 to assist in leading chemical processing industry companies in ethical ways that increasingly benefit society, the economy and the environment while adhering to ten key principles.

Retains: The amount of a substance left behind during chemical processing. Also refers to samples retained for reference after undergoing analysis.

Risk Management Program (RMP): EPA's rule requiring some facilities to prepare, submit, and implement a risk management plan.

Round robin: A process involving an exchange of samples intended to transfer analytical capabilities from the client to the toller to support the toll project.

Spill Prevention Control and Countermeasures Plan: The document prepared in compliance with U.S. regulation "Guidelines For The Preparation and Implementation of a Spill Prevention Control and Countermeasure Plan (SPCC)"—EPA 40 CFR part 112.7.

Statistical Process Control (SPC): The use of statistical techniques (such as control charts) to analyze a process and take appropriate action to maintain statistical control and improve process capability.

Task analysis: A method for determining the detailed performance required of people and equipment and determining the effects of the surroundings, malfunctions, and other unexpected events on both.

Technology package: Information typically provided to a toller by their client delineating specifications for the equipment, chemicals, processing and quality control for a toll. Process safety information is a subset of the technology package.

Toller: An outsourced manufacturing company contracted to process materials to another company's specifications. Sometimes called third party service provider, toll processor, supplier of outside services, external contract manufacturer, contract processor, contract manufacturer, custom chemical manufacturer.

Tolling: Providing manufacturing services for a fee by a contractor (the toller), to a company issuing (letting) a contract for those services. Tolled services can include, reaction processes, formulation, blending, mixing or size reduction, separation, agglomeration, packaging/repackaging, and others or a combination of the above.

Appendix A

SAMPLE TOLLER PRE-ASSESSMENT QUESTIONNAIRE

This assessment tool is referred to and explained in Chapter 2, *The Toller Selection Process*. It can be used to collect data about tollers before and during selection. As with all examples, this should be modified to address the user's specific needs.

Sample Toller Pre-Assessment Questionnaire

Facility: _____

Address: _____

City:_____State: _____ Zip: _____

Toller Contact:_____Date: _____

Title: _____Telephone:_____

Type of Service to be provided:
(Check all that apply.)

Custom Manufacturing ❑

Bulk Storage ❑

Repackaging ❑

Other ❑

General Instructions:

For each topic item, check one: (Y) Yes, (N) No and add any comments. Attach additional comment pages if necessary.

Topic–Item		Y	N	Comments
1.	**Policies, Affiliations, and Certifications**			
1.1.	Does your company have a documented Responsible Care (or equivalent) policy that is fully supported by your management?			
1.2.	Does your company have a documented product stewardship policy, or a health, safety and environmental policy which incorporates the management of chemicals through their total life cycle, thus minimizing adverse effects on human health and well-being and on the environment? If so please attach.			
1.3.	Is your company a member of a trade or related organization? If so, which one(s) _____			
1.4.	Is any processes' quality management system certified under the requirements of an ISO 9000 or ISO 14000 standard? If yes, skip question number 5.			
	a. Which standard?			
	b. Certification date?			
	c. Registrar's Name?			
1.5.	Are you currently working on obtaining an ISO 9000 or ISO 14000 type certification?			
	a. Which standard?			
	b. Expected application date?			
2.	**Character of Area around the Plant**			
2.1.	Are there any nonindustrial, noncommercial neighbors?			
	a. Distance from facility_____ Describe _____			
	b. Adjacent? Describe _____			

Topic–Item		Y	N	Comments
2.2.	Is the facility near:			
	a. Major highway?			
	b. Railroad?			
	c. Waterways, ponds or lakes (note distances)			
2.3.	Are any utilities provided by nonpublic sources? If yes, describe _____			
2.4.	Are there industrial and/or commercial neighbors that have highly hazardous chemicals, such that a release of one of these chemicals could have an affect on the facility and its people?			
3.	**Personnel**			
3.1.	Is there a documented organizational chart showing departmental responsibilities at the facility? If so, please attach along with a summary of technical, analytical, HS&E professional staff (for example, number of process engineers, project engineers, production engineers).			
3.2.	Are there training materials for:			
	a. New employees?			
	b. Basic job skills?			
	c. Environmental, health, and safety?			
	d. Statistical process control (SPC)?			
	e. Process overviews (when applicable)?			
3.3.	Is training implementation well documented for each employee?			
3.4.	Is the labor force unionized? Number of employees at facility. _____			
3.5.	Are temporary employees used? (Note whether they receive appropriate training.)			
4.	**Environmental**			
4.1.	Does the facility have written goals in place for pollution prevention or waste minimization?			
4.2.	Have there been any chemical spills or releases within the last year?			

Topic–Item		Y	N	Comments
	a. Reportable? (note number and chemicals involved)			
	b. Nonreportable? (note number)			
	c. Any with off-site consequences? (describe)			
4.3.	Is the groundwater at the facility routinely monitored?			
4.4.	Is solid waste disposed of:			
	a. On-site?			
	b. Off-site? (note criteria for selecting off-site facility)			
4.5.	Does the facility have pollution control equipment for:			
	a. Air?			
	b. Water?			
	c. Waste?			
4.6.	Does the facility have permits for:			
	a. Air emissions?			
	b. Waste water discharge?			
	c. Waste water treatment, storage and/or disposal?			
	d. Storm water discharge?			
4.7.	Have there been any noncompliance reports sent to a government agency within the last year for:			
	a. Air emissions			
	b. Waste water discharge?			
	c. Waste treatment, storage and /or disposal?			
	d. Storm water discharge?			
4.8.	Will the initiation of manufacture or packaging for ABC Co. compromise the facility's existing permit?			
4.9.	Have any environmental regulatory agencies visited the site during the past 3 years?			

Topic–Item		Y	N	Comments
4.10.	Does the EPA Risk Management Program (RMP) apply to this facility?			
4.11.	Does the facility have environmental catastrophe insurance coverage?			
5.	**Security and Maintenance**			
5.1.	Does facility have a documented preventative maintenance program to minimize equipment downtime?			
5.2.	Is the equipment to be used for manufacturing ABC Co. products greater than ten years old? (note specific equipment)			
5.3.	Does the facility have the following security features:			
	a. Perimeter security?			
	b. Guard services?			
	c. Controlled entry points?			
	d. Special monitoring features?			
5.4.	Does the facility have an inspection program for pressure vessels that meets API 510 guidelines?			
5.5.	Does the facility have an inspection program for tanks that meets API 653 guidelines?			
5.6.	Does the facility have a program for regular inspection and testing of process safety valves and other process safety devices including interlocks?			
5.7.	Does the facility have personnel whose duties include Reliability Engineering responsibilities?			
5.8.	Are employees bound by a confidentiality/ secrecy agreement?			
5.9.	Is maintenance provided by in house maintenance or contract maintenance?			
6.	**Storage**			
6.1.	Is a physical inventory performed on a periodic basis? Every _____ months.			
6.2.	Is Electronic Data Interchange (EDI) available for inventory transactions with ABC Co.?			

Topic–Item		Y	N	Comments
6.3.	Are compressed gases stored on-site? If yes, describe. _____			
6.4.	Are any underground storage tanks on-site? (Note number.)			
6.5.	Are all aboveground storage tanks within containment systems? (If not, explain.)			
7.	**Preparedness, Prevention, and Emergency Response**			
7.1.	Have there been any fires or fire department responses at the facility within the last five years?			
7.2.	Is the responding fire department a paid department? (Note distance.)			
7.3.	Does the facility have:			
	a. Sprinklered features? (Note if there is containment for the spent sprinkler water.)			
	b. Nonsprinklered features?			
	c. Adequate fire protection water supply? Source?_____			
	d. Fire pumps?			
	e. Fire hydrants?			
	f. Central station supervisory monitor system?			
	g. Pull box alarms?			
	h. Public Address notification warning system?			
	i. Any special fire protection systems?			
	j. On-site fire brigade/emergency response team?			
	k. Hot work permit procedure?			
7.4.	Are emergency self-contained breathing apparatus (SCBA) or escape air packs available in the work areas involved in the ABC Co. processing?			
7.5.	Is employee training on emergency airpack use documented?			

Topic–Item		Y	N	Comments
7.6.	Has the facility conducted an emergency drill within the last two years? (Note date of last drill and whether coordinated with local emergency planning committee.)			
7.7.	Is there formal communication between plant management and the local community through a community advisory panel or equivalent?			
7.8.	Was the facility required to submit a risk management plan to the EPA?			
7.9.	Does the facility have written operating procedures for emergency shutdown?			
8.	**Health and Safety**			
8.1.	Does the company have a written health and safety program?			
8.2.	Are any raw materials or finished products handled at the facility considered hazardous? If yes, describe_____			
8.3.	Has there been an OSHA related lost time injury in the last three years? If yes, explain _____ _____			
8.4.	How many OSHA Recordable Injuries have occurred at this facility in each of the last 3 calendar years?			
8.5.	Has there ever been a fatality at the facility?			
8.6.	What is the company's Experience Modification Rate with respect to worker's compensation for the last three years? _____ _____			
8.7.	Has OSHA visited this facility in the past 5 years?			
8.8.	Has there been any OSHA violations at the facility within the last five years? (Note date and citation.)			
8.9.	Are emergency eyewash and shower stations available in the work areas involved in the ABC Co. processing?			

Topic–Item		Y	N	Comments
8.10.	Does the site have written safety procedures for:			
	a. Use of Respirators?			
	b. Hazard Communication (HAZCOM)?			
	c. Lock out/tag out?			
	d. Confined space entry?			
	e. Line entry?			
	f. Safety meetings? (Note frequency.)			
	g. Natural disasters?			
	h. Management of Change?			
8.11	Is any part of the facility covered under OSHA's Process Safety Management rule?			
8.12	Does the facility conduct documented process hazard analyses on new processes?			
8.13	Do plant facilities conform to appropriate area electrical classifications?			
8.14	If powdered materials are being handled, does the site evaluate dust explosion issues?			
8.15	Are employees required to shower prior to leaving the site for the day?			
8.16	Are there provisions for daily uniform changes/cleaning?			
9.	**Production**			
9.1.	Is the proposed ABC Co. activity similar in nature to the facility's core activities?			
9.2.	Does the facility have previous experience in producing the material in question? (Note last production date.)			
9.3.	Does the facility currently have sufficient idle capacity available for the process and volumes of interest?			
9.4.	Does the facility currently handle the key raw materials and finished products of interest to ABC Co.?			

Topic–Item		Y	N	Comments
9.5.	Is the following material handling equipment used:			
	a. Mass Flow Meters? Describe type. _____			
	b. Digital Scales? Describe type. _____			
	c. On-line QA Instruments (for example, in-line pH, GC) Describe type. _____			
9.6.	Is precision of production measuring equipment routinely monitored (via control charts or other similar techniques)?			
9.7.	Is production and packaging equipment routinely calibrated according to a schedule?			
9.8.	Does the company have an engineering staff which supports the facility?			
9.9.	Are operating procedures reviewed regularly by a technically qualified professional? If so, how often? _____			
9.10	Is there a system to ensure operating procedures are current and accurate?			
9.11	Is there a system to verify that only the current procedure and batch sheet are used and that obsolete procedures are removed from circulation?			
9.12	Are all production batches sampled for Quality Assurance approval?			
9.13	Are standard production batches with added rework material sampled for quality assurance approval after rework is added?			
9.15	Are appropriate directions for reacting to "out-of-specification" situations documented in standard operating procedures?			
9.16	Are detailed records of all problems during production (including nonstandard adjustments) kept?			

Topic–Item		Y	N	Comments
9.17	Are production log sheets and production records kept for a minimum of one year? If not, how long? _____			
9.18	Are specific packaging/repackaging instructions (for example, specific container type, pounds) documented?			
9.19	Are detailed records of all problems in packaging kept?			
9.20	Are nonconformance summaries sent to facility manager at least quarterly?			
9.21	Are SPC control charting techniques routinely used to monitor:			
	a. In-process variables?			
	Three examples 1. _____ 2. _____ 3. _____			
	b. Material charging activities?			
	Three examples: 1. _____ 2. _____ 3. _____			
	c. Packaging activities?			
	Three examples: 1. _____ 2. _____ 3. _____			
9.22	If process is not in statistical control, is there a plan to achieve control?			
9.23	Have several final product parameters been shown to have process capability (Cpk) > 1?			
	Name three: 1. _____ 2. _____ 3. _____			

Topic–Item		Y	N	Comments
10.	**Quality Assurance**			
10.1.	Is there a Quality Assurance Policy & Procedure Manual? Date issue _____/_____/_____			
10.2	Are SPC/SQC charts maintained and used for continuous product quality improvement?			
10.3	Are there documented specifications for all incoming raw materials used in products?			
10.4	Does Quality Assurance control the approval of raw materials prior to use in production?			
10.5	Is incoming material lacking a lot number either rejected or supplied a facility-created lot number?			
10.6	Is there a procedure for quarantine of incoming material until approval for use is given by Quality Assurance?			
10.7	Are control charts used and monitored for the majority of incoming raw materials?			
10.8	Are raw material test results saved at least one year?			
10.9	Are raw material suppliers notified of all nonconformances?			
10.10	Is evidence of SPC/SQC required of suppliers?			
10.11	Are raw material suppliers audited?			
10.12	Are analytical test methods documented?			
10.13	Is all laboratory equipment calibrated according to a schedule?			
10.14	Is precision of all laboratory equipment known?			
10.15	Is precision routinely monitored (via control charts or other similar techniques) of all equipment?			
10.16	Are Repeatable and Reproducibility (R&R) studies available for the test procedure?			
10.17	Is precision routinely monitored (via control charts or other similar techniques) for the majority of the procedure?			

Topic–Item		Y	N	Comments
10.18	Are final product specifications on file for all products?			
10.19	Are product test results saved at least one year?			
10.20	Is there a documented procedure for retaining product samples? How long?_____			
10.21	Is there a documented procedure for quarantine of off-spec materials?			
10.22	Does all rework of off-spec materials require documented Quality Assurance authorization?			
10.23	Have all production processes (final batch and in-process parameters) been shown to be in statistical control?			
10.24	Are there documented specifications for approval to ship final product containers (for example, tank trucks, drums, and bags)?			
10.25	Are batch/lot numbers of all shipments recorded?			
10.26	Is there a system to confirm that the only material to be shipped is Quality Assurance approved?			
10.27	Is there a system to confirm that the material ordered is the right material shipped?			
10.28	Are certificates of analyses included with shipping papers?			
10.29	Can shipments of a given lot/batch be easily traced to all customers?			
10.30	Is there a documented procedure for recalling material from a customer?			
10.31	What is the site's experience with cGMPs?			
10.32	What are the results of any FDA or quality agency audits during the past three years?			
10.33	Does the facility have a QC laboratory with analytical capabilities for the tolling contract? Level of staffing _____			
10.34	Does the facility have a process for GMP where applicable?			

Topic–Item		Y	N	Comments
11.	**Potential Exposure**			
11.1	Are material handling systems engineered and/or personal protective equipment used to prevent physical exposure to personnel, including inhalation and skin?			
11.2	Is there a certified industrial hygienist on staff or accessible within the company or through a consultant?			
11.3	Are personnel and air monitoring conducted for chemicals with TLVs?			
11.4	Is required personal protective equipment easily and readily available and worn by personnel during manufacturing and packaging operations?			
11.5	Is spill containment in place around transfer pumps, pipe manifolds, production vessels, packaging lines and storage containers?			
11.6	Are there procedures for performing PPE hazard assessments, specifying PPE and training employees on required PPE?			
12.	**Addendum for Existing Tollers**			
12.1	Is there a copy at the facility of all Material Safety Data Sheets for ABC Co. raw materials and products used at the facility?			
12.2	Are the ABC Co. products currently contracted for manufacture or repackaging specifically listed in the contractual agreement? (Please attach a list of pounds received and shipped of ABC Co. owned raw materials, intermediates and finished products for the last twelve months.)			
12.3	Does contractor maintain an insurance policy of the type and minimum amount as specified in the contracted agreement? (Please attach a copy of current insurance certificate.)			
12.4	Does the contractor have any ABC Co. owned inventory at a separate location other than at facility under review?			

Topic–Item		Y	N	Comments
12.5	Does contractor provide month-end balances to ABC Co. of ABC Co. owned raw materials, intermediates and finished product volumes?			
12.6	Does contractor ship direct to ABC Co. customers?			

Appendix B

SAMPLE TOLLER HS&E ASSESSMENT

This assessment can be used to collect data about tollers during selection or for auditing an ongoing toll. It is discussed in Chapter 5, *Ongoing Operations: Audits and Follow-up*. As with all examples, this should be modified to address the user's specific needs:

SAMPLE TOLLER HS&E ASSESSMENT

This checklist presents a number of questions to assist in identifying environmental and health and safety issues at facilities where ABC Co. product(s) are manufactured (all or in part) by another company or where ABC Co. product(s) are licensed to another company.

The checklist is a tool to help obtain the information needed for internal decision making. The decision to approve the facility for continued use should be based on a number of factors including but not limited to the facility's ability to:

- Protect human health and the environment,
- Prevent business interruption, and
- Prevent possible loss of public confidence as a result of manufacturing the product(s).

When using the checklist, the reviewer should decide in advance which questions would not be applicable to the toller's operations. For example, the environmental and healthand safety issues associated with a toller that will be used solely to conduct packaging will greatly differ from a of a toller that will be used to perform an organic synthesis step.

Questions that relate to specific considerations contained in company environmental guidelines apply to licensing and tolling of products (all or in part). They do not apply to suppliers of laboratory quantities of proprietary materials, raw material suppliers, or arrangements made with other companies to recover nonproprietary raw materials (for example, solvents and metal compounds).

GENERAL QUESTIONS

Health, Safety, and Environmental Concerns

1. Are there environmental or health and safety liabilities (for example, the facility falsified a permit application) which may reasonably be expected to result in criminal prosecution?
2. Are there any environmental, health and safety liabilities (for example. the facility failed to conduct an investigation following a serious accident) which may reasonably be expected to result in suspension or closure of any or all site operations or curtailment of production? If yes, explain.
3. Has the facility received complaints from the public or received attention in the local media for noise, odor, or any other issue? If yes, indicate the approximate number of complaints and describe the nature of complaints.
4. Has the facility received a notice of violation, penalty or fine concerning an environmental or health condition? If yes, explain the cause of the violation, penalty or fine and agency involved.
5. Have allegations been made by a regulatory agency or third party that releases of hazardous materials from the facility (for example, the facility releases contaminants to nearby wells) harmed or threatened to harm persons, property or the environment? If yes, explain.
6. Are there any liabilities attributable to facility operations that may endanger worker health? If yes, explain.
7. Obtain and review copies or summaries of permits, licenses, consent orders and other relevant documentation. Are there current operations that do not have appropriate permits? If yes, explain.
8. Do existing environmental, health or safety permits or authorizations have to be modified prior to producing the material? If yes, please explain which permits authorizations need to be modified. How long will these modifications take?
9. Are new environmental, health and safety permits, authorizations or licenses needed prior to producing the material? If yes, explain what additional permits or authorizations are needed and how long they will take to secure.
10. Are there other environmental or health and safety reviews or approvals (for example, need for public hearings, notification, registrations) which need to be obtained? If yes, how long will it take to secure these approvals? If yes, explain.
11. Describe any foreseeable changes and developments in environmental, health and safety regulations that have the potential to impact the facility's ability to produce the material.

12. Is there potential that the product may result in the environmental or non-workplace release of a highly hazardous substance or an environmentally difficult material? If yes did the toller receive a life cycle evaluation (for example, disposal of products, handling returns and rejects)? Does the Toller understand the information? Was written acknowledgment obtained indicating that the information was received?

13. Did the Toller receive information on manufacturing implications of new products and major projects? If not, was other information provided? Does the Toller understand the information? Was written acknowledgment obtained indicating that the information was received?

SPECIFIC ENVIRONMENTAL CONSIDERATIONS

(refer to Tables A and B at the end of this form as needed)

Facility operations and management practices

14. Is the facility aware of noncompliance with any environmental, health and safety regulations? If yes, explain.

15. Has the facility been a party to any agreement, consent order, administrative order or other legal proceeding with a regulatory agency regarding any environmental issue at the facility? If yes, explain.

16. Are there any zoning, variance or conditional use regulations associated with the site that may restrict or delay production of the material? If yes, explain.

17. Does the Toller use a primary ozone depleting compound (ODC , for example, a CFC or 1,1,1, -trichloroethane) in their process? Are ODC management practices followed (for example no uncontrolled releases of ODCs, installation of capture and recycle equipment, leak detection and repair, use of well trained personnel)?

18. Are any of the following materials used or present at the site:
    - PCBs?
    - Asbestos?
    - Ozone depleting compounds (ODCs) (other than refrigerants)?
    - Low level radioactive compounds or wastes?
    - Hazardous substances in soil or groundwater?
    - Heavy metals?

    (a) If yes, describe how and where these materials are used and the controls the site has been in place to prevent releases to the environment.

    (b) Is the plant staff knowledgeable with regard to the management of these materials? If yes, explain.

19. Identify whether any of the following are currently (or previously) located on the site?
    - Lagoons
    - Underground storage tanks
    - Surface impoundments
    - Streams
    - Disposal areas or landfills
    - Waste piles
    - Railroad tracks
    - Septic systems

    For any of the items identified above, describe the present use or condition.
20. Are hazardous substances (for example, fuel oil, gasoline, acids, bases, solvents, or metal bearing solutions) stored on-site? If yes, describe usage, storage method and location.
21. During the site visit, auditors should identify any potential groundwater contamination sources or unusual odors observed at the facility. If any, explain.
22. Is the facility a Superfund or RCRA site?

Solid waste management

23. For those waste streams that can impact public health or the environment (if mismanaged), provide a summary of the treatment and disposal methods (for example, solvents are incinerated or recycled, lab wastes are incinerated) used to manage them and identify the on-site or off-site facilities used. Is the disposal of the waste adequately documented (for example, retention of manifests, bills of lading or transfer notes)?
24. Are the hazards associated with handling hazardous wastes disclosed to the disposal facility? If yes, does the disclosure include information on proper spill response measures and is it protective of employees, transporters and waste handlers.
25. Does the facility evaluate (for example, audit) the off-site waste management facilities used to manage hazardous wastes? If yes, do the evaluations ensure that wastes will be handled safely, without causing harm to waste handlers, the public, or the environment? Have the reviews been documented?

Groundwater

26. Are there any surface water, groundwater or soil monitoring data available that have been generated for any reason for the site? If yes, analyze and summarize the data.

27. Is the facility located in an "area of high (groundwater) sensitivity" (for example, groundwater or surface water within 3 miles of site is used as a source for drinking water)? Will manufacture of the product contribute to contamination of groundwater?
28. Has there ever been any on-site disposal of wastes? If yes, explain.
29. Are wastewaters discharged to a municipal sewage treatment system? Discharge in compliance with the treatment system's permit?
30. Is a spill prevention control and countermeasures plan (SPCC) required? If so, is a valid one in place?
31. Are there any wastewater treatment facilities or processes on-site? If yes, are sludges generated from treatment process? If yes, how is the sludge managed, stored, and disposed of?
32. Is there a concern that untreated wastewater effluent could be creating adverse impacts to public health or the environment? If yes, was an impact assessment (for example, through a paper study or actual monitoring of the receiving water) conducted to eliminate the concerns or to evaluate the impacts?

Air Issues

33. Provide a list of all air pollution control devices and identify point and fugitive emission air pollution sources.
34. Provide an explanation of the method(s) used by the site to verify that the control device(s) are operating as designed and in compliance with all regulatory requirements.
35. Provide annual estimates of all point and fugitive emission sources (tons per year) of hazardous substances, volatile organic compounds (VOCs), heavy metals and fossil fuel products (for example, NOx and SOx) that are released to the environment.
36. Is the facility buying or trading air pollution credits? If so, note the details.

Facility Setting

37. Identify and describe the following areas if located adjacent to the site:
    - Areas of known groundwater contamination or pollution
    - Sensitive ecological areas, wetlands, floodplains, wildlife refuges
    - Surface water bodies
    - Drinking water sources and groundwater protection zones
    - Residential areas, hospitals and schools

SPECIFIC HEALTH AND SAFETY CONSIDERATIONS

(refer to Table C at the end of this form as needed)

Regulatory and Liability Issues

38. Is the toller aware of any activities or operations that are not in compliance with any health or safety regulations?
39. Has the toller's facility been a party to any agreement with a regulatory agency regarding any safety and health violations? If yes, explain.

Injury and Illness Prevention Programs

40. Has the toller's facility had any serious incidents, injuries or illnesses during the past five years? If yes, explain. What is the toller's 11R?
41. Does the toller investigate serious incidents, injuries or illnesses and implement appropriate corrective actions? If no, explain.
42. Has an effective safety and health program (for example, safety procedures, training, hazard identification and analysis) been established to protect personnel on the work site, including employees and contractors? If no, explain.
43. Does safety and health training cover all subjects and areas necessary to address critical hazards at the site? If no, explain.

Hazardous Agent Exposures (Chemical, Physical or Biological)

44. Are there any exposures to hazardous agents that may endanger worker health or cause worker exposure concerns? If yes, explain.
45. Do workplace exposures comply with occupational exposure limits or applicable regulatory limits, if they are more stringent? If no, explain.
46. Do employee exposures to hazardous agents exceed applicable occupational exposure limits, including those of the ACGIH and the applicable local regulatory authority? If yes, explain.
47. Are engineering and administrative controls properly maintained and enforced? If no, explain.
48. Does the toller rely upon respiratory protective equipment to maintain employee exposures below applicable occupational exposure limits? If so, for what materials? Explain.
49. Are there any chemicals used that are known or suspected carcinogens, mutagens, teratogens, etc?
50. Is there an industrial hygiene monitoring program?
51. Has the toller established a comprehensive respiratory and personal protective equipment program to insure proper selection, maintenance and use of equipment?

52. Have there been adverse health reactions by employees exposed to hazardous agents? If yes, explain.

Process Safety Management

53. Have there been fires, explosions or chemical release incidents? If yes, explain.
54. Have formal process hazard analyses (PHAs) been completed for highly hazardous processes (for example, those processes involving toxic or volatile substances, highly toxic materials, severe lachrymators, flammables, explosive compounds or potential runaway reactions)? If yes, please summarize status of each.
55. Has the facility identified, evaluated and implemented controls to reduce risks associated with catastrophic chemical releases (for example, implemented any of the following measures: minimization of on-site inventories, installation of early warning systems of chemical releases, proper containment or durable piping) involving toxic or volatile substances? If yes, summarize the results.
56. Has the facility established an effective critical equipment maintenance program to prevent hazardous failures? If no, explain.
57. Is there a working management of change system in place?
58. Are there appropriate planning, training and drills and equipment for response to emergencies? (Note: In some facilities, the employer's plan is to evacuate and call the fire department.) If no, explain.
59. Has a facility siting study been completed? If so, what were the results?

Table A. Potential Source Activity Examples

Consider the following as appropriate.

1. Tanks and Appurtenances Used to Contain Hazardous Substances

A. Aboveground Tanks

- Aboveground storage tanks
- Process tanks
- Silos
- Degreaser tanks
- Waste collection or storage tanks

B. Underground Tanks

- Underground storage tanks
- Spill containment tanks
- Flow-through process tanks
- Degreaser tanks
- Waste collection or storage tanks

C. Piping and Appurtenances

- Fill and drain ports
- Sampling ports
- Leaking valves and flanges
- Underground piping, including process piping
- Aboveground piping, including process piping

D. Storm Water Management Systems Associated

- Drainage ports
- Gate valves
- Collection sumps
- Discharge (cleanout) systems

2. Material Handing Areas

A. Solid Waste Staging

- Dumpsters
- Waste piles
- Scrap piles
- Debris piles
- Compactors

B. Material Storage Areas

- Waste storage pads
- Raw material storage areas
- Chemical storage cabinets or closets

C. Waste Management Areas

- Drum cleanout areas
- Waste treatment areas
- Waste consolidation areas
- Incinerators
- Boilers

D. Loading, Unloading and Transfer Areas (for raw materials and wastes)

- Truck loading and unloading
- Tank truck loading and unloading
- Rail car loading and unloading
- Hazardous substance transfer areas

E. Disposal Areas

- Landfills
- Waste piles
- Burning grounds

3. Wastewater and Storm Water Management Systems

A. Drainage Systems

- Floor drains and associated piping
- Trench drains and associated piping
- French drains
- Stormwater roof leaders when process operations vent to the roof
- Drainage swales and culverts
- Process area sinks and sumps that receive process wastes

B. Sewer Piping

- Process sewer piping
- Sanitary sewer piping
- Storm sewer piping

C. Collection and Treatment Systems

- Sumps
- Pits
- Wet wells
- Retention basins
- Lagoons
- Impoundments
- Ponds
- Pumping station
- Septic system collection boxes/tanks
- Fire water ponds

D. Underground Discharge Systems
- Dry well
- Leach fields
- Infiltration galleries
- Seepage pits
- Injection wells

E. Aboveground Discharge Systems
- Sprayfields
- Open pipe discharges
- Ponds
- Lagoons
- Impoundments

F. Noncontact Cooling Water Discharges

4. Other Discharge Sources

A. Process Water Treatment
- Mixing or flocculating basins
- Settling basins
- Filter backwash pits

B. Air Pollution Control Systems
- Solids collection associated with dust collectors and cyclones
- Water collection and treatment ponds associated with wet scrubbers

C. Compressor Blowdown

5. Other Potential Sources

A. Maintenance Areas
- Vehicle maintenance areas
- Equipment maintenance areas
- Parts washing areas

B. Potential Polychlorinated Biphenyl (PCB) Sources
- Compressor oils
- Hydraulic systems
- Transformers
- Capacitors
- Switch boxes

C. Fire Training Areas

D. Fill Material Associated with Site Grading

Table B. Potential Release Indicators

1. Tanks and Appurtenances Used to Contain Hazard Substances Including Aboveground Tanks, Underground Tanks, Piping and Appurtenances. and Storm Water Management Systems Associated with Containment Systems
   - Spills or overfills
   - Draining of heels and wash waters to ground surface
   - Releases from holes caused by puncture or corrosion
   - Inventory reconciliation problems
   - Visual evidence of leaks
   - Visual evidence of stained soils, stained pavement or stressed vegetation
   - Failed integrity tests
   - Indications of release based upon vapor or ground water monitoring
   - Tank failure
   - Releases during removal or replacement
   - Historical releases during maintenance activities
   - Sumps and containment systems lacking impermeable surfaces
   - Unexplained presence of water in systems
   - Erratic operation of pumping equipment
2. Materials Handling Areas Including Solid Waste Staging, Material Storage Areas, Waste Management Areas, Loading, Unloading and Transfer Areas (for raw materials and wastes) and Disposal Areas
   - Visual evidence of stained soils, stained pavement or stressed vegetation
   - Presence of liquid wastes or residual liquids
   - Storm water infiltration or runoff which could transport hazardous substances
   - Staging directly on ground surface, without an impervious containment system
   - Spills or releases resulting from puncture, dropping or corrosion of containers
   - Historical releases during transfer from or to drums and other containers
   - Historical releases during transfer of materials into or out of storage
   - Discharges of wash water or other liquids during operation or maintenance
   - Overfills
   - Spills and releases from vehicles during loading or unloading operations
   - Spills and releases from transfer hoses during decoupling operations
   - Subsurface disposal of materials containing hazardous substances

3. Wastewater and Storm Water Management Systems Including Drainage Systems, Sewer Piping, Collection and Treatment Systems, Underground Discharge Systems, Aboveground Discharge Systems, and Noncontact Cooling Water Discharges
   - Drains lacking impermeable surfaces
   - Floor or trench drains, sumps and sinks that discharge to ground surface
   - Suspect pipe integrity due to age, materials of construction and /or type of joint
   - Visual evidence of stained soils, stained pavement or stressed vegetation
   - Historical releases during draining or cleanout operations
   - Runoff from areas where hazardous substances are or were used into storm water drainage systems
   - Storm water runoff where process operations vent to roof
   - Historical releases during operation or repair
   - Wastewater infiltration due to absence of impervious containment
   - Overflows cause by pump failure or restrictions in discharge piping
   - Breaches and containment walls or beams
   - Tank failure
   - Releases during removal or replacement
   - Direct discharges of process wastes
   - Direct discharges of wash waters
   - Discharges from wastewater treatment systems
   - Discharges from sinks and fixtures serving maintenance and process functions
   - Discharges of storm water runoff from process areas
   - Knowledge of discharge based upon historical ground water monitoring
   - Discharges of hazardous substances due to failure or holes in heat exchangers
   - Unusual color or odor to discharge
4. Other Discharge Sources Including Process Water Treatment , Air Pollution Control Systems and Compressor Blowdown
   - Visual evidence of stained soils, stained pavement or stressed vegetation
   - Wastewater infiltration due to absence of impervious containment
   - Overflows caused by pump failure or restrictions in discharge piping
   - Breaches and failures of containment walls or berms
   - Tank failure
   - Evidence of spills or overflow of particle collection equipment (for example, hoppers)

5. Other Potential Sources Including Maintenance Areas, Potential Polychlorinated Biphenyl (PCB) Sources, Fire Training Areas, and Fill Material Associated with Site Grading
   - Visual evidence of stained soils, stained pavement or stressed vegetation
   - Storage directly on ground surface, without an impervious containment area
   - Spills or releases resulting from puncture, dropping or corrosion of containers
   - Releases during operations (for example. oil change, battery recharge, parts cleaning)
   - Discharges of wash water or other liquids during operations or maintenance
   - Releases during maintenance, retrofit or repair operations
   - Spills or releases resulting from historical fires
   - Storage of fuels without an impervious containment system
   - Use of petroleum fuels to start fires
   - Historical use of trash, slag and other wastes to reclaim low-lying or wet areas
   - On-site disposal of excess soils during new construction or renovation

Table C. Definitions of Highly Hazardous Processes

Highly hazardous processes have the following characteristics:

1. Based upon the Material	
Toxic Volatile Substances	Ratio of Equilibrium Vapor Concentration over the Acute Toxic Concentration (in ppm) is greater than 1000
Highly Toxic Materials	*Oral:* LD_{50} of 50 mg/kg or less in rats; *Dermal:* LD_{50} of 200 mg/kg or less with continuous contact with rabbit skin for 24 hours; *Inhalation:* LD_{50} of 200 ppm or 2 mg/L or less for one hour.
Severe Lachrymators	Chemicals for which toxicological studies report tearing of the eyes at low doses.
Flammables	*Liquids:* Flashpoints below 100°F (37.8°C); *Gases:* At ambient temperature and pressure, form flammable mixtures at 13 percent or less by volume.
Explosive Compounds	Chemical causing a sudden, almost instantaneous release of pressure, gas, and heat when subjected to shock, pressure, high temperature or other energy sources; excludes inert gases.
Potential Runaway Reactions	System with sufficient exothermic (heat evolving) capacity to raise the temperature of a reaction above its boiling point or to evolve gaseous substances that could exceed system pressure limitations (under abnormal conditions).
2. Based upon the Threshold	
Toxic Volatile Substances	Dispersion modeling of credible worse case scenarios indicates the one-hour exposure to nearest human receptor exceeds ERPG-2 level or equivalent.
Highly Toxic Materials	Facility assessment of toxicological data, quantity of material used, and operating conditions indicated plausible conditions exist which could cause serious health effects to nearby receptor.
Flammables	Quantities of 10,000 pounds (4535 kilograms) or more accumulated in a single area or building.
Type of Process	All processes except laboratory operations. A laboratory operation is defined as any work with substances in which the containers used for reactions, transfers and other handling of substances are designed to be easily manipulated by one person. This does not include operations whose function is to produce commercial quantities of material.

Appendix C

SAMPLE TOLLER ASSESSMENT: QUANTITATIVE FORMAT

This sample, referred to in Chapter 2, can serve as a guide for planning and conducting assessments of tollers. It may require additions, revisions, or other modifications in order to meet the needs of facility specific assessment objectives, the facility setting, or other special circumstances. This sample includes:

- General Scoring Guideline
- Evaluation Summary
- Assessment Forms
- Component Descriptions and Assessor Guidance

It is based on a philosophy of continuous improvement and partnership. The intent is to establish dialogue and feedback for a clearer understanding of requirements and capabilities. The system has several basic steps:

- prioritization of tollers
- communication and dialogue for understanding
- assessment
- feedback
- follow-up and future reassessment

An assessment package is a tool within a system. It can provide assessment forms, guidance notes and scoring guidelines to conduct an evaluation of a toller's quality/safety system. This sample uses assessment forms to evaluate fourteen components. The results are then compiled in the evaluation summary. The evaluation summary is the basis for a report back to the toller and for mutual discussion

and direction setting for continuous improvement. Fourteen components of an overall quality improvement process are listed below. They are described in some detail in this sample.

1. Management Responsibility
2. Training
3. Quality Manual, Plan and Standards
4. The Toller of Goods or Services
5. The Client
6. Personnel
7. Operations
8. Maintenance
9. Reporting, Investigating, and Analysis
10. Administrative Support
11. Safety
12. Occupational Health/Environmental Protection
13. Security
14. Self-Audit

All of the components should be incorporated in the quality process, not just a few.

General Scoring Guidelines

Answers to each question on this sample assessment form should be noted when appropriate. Each question also includes two subsequent questions: is a system (S) in place, which addresses the specific question and does documentation (D) exist for that system. In those instances where one or the other does not apply, the assessor will mark N/A for not applicable and no points will apply.

Where applicable, the assessor will award points of 0, 1, or 2, based on the following criteria:

0 No evidence of either a system or documentation exists for this question. The company has yet to address or define this area or is just beginning to actively address this particular area.

1 Evidence is demonstrated that the company is active to some degree for the specific area in question. This accounts for instances of partial compliance; however, the system or documentation is not complete enough to avoid noncompliance in the near term.

2 The company has shown adequate evidence that a well-defined system is in place and documented which addresses the area in question. Ultimate goals may not have necessarily been reached; however, the company is well on their way towards continuous improvement for the specific question/area.

The assessor will total both the actual points and total points possible for each component. No points will apply for any questions that were marked N/A. The percentage based on total possible points is calculated for each component for both System and Documentation.

The assessor will summarize the results for each component (percentage S & D) in the Evaluation Summary table. A score will be awarded for the entire assessment and will be recorded average percentage. In the following tables, S = System; D = Documentation.

Evaluation Summary

	S	D
1. Management Responsibility	%	%
2. Training	%	%
3. Quality Manual, Plan and Standards	%	%
4. The Toller of Goods or Services	%	%
5. The Client	%	%
6. Personnel	%	%
7. Operations	%	%
8. Maintenance	%	%
9. Reporting, Investigating and Analysis	%	%
10. Administrative Support	%	%
11. Safety	%	%
12. Occupational Health, Environmental Protection	%	%
13. Security	%	%
14. Self-Audit	%	%
Average S/D	%	%
Average Overall Score	%	

Assessor's Name/Date/Signature _____

Assessment Forms

1. MANAGEMENT RESPONSIBILITY	S	D
1.1 Is there a quality policy?		
1.2 Has one person been designated as the quality assurance coordinator?		
1.3 Is the proportion of his time spent on quality matters sufficient to meet the requirements of the job?		
1.4 Does the Quality Assurance Coordinator have clearly defined authority and responsibility and does he report directly to a senior manager?		
1.5 Is there an organization chart/are there job descriptions, defining the responsibilities for quality?		
1.6 Are there specific and measurable quality improvement goals for the organization and is there a defined quality improvement process in place?		
1.7 Does management throughout the company promote quality in order to increase quality awareness?		
Total Points		
Total Possible		

Percentage.....		

2. TRAINING	**S**	**D**
2.1 Is there a well-defined and functioning training program for • managers • supervisors • operators which ensures their knowledge and understanding of their role and responsibility in their particular function?		
2.2 Is there a well-defined and functioning training program for all personnel to insure knowledge and understanding of state-of-the-art methods and systems as they relate to their business functions?		
Total Points		
Total Possible		

Percentage.....		

3. QUALITY MANUAL, PLAN AND STANDARDS	**S**	**D**
3.1 Is there a quality manual clearly describing the management system, i.e. as per ISO 9000 series or other?		
3.2 Is there a comprehensive quality improvement plan?		
3.3 Are there performance standards?		
3.4 Are the quality manual, improvement plan/ objectives and performance standards available to those who need to use them?		
Total Points		
Total Possible		

Percentage.....		

4. THE TOLLER OF GOODS OR SERVICES	S	D
4.1 Is there a purchasing policy that includes quality requirements?		
4.2 Are your tollers evaluated and rated?		
4.3 What percentage of tollers is certified under ISO 9000 series or other?		
4.4 Is there a written policy on the selection and use of (sub) contractors?		
4.5 Is there a quality control system?		
4.6 Is there a program for the design and development of new major equipment?		
Total Points		
Total Possible		

Percentage.....		

5. THE CLIENT	**S**	**D**
5.1 Is there a formal written contract between your company and the client, covering all commercial, compliance, safety, operational and quality requirements?		
5.2 Are you discussing current performance under the contract at regular intervals?		
5.3 Is there a system in place that insures that for each order all relevant data (i.e., product name, volume, product information, time, place, documentation etc.) is collected prior to execution?		
Total Points		
Total Possible		

Percentage.....		

6. PERSONNEL	S	D
6.1 What are your selection criteria for new personnel?		
6.2 Is there a personnel assessment and development system?		
6.3 Is there a system to motivate employees through a reward and recognition program?		
Total Points		
Total Possible		

Percentage.....		

7. OPERATIONS	S	D
7.1 Has each task that has been identified as critical in the area of quality and/or safety been documented with full operating instructions and are these instructions reviewed regularly?		
7.2 Is there a written procedure for the cleaning of equipment: • Stationary tanks? • Truck tank barrels? • Pumps, valves, hoses? • Hard arms?		
7.3 In case truck barrel cleaning is done by a third party: • What are the selection criteria? • What are the requirements as regards to the method to be used?		
7.4 Have the responsibilities for loading and discharging been clearly defined with your client?		
Total Points		
Total Possible		

Percentage.....		

8. MAINTENANCE	S	D
8.1 Is there a documented preventive maintenance program for major equipment?		
8.2 Is there a statutory or regulatory inspection of the major equipment and do records indicate that tests are passed without problems?		
8.3 Is there over and above the statutory inspection a further detailed inspection program?		
8.4 Are all substandard or hazardous conditions reported in writing and acted upon immediately?		
8.5 Are overdue inspections reported to the operations manager for his authorization for use of the equipment?		
8.6 Is all measuring equipment used, tested and calibrated for accuracy at regular intervals?		
Total Points		
Total Possible		

Percentage.....		

9. REPORTING, INVESTIGATING AND ANALYSIS	S	D
9.1 Is there a written procedure for handling non-conformance with quality of service?		
9.2 Is the root cause ascertained before taking corrective measures?		
9.3 Is there a system in place to determine the cost of quality loss?		
9.4 Is the client informed immediately of any non-conformance?		
Total Points		
Total Possible		

Percentage.....		

10. ADMINISTRATIVE SUPPORT	**S**	**D**
10.1 Is there a list of tasks that specific administrative personnel are expected to perform?		
Total Points		
Total Possible		
Percentage.....		

11. SAFETY	**S**	**D**
11.1 Is there a safety policy?		
11.2 Has one person been designated as the safety coordinator?		
11.3 Is the proportion of his time spent on safety matters sufficient to meet the requirements of the job?		
11.4 Does the safety coordinator have clearly defined authority and responsibility and does he report directly to a senior manager?		
11.5 Does management throughout the organization promote safety in order to increase safety awareness?		
11.6 Is there a system for ensuring the compliance of the subcontractor with your standards and procedures?		
11.7 Is there a written reporting and investigation procedure for accidents, near misses, damage occurrence and potential hazards?		
11.8 Are records of safety performance maintained, analyzed and communicated to all employees?		
11.9 Is there a written plan for dealing with emergencies?		
11.10 Are emergency tests and exercises carried out at least annually?		
11.11 What kind of training is provided over and above regulatory requirements?		
Total Points		
Total Possible		
Percentage.....		

12. OCCUPATIONAL HEALTH/ ENVIRONMENTAL PROTECTION	**S**	**D**
12.1 Have all tasks been examined to identify and evaluate all occupational health hazards?		
12.2 Is all product data information available?		
12.3 Are there written procedures for the handling of all chemicals?		
12.4 Are prevention measures being defined and used to control all identified potential health hazards adequately?		
12.5 Is there a policy emphasizing the importance of environmental protection?		
12.6 Has each employee received job instruction on applicable environmental protection procedures?		
12.7 Are there written procedures for the safe disposal of waste resulting from cleaning?		
12.8 Is there an alcohol, drugs and substance abuse policy?		
Total Points		
Total Possible		
Percentage.....		

13. SECURITY	**S**	**D**
13.1 Is there a security policy?		
13.2 Is there access control?		
13.3 Are security inspections being held?		
Total Points		
Total Possible		
Percentage.....		

14. SELF-AUDIT	S	D
14.1 Is there a comprehensive, formal system which specifies self-audits at a planned frequency with results reported to and reviewed by management?		
14.2 Do audits assess that quality and safety activities comply with planned activities, that the quality and safety system are effective and that defined procedures and methods are being followed?		
Total Points		
Total Possible		
Percentage.....		

Audit Protocols for the Assessor

1. Management Responsibility

Management should demonstrate more than arm's length support for quality improvement. They should provide involved leadership and constancy of purpose. There are three key aspects of this leadership.

- Instituting a formal quality policy,
- Assigning responsibility for quality improvement, and
- Installing a process for quality improvement.

The chief executive should formally document the organization's quality policy. This policy should include the relative priority assigned to continuous quality improvement, the acceptable standard for quality, and the system to achieve that standard.

The quality policy should be communicated throughout the organization and all personnel should be familiar with it.

Management should assign clear responsibility for quality improvement. Those responsible should have the authority, or

access to the authority, to assure the quality policy is being implemented. Management should also provide any additional resources necessary to carry out this responsibility.

Management should also install a process for quality improvement. Continuous quality improvement will occur only through a defined, planned, documented and systematic approach that involves every employee.

Quality goals should be set for all aspects of the operation, and there should be evidence that progress is being made towards those goals. There should be a system for error cause removal.

The quality improvement process should become a part of the organization's culture.

Guidance Notes for the Assessor

1.1. This policy statement may be combined with that of safety (quality and safety should be twin objectives) and should be signed or properly reviewed within the last 12 months.
1.2. The company should have a quality assurance/improvement coordinator. in smaller companies it may be on a part-time basis.
1.3. The proportion of time spent on quality matters will vary with the size of the company. The assessor should make a personal judgment.
1.4. The coordinator should have authorities and responsibilities that are defined and documented, for example, in the job description. He or she should report directly to a senior manager in quality matters even if reporting to a lower level on other duties.
1.5. There should be an organization chart for the company showing individual functions and to whom they are responsible. Job descriptions should clearly indicate responsibilities for quality. The assessor should read the job description of the quality assurance/improvement coordinator as well as of a few managers and supervisors to establish the answer to the question.
1.6. The assessor should establish whether management specific and documented quality objectives are defined. The improve-

ment process could be checked by evidence that quality meetings and audits are actually being held. Ask for agendas/minutes and action plans/audit reports.

1.7. All employees should be made aware of the consequences of poor job performance, at all levels, on other employees, on client satisfaction, cost and economic well being of the organization. The need for quality should be emphasized through an awareness program that may include training, problem-solving corrective actions and other measures. Check whether bulletin boards, meetings, publications, planned personal contacts, are used to promote quality and are given due prominence.

2. Training

There should be an active and functioning training program that covers two basic areas:

1. Employees should have adequate training ensuring that they understand their role and responsibilities in their assigned job. They should also understand the role and responsibility of their work group's function and how it relates to the overall business.
2. Employees should have access to training that develops their work skills in order that they may use state-of-the-art methods and systems related to their particular functions.

The training program should not only provide timely training but should also identify additional training needs. Further, there should be overall training goals to ensure all employees continue to expand and grow. Accurate and timely record keeping in this area is critical.

Guidance Notes for the Assessor

2.1–2. Check whether for the various levels of personnel there is an induction training for all new-hires, a formal training and refresher training in the area of quality, safety, job skill improvement and so on.

3. Quality Manual, Plan and Standards

Documented procedures are often necessary to ensure consistency and correctness for any type of transaction. This section refers to the overall system of communicating, updating, and approving procedures. The procedures pertinent to the implementation of the quality assurance/improvement process should be compiled in a quality manual. the quality manual should be communicated throughout the organization.

A key aspect of this quality process component is to evaluate if the people doing the job have access to and are following the established procedures. There should be a system to manage the updating of procedures, communicating the changes, and training personnel on the procedures.

The system should assure all changes are reviewed and approved by a designated authority. All personnel need to understand their role in this updating process and whether they have authority to deviate from procedures. Formal review and update should be part of this system.

Guidance Notes for the Assessor

3.1. This manual is one of the most important documents in controlling quality.
3.2. The achievement of more effective levels of quality requires systematic planning and budgeting. There should be evidence of ongoing effort to identify variability in the quality of service and plans for improvement in areas that will have major benefits to the client.
3.3. The company should have set standards for all employees to indicate the quality/safety performance expected of them.
3.4. The quality manual, improvement plan and performance standards should be available to be seen by all employees. Check that this is the case

4. The Toller of Goods or Services

The business group should be able to demonstrate that they assessed their tollers regarding commitment to quality and continu-

ous improvement. This includes establishment of quality partnership, development of toller selection criteria, ongoing exchange of quality data, procedures for testing incoming material and/or services or equipment and toller reduction efforts.

All tollers should eventually be assessed regarding their own quality improvement programs as well as meeting requirements. This can be done either formally, such as with an assessment process and form, or informally through normal communications. In either case, the results of the toller assessment should be documented and well understood within the organization.

Guidance Notes for the Assessor

4.1. Purchasing may be critical to quality, cost efficiency and safety of the service provided. Therefore evidence should be given that there is a written management policy or directive establishing quality criteria.

4.2. This can be a formal or an objective, informal approach however documentation should be available.

4.3. The assessor should establish what percentages of key tollers do have an ISO 9000 series quality assurance system or other. Check whether the purchasing function has copies of certification including scope of certification.

4.4. This note applies to roadhaulage only. Haulers may subcontract the haulage, or employ independent traction (driver/tractor) or employ interim drivers. A written policy is expected, detailing what criteria have to be met in such cases, and at what stage the client is to be informed about the use of subcontractors.

4.5. Check whether controls are exercised on the material and services supplied to ensure that they meet the contract specification requirements.

4.6. It may not be expected that the toller will carry out the design of hard arms, drums or tanker barrels; but concern for reliable and safe operations, and client requirements would result in an interest in design. Look for evidence of having met specific client requirements or correspondence with the manufacturer on details of reliability and testing

requirements for items like hoses, valves and alarms for prevention of overfilling.

5. The Client

Sales/marketing personnel may typically handle issues related to price, volume, specifications, etc. whereas they are charged also with developing/fostering relationships with either existing or potential clients. The company should have full understanding of and agreement with the client about the client's expectations/requirements. Furthermore the toller should initiate performance discussions with the client.

Guidance Notes for the Assessor

5.1. The assessor should establish whether there is complete agreement and understanding between toller and the client about the requirements to be met (service level liabilities and so on).

5.2. The assessor should establish whether the toller initiates regular formal (minimum biannually) performance review meetings with the client. Look for minutes, action plans, etc.

5.3. The assessor should establish that for each individual order information is being collected from the client and recorded prior to order execution. Do random checks of records.

6. Personnel

Experienced and qualified people are important to the performance level of a company. Proper personnel selection and career planning are therefore complimentary to the success of a company.

Guidance Notes for the Assessor

6.1. The assessor should establish whether for various types of jobs or job-levels criteria are formalized: is there a job profile? What formal education is required? Is there an age limit? Past experience? Language ability? Medical examinations? Interview system?

6.2–3. Career planning is a necessary component of an overall approach to quality. Each employee should be viewed as having a career within the organization. People are more likely to take an innovative approach when they know that they have a long-term relationship with the organization. Confirm records and examine career plans.*

7. Operations

In order to maintain a high level of quality and safety in the actual operations, whether chemicals are transferred, loaded/unloaded or transported, proper operating instructions/procedures are crucial and should be regularly reviewed.

Guidance Notes for the Assessor

It should be expected that tasks for all operations are defined and those critical to quality and/or safety are identified. Critical tasks should have detailed operating instructions.

7.1. Instructions should be in writing and clearly expressed.

7.2. This question refers to situations where the toller himself is carrying out cleaning operations at his own premises. Cleaning is a very important element of toller's effort to maintain quality. The assessor should read and check all written procedures carefully.

7.3. Truck barrel cleaning may be done by third party cleaning stations and the assessor should establish what the selection criteria are. Are cleaning stations assessed by the toller on a regular basis as regards capability, quality of service, costs, cleaning methods used, quality assurance management system, safety? The assessor should check records for objective evidence.

7.4. The assessor should establish whether in the contract with the client those responsibilities are defined: for example, who is loading or discharging the truck (the driver or the supplying or receiving facilities' personnel?) or is the ship/shore interface established?

*The confidential nature of individual records should be respected and therefore the assessor may have to rely on the verbal assurance of the personnel manager.

8. Maintenance

A quality service can be provided only by reliable equipment. This section seeks to ensure that effective routine inspection and maintenance programs are in place in order to detect defects before they cause accidents or breakdowns.

Guidance Notes for the Assessor

8.1–3. Preventive maintenance on vital equipment, such as tractor units, tanks, pumps, hoses, hard arms, pipelines, and mooring facilities, should be properly scheduled, carried out and documented. This program should be separate from the regulatory inspection. Verify from records.

8.4. Formal reporting and follow-up of substandard or hazardous conditions is imperative. The assessor should verify whether such a system is in place and is effective.

8.5. The purpose of this question is to establish that proper management control is exercised. Verify from records.

8.6. The assessor should find out that a testing program is in place, which ensures the serviceability of the existing measurement equipment. They should have an established calibration program, which addresses the accuracy of all measurement equipment.

9. Reporting Investigating and Analysis

Data should be available at every phase of the service quality loop from soliciting business through client reaction and feedback. The collection and analysis of data is a means of improving the service or conversely can detect the onset of an insidious degradation of the service before it becomes a major issue.

Guidance Notes for the Assessor

9.1-2. Check whether a documented system is in place, which covers the reporting, investigation, root cause analysis and corrective actions taken.

9.3. Look for any evidence that the toller puts in an effort to try to determine the value of quality loss.
9.4. Check records.

10. Administrative Support

These areas provide services necessary for certain fundamental elements of transacting business:

Client Service/Order Entry

This group is responsible for obtaining the routine orders for service from clients and processing that information to allow the scheduling group to deliver the service. This group is also responsible for client service including maintaining open dialogue to monitor service as defined by the client.

Accounting

This group is very visible to the client. Its major role is generating invoices that are consistent with what actually took place.

10.1. Attention should be given toward both client service/order entry and invoicing. The assessor should evaluate the administrative process of order entry, data processing, scheduling, shipment data collection, whereby the focus should be on invoice generation with monitoring correctness.

11. Safety

Similar as to quality, management should demonstrate indeed more than arm's length support for safety and safety improvement leading to the highest possible safety standards. Involved leadership and constancy of purpose is critical.

Guidance Notes for the Assessor

11.1. This policy statement may be combined with that on quality and should be signed or properly reviewed within the last 12 months.

11.2. The company should have a safety coordinator. In smaller companies it may be on a part-time basis.
11.3. The proportion of time spent on safety matters will vary with the size of the company. The assessor should make a personal judgment.
11.4. The coordinator should have authorities and responsibilities that are defined and documented, for example, in the job description. He or she should report directly to a senior manager on safety matters even if reporting to a lower level on other duties.
11.5. All employees should be made aware that maintaining the highest standard of safety is critical and everybody's responsibility. The need for the highest safety standards should be emphasized through an awareness program that includes training and other measures. Check whether bulletin boards, meetings, publications, planned personal contacts are used to promote safety attitudes and are given due prominence.
11.6. The assessor should look for objective evidence that subcontractors are made aware of and comply with the tollers' safety standards and procedures.
11.7–8. The accident reporting procedure should be more than reporting of equipment damage for insurance purposes. The report should show appropriate action taken to prevent a recurrence.
11.9. The emergency plan should state the action to be taken, by whom, to inform the local authorities, and the client. In turn the plan should detail the response to overcome the problem quickly.
11.10. Check when the emergency plans were last tested. Ask what simulations are used to train people in emergency management.
11.11. Look for a documented system of training that complements those required by law.

12. Occupational Health/Environmental Protection

Care and concern for the well being of people and the environment should be a main concern of management and all people employed.

Product information in detail should be available and potential hazards should have been identified and occupational health preventive measures taken. Safe disposal of waste should be well under control.

Guidance Notes for the Assessor

12.1. The assessor should determine whether any serious effort is being undertaken by the toller to examine all tasks in detail to identify possible exposure risks, for example, is opening of a tank lid manhole a potential health hazard with certain chemicals?

12.2. Implied is the availability of Material Safety Data Sheets (MSDS) for all products handled by the toller. The assessor should question the distribution system of product information.

12.3–4. Procedures should cover the need for protective equipment.

12.5. Is environmental protection receiving appropriate attention and being emphasized by management?

12.6. Is environmental protection a topic in the (on the job) training program.

12.7. Check whether there is a formal system for waste disposal. Is off-site waste disposal covered by contract or letter of agreement that specifies the mode of disposal, liabilities and responsibilities? Is waste disposed on-site covered by permits as required by applicable legislation?

12.8. Check that there is an alcohol, drug and substance abuse policy that gives clear guidelines on handling the issues, dismissal, and rehabilitation.

13. Security

High value products and often proprietary information are given into the custody of a third party. It is therefore essential to determine what measures are being taken by tollers to safeguard products and information.

Guidance Notes for the Assessor

13.1. The policy should emphasize the importance of protecting people, property and the operational practices against loss by intentional destruction or theft.
13.2. Check whether methods are taken to control entry and movement of people and vehicles as a security measure.
13.3. Check whether any security inspections are being held during off-duty hours.

14. Self-Audit

Self-audit is a monitoring device used to establish any varying degrees of detail or performance of an organization to define areas of deficiency and to correct such deficiencies before they cause further problems.

Guidance Notes for the Assessor

14.1. The assessor should verify that there is a comprehensive formal system that specifies self-audits on a planned frequency. Over time, all areas should be audited. Results should be reported to management with appropriate follow-up documented. Self-audits should be thorough, addressing all aspects of the area's functions. Outsiders not working in the specific audit area should be included in the exercise for objectivity.
14.2. Audits should assess whether the actual quality improvement and safety activities comply with planned activities. The effectiveness of the overall quality and safety system should be scrutinized. Fundamental procedures and methods should be investigated to insure they are up-to-date and being followed in actual practice. The focus of the audit should be prevention, that is, finding areas needing improvement before they actually turn into situations that generate nonconformance.

Appendix D

THE ISD MODEL AND JOB TASK ANALYSIS TECHNIQUES

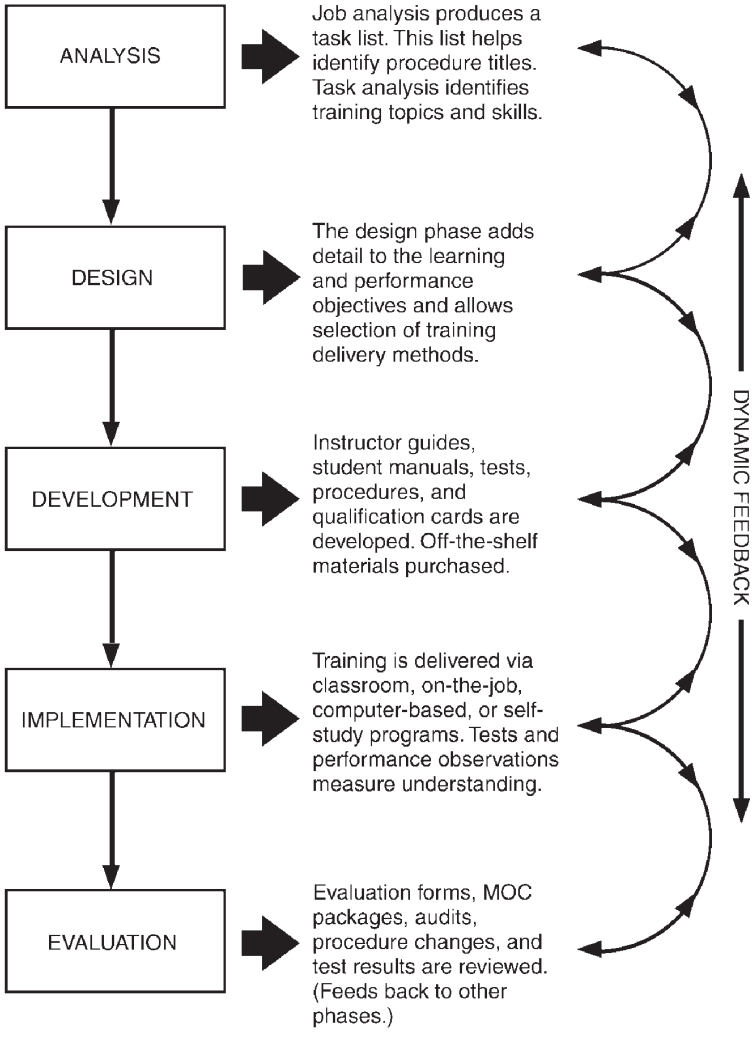
Two elements of process safety that deal with human performance are procedures and training. These elements benefit from using an engineering approach to determine which procedures to write and what training needs to be conducted. This systematic approach can help keep a plant's procedures and training program accurate and effective as the facility and people change. The Instructional Systems Design (ISD) model (shown in graphic form on page 204) provides just such an approach. It consists of five phases:

- Analysis
- Design
- Development
- Implementation
- Evaluation

The analysis phase of the instructional systems design (ISD) model, as referred to in Chapter 4, consists of a job task analysis based upon the equipment, operations, tools, and materials to be used as well as the knowledge and skills required for each position. Most important in this phase is the selection of the performance and learning objectives each employee must master to be successful in their job as related to the toll.

The design phase examines the best methods with which to impart the knowledge or develop the skills required to achieve the objectives. It allows management to lay out the most cost-effective training plan.

Development is the phase in which the modules, such as process overview training or safety training modules, are physically con-



structed or purchased. As operating and maintenance procedures become training tools as well as job aids and process safety documentation, their revision or development could be considered as part of this phase in the ISD training model.

The implementation phase represents the delivery of the training. Classroom, self-study or computer based training is typically suitable for knowledge related objectives. Hands on performance training, walkthrough or simulation is most appropriate for procedure tasks.

BASIC STEPS FOR A JOB AND TASK ANALYSIS

1. First, collect information about the job position from various sources such as:
   - Job descriptions
   - Standard operating procedures, maintenance procedures, emergency response plan procedures, administrative procedures, safe work practices
   - Equipment lists
   - Operating or maintenance manuals
   - Other current data such as written reports, memos, instruction sheets, P&IDs
2. Develop a list of tasks. A task can be defined as a series of steps leading to a meaningful outcome.
3. Review the list with your Subject Matter Experts (SMEs). Subject matter experts are generally persons who can competently perform the task. This review will enable you to remove tasks that are no longer performed, add any tasks that were omitted, and correct any errors.
4. With the SMEs, rate each task in terms of Frequency, Importance, and Difficulty.
5. Summarize the ratings to identify which tasks are critical, that is, which ones are most frequent, important, and difficult.
6. The following information is needed for each task:
   - What steps are taken to perform the task?
   - What standards are used in performing the task?
   - Under which conditions will the task be performed?
   - What tools, equipment, and references are used in performing the task?
   - What safety precautions does the person performing the task need?
   - What knowledge and skills are needed to perform the task?
   - What training does a person need to perform the task?

The evaluation phase of the model exists to ensure that the organization has learned from the experience of doing the training and applies that learning to the previous phases of the model. Evaluating the worker's performance on tests or during operation may lead to revisiting the task analysis to include missed tasks or possibly redistributing tasks among the positions. This phase is a self-audit of how effectively and efficiently the training was completed.

Applying this training model results in what can be seen as three levels of training topics.

1. **Fundamentals:** Fundamentals include topics such as pressure, temperature, flow, general safe work practices, regulatory training, common processing steps such as distillation, heat exchange, pump operation, mixing and blending as appropriately indicated by the analysis phase.
2. **Process Overview:** The process overview includes topics related to the equipment configuration, chemical and physical changes achieved in the specific toll, and special safe work practices related to the operations, maintenance and materials. Emphasis should be given to any new equipment and chemical hazards the startup team will encounter.
3. **Job Specific:** Job-specific topics include training on new or revised operating, safety and maintenance procedures related to the toll. It could include emergency response plan training or laboratory technician training as well if those procedures were changed.

A curriculum developed for an operator position at a toller's facility would list:

- the fundamental training the employee received upon hiring (or had completed previously),
- followed by process overviews for each toll they have performed, and finally
- the list of job specific procedures for the equipment and the batch instructions for each task they are expected to perform.

Appendix E

LIST OF REFERENCED REGULATIONS

- Employee Emergency Plans and Fire Prevention Plans—29 CFR 1910.38
- Federal OSHA "Hazard Communication Standard," codified as 29 CFR 1910.1200 and any similar state "right-to-know" laws
- Guidelines for the Preparation and Implementation of a Spill Prevention Control and Countermeasure Plan (SPCC)—EPA 40 CFR part 112.7
- Hazardous Waste Operations And Emergency Response (HAZWOPER)—29 CFR 1910.120
- Oil Pollution Act (OPA) Facility Response Plans (FRP)—EPA 40 CFR part 112.20
- Process Safety Management of Highly Hazardous Chemicals (PSM)—OSHA 29 CFR 1910.119
- Resource Conservation and Recovery Act (RCRA)—Contingency Plan and Emergency Procedures—EPA 40 CFR part 264 or part 265, Subpart D
- Resource Conservation and Recovery Act (RCRA)—Preparedness and Prevention—EPA 40 CFR part 264 or part 265, Subpart C
- Risk Management Program Rule (RMP)—Emergency Response Program—EPA 40 CFR parts 68.90 and 68.95

Appendix F

SELECTED RESOURCES

American Chemical Society
http://www.acs.org
1155 16th Street NW
Washington DC 20036
(202) 872-4600
(800) 227-5558

American Industrial Hygiene Association
http://www.aiha.org/syn.html
2700 Prosperity Ave., Suite 250
Fairfax, VA 22031
(703) 849-8888

American Institute of Chemical Engineers/
Center for Chemical Process Safety
http://www.aiche.org
3 Park Ave.
New York, NY 10016-5991,
(800) 242-4363,
E-mail: xpress@aiche.org

American Petroleum Institute
http://www.api.org
1220 L Street NW
Washington, DC 20005-4070
(202) 682-8000

Chemical Manufacturers Association
http://www.cmahq.com/cmawebsite.nsf
1300 Wilson Boulevard
Arlington, VA
(703)-741-5000

National Safety Council
http://www.nsc.org
1121 Spring Lake Drive
Itasca, IL 60143-3201
(630) 285-1121

Synthetic Organic Chemical Manufacturers Association (SOCMA)
http://www.socma.com/index.html
1850 M St N.W., Suite 700
Washington, D.C. 20036
(202) 721-4100

United States Chemical Safety and Hazards Investigation Board
http://www.cshib.gov
2175 K Street N.W. Suite 400
Washington, D.C. 20037-1809
(202) 261-7600

United States Department of Labor,
Occupational Safety and Health Administration
http://www.osha.gov
Washington, DC 20210
(800)488-7087

United States Department of Transportation
http://www.dot.gov
400 Seventh Street, SW
Washington, DC 20590
(202)-366-4000

United States Environmental Protection Agency
http://www.epa.gov
401 M Street S.W.
Washington, DC 20460
(202) 260-2090

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