



# Ethiopian TVET-System



# Furniture Making L-I

# Based on Sept. 2012G.C. Occupational standard

Module Title:

- Applying Quality Standards

TTLM Code:

IND-FMK1 M10-TTLM 0919v1

# This module includes the following Learning Guides

LG29: Assess own work

LG Code: IND-FMK1 M10 LO1-LG-29

LG30: Assess quality of received articles

LG Code: IND-FMK1 M10 LO2-LG-30

LG31: Record information

LG Code: IND-FMK1 M10 LO3-LG-31

LG32: Study causes of quality deviations

LG Code: IND-FMK1 M10 LO4-LG-32

LG33: Complete documentation

LG Code: IND-FMK1 M10 LO5-LG-33





#### LG29: Assess own work

This learning guide is developed to provide you the necessary information regarding the following **content coverage** and topics:

- Quality Systems in a furniture industry
- Impact of Work to Quality System

This guide will also assist you to attain the learning outcome stated in the cover page. Specifically, upon completion of this Learning Guide, you will be able to:

- follow procedure and instruction to requirement quality system
- Identify, impact of work to quality system

#### **Learning Instructions:**

1. Read the specific objectives of this Learning Guide.

2. Follow the instructions described below 3 to 5.

3. Read the information written in the information "Sheet 1, Sheet 2," Try to understand what are being discussed. Ask you teacher for assistance if you have hard time understanding them.

4. Accomplish the "Self-check 1, Self-check 2, in page \_\_, and \_\_\_\_ respectively.

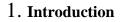
5. Ask from your teacher the key to correction (key answers) or you can request your teacher to correct your work. (You are to get the key answer only after you finished answering the Self-check

6. If you earned a satisfactory evaluation from the "Self-check" proceed to "Information Sheet 2"
in page \_\_\_\_\_. However, if your rating is unsatisfactory, see your teacher for further instructions or go back to Learning Activity #1.

7. Submit your accomplished Self-check. This will form part of your training portfolio.

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#### 1.1 Quality system

Develop a quality system and a manual that describes it. Your quality system should ensure that your products conform to all specified requirements.

Your quality manual should:

- State your quality policy.
- List your quality objectives.
- Provide an overview of your quality system.
- Describe the structure of your organization.
- Discuss your quality system procedures.
- Introduce your quality documents and records.
- Teach people about your quality system.
- Control quality system work practices.
- Guide the implementation of your quality system.
- Explain how your quality system will be audited.

#### **1.1.1 Quality system procedures**

Develop and implement quality system procedures that are consistent with your quality policy.

- Develop your procedures for all areas of your quality system.
- Document your procedures, and keep them up to date.
- Each procedure should:
  - Specify its purpose and scope.
  - Describe how an activity should be carried out.
  - Describe who should carry out the activity.
  - Explain why the activity is important to quality.
  - Describe when and where it should be carried out.
  - Explain what tools and equipment should be used.
  - Explain what supplies and materials should be used.
  - Explain what documents and records should be kept.

#### **1.2 Quality policy**

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Quality policy is a document jointly developed by management and quality experts to express the quality objectives of the organization, the acceptable level of quality and the duties of specific departments to ensure quality.

Your quality policy should:

- State a clear commitment to quality.
- Recognize customer needs and expectations.
- Be actively supported by senior management.
- List the quality objectives you want to achieve.
- Be understood by everyone in the organization.
- Be consistent with your organization's goals.
- Be maintained throughout your organization.
- Be applied throughout your organization.

#### 1.3 Responsibility and authority

Define quality system responsibilities, give quality system personnel the authority to carry out these responsibilities, and ensure that the interactions between these personnel are clearly specified. And make sure all of this is well documented. This requirement must be met for those who:

Manage quality system work.

Perform quality system work.

Verify quality system work

#### **1.4 Quality Management Plan (QMP)**

A QMP is a formal plan that documents an entity's management system for the environmental work to be performed. The QMP is an "umbrella" document which describes the organization's quality System in terms of the organizational structure, functional responsibilities of management and staff, lines of authority, and required interfaces with those planning, implementing, and assessing all environmentally related activities conducted.

#### **1.5 Quality Assurance**

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Quality Assurance is a system of management activities involving planning, implementation, assessment, and reporting to make sure that the end product (i.e., environmental data) is of the type and quality needed to meet the needs of the user.

#### **1.6 Quality Control**

Quality Control is the overall system of operational techniques and activities that are used to fulfill requirements for quality. The QC activities are used to produce and document the quality of the end product.

#### **1.7 Quality planning**

Develop quality plans that show how you intend to fulfill quality system requirements. You are expected to develop quality plans for products, processes, projects, and customer contracts.

- Your quality plans should list the quality objectives you intend to achieve, and the steps you intend to take to achieve these objectives.
- When you construct your quality plan, consider the following questions:
  - Do you need to purchase any new equipment or instruments, or any new inspection and test tools?
  - Do you need to carry out any special training in order to fulfill all quality system requirements?
  - Do you need to improve design, production, testing, inspection, installation, or servicing procedures?
  - Do you need to improve your quality measurement and verification procedures?
  - Do you need to develop any new measurement methods or instruments?
  - Do you need to clarify your organization's standards of acceptability?
  - Do you need to develop any new documents, forms, reports, records, or manuals?
  - Do you need to allocate more resources in order to achieve the required levels of quality?

#### **1.8 Quality management standards**

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Quality management system (QMS) standards establish a framework for how a business manages its key processes. They can help whether your business offers products or services and regardless of your size or industry. They can also help new businesses start off on the right foot by ensuring processes meet recognized standards, clarifying business objectives and avoiding expensive mistakes.

To comply with the standard you'll first need to implement a QMS. Implementing a QMS can help your business to:

- achieve greater consistency in the activities involved in providing products or services
- reduce expensive mistakes
- increase efficiency by improving use of time and resources
- improve customer satisfaction
- market your business more effectively
- exploit new market sectors and territories
- manage growth more effectively by making it easier to integrate new employees
- constantly improve your products, processes and system

For example, the quality system of a manufacturing business might include looking at more efficient manufacturing processes or speeding up distribution.

The **ISO 9000 series** of standards is the main set of International Standards applying to the management of quality systems. It includes ISO 9001, the key internationally agreed standard for a QMS. Businesses can be certified against this standard when they meet its requirements.

#### The ISO 9001:2008 standard

ISO 9001:2008 is the key internationally agreed standard for quality management systems. It is used by over 951,000 businesses in 175 countries worldwide (source: British Standards Institution (BSI), 2010).

The ISO 9001:2008 standard has four elements:

- **management responsibility** ensuring top level management shows commitment to the quality system and develops it according to customers' needs and the business' objectives
- **resource management** ensuring the people, infrastructure and work environment needed to implement and improve quality systems are in place
- **product realization** delivering what customers want, looking at areas such as sales processes, design and development, purchasing, production or service activities

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• measurement, analysis and improvement - checking whether you have satisfied customers by carrying out other measurements of your system's effectiveness

#### The advantages of ISO 9001:2008 for your business can include:

- greater efficiency and less waste
- consistent control of major business processes, through key processes lists see our example key processes master list Opens in a new window
- regulation of successful working practices
- risk management
- increased customer satisfaction
- greater consistency in the quality of products and services through better control of processes
- differentiation of your business from its competitors
- increased profits
- exploitation of new markets, both in the UK and overseas

However, you should also be aware of some of the **disadvantages** to implementing the standard. These can include:

- the cost of getting and keeping the certification
- the time involved
- overcoming opposition to implementing change from within the business

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Self-Check -1

**Directions:** Answer all the questions listed below. Use the Answer sheet provided in the next page:

- 1. Defines Quality Management Plan (QMP)?
- 2. Define the Quality Assurance?
- 3. What is Quality system?

Score = \_\_\_\_\_

Rating: \_\_\_\_\_

Note: Satisfactory rating –above 2 pointsUnsatisfactory - below 2 pointsYou can ask you teacher for the copy of the correct answers

Name: \_\_\_\_\_

Date: \_\_\_\_\_

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**Information Sheet-2** 



#### 2. INTRODUCTION

In many organizations, quality is the most important matter. With new technology, customers can easily compare qualities from around the world. if a customer is unhappy, an organization will lose the customer and its reputation will be negatively impacted. As a result of this, pressure management of the past.

Quality of work varies significantly from one organization to another.

Work quality and productivity is impacted by the surrounding internal and external factors, inside and outside the organization, oc can have impact on employees, behavior and their performance and work quality.it could inspire management to develop existing oc in a way that leads to better work quality.

#### Impact of organization culture on work quality

Quality systems impact on the service experience implementation of the quality components as these affect the work setting in which quality has an impact on your company uses low-quality parts, systems break down, regardless of any high-quality parts also used.

#### What are the four ways in which quality can affect a company?

Quality affects a company in a variety of ways, from productivity and profitability to customer satisfaction and public perception.

Focusing on quality helps keep a company strong in all areas.

#### Causing problems with productivity

Poor quality costs company money in terms of productivity problems. If a company uses lowquality parts, systems break down, regardless of any high-quality parts also used.

#### **Impacting company's profitability**

Quality increases profitability. When employees are engaged in a work environment in which teamwork is emphasized and where quality products more smoothly than one in which quality is an afterthought.

#### Influencing customer satisfaction

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Quality has a direct bearing on customer satisfaction. if a company produces a quality products, satisfied customers will rank that company higher in surveys than companies that fail to provide quality product or services.

#### Directly affecting costs

Quality directly affecting costs in a business. While using less expensive parts and equipment might cut costs in the short-term, the long-term effects might be far more expensive.

Self-Check -2	Written Test

**Directions:** Answer all the questions listed below. Use the Answer sheet provided in the next page:

1. List and explains the four ways in which quality can affect a company.

Score = \_\_\_\_\_

Rating: \_\_\_\_\_

*Note:* Satisfactory rating – above 3 point

**Unsatisfactory - below 3 points** 

You can ask you teacher for the copy of the correct answers.

Name: \_\_\_\_\_

Date: \_\_\_\_\_

Short Answer Questions





### Instruction Sheet LG30: Assess quality of received articles

This learning guide is developed to provide you the necessary information regarding the following **content coverage** and topics:

- Concepts of Product Quality
- Identification of Deviations from Standards
- Recording and Reporting Procedures

This guide will also assist you to attain the learning outcome stated in the cover page. Specifically, upon completion of this Learning Guide, you will be able to:

- Check materials, final product against workplace standards.
- Measure the materials, products using appropriate measuring instruments in accordance with workplace procedures.
- Identify and correct the causes of any identified faults in accordance with the workplace procedures.

#### **Learning Instructions:**

1. Read the specific objectives of this Learning Guide.

2. Follow the instructions described below 3 to 5.

3. Read the information written in the information "Sheet 1, Sheet 2, Sheet 3". Try to understand what are being discussed. Ask you teacher for assistance if you have hard time understanding them.

4. Accomplish the "Self-check 1, Self-check t 2, Self-check 3" in page \_\_, \_\_, \_\_ and \_\_\_\_ respectively.

5. Ask from your teacher the key to correction (key answers) or you can request your teacher to correct your work. (You are to get the key answer only after you finished answering the Self-check

6. If you earned a satisfactory evaluation from the "Self-check" proceed to "Information Sheet 2"

**in page** \_\_\_\_\_. However, if your rating is unsatisfactory, see your teacher for further instructions or go back to Learning Activity #1.

7. Submit your accomplished Self-check. This will form part of your training portfolio.





#### 1. Concepts of Product Quality

#### 1.1 Quality

- Quality is the customers' perception of the value of the suppliers' work output.
- A product or process that is Reliable, and that performs its intended function is said to be a quality product.

Quality is nothing more or less than the perception the customer has of you, your products, and your services!

Quality standard is a set of specific, concise statements and associated measures. It will be reflected in the new commissioning outcomes framework and will inform payment mechanisms and incentive schemes. Such as:

- The quality and outcome framework
- Commissioning for quality and
- Innovation payment framework.

Quality standard is the core, they inform the other key aspect of the framework, Stakeholders are encouraged to work towards continuous improvement through engagement in process of planning and evaluation centers should be in place in centers while allowing to local flexibility in the way stakeholders choose to achieve standards.

**Understanding Quality: -** We all have needs, wants; requirements, and expectations, needs are essential for life to maintain certain standards or essential for products and service, to fulfill the purpose for which they have been acquired.

These needs determine quality of products or services we acquire and are fulfilled by the individual purchasing, renting or leasing. Most of our lines are department in many ways on individual products such as our shelter, nutrition, work, communication, health care, recreation.

One basic aspect of products of this type is that they must be fit for use /purpose. Failure in this respect can lead to death, injury, discomfort or economical loss.

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As user of these industrial products, we all value their price, quality and delivery. We require products of a given quality to be delivered by or be available by a given time and to be of a price that reflects value for money.

The work quality has been defined as:

- Fitness for purpose
- Conformance with requirements
- The degree to which a set of inherent characteristics fulfill requirements.

#### Benefits of implementing quality management system:

#### **Internal benefits**

- Improved management
- Improved awareness of company objectives
- Improved communications
- Responsibilities and authorities are adequately defined.
- Improved traceability to root causes of quality problems.
- Improved utilization of resources.
- Fewer reject therefore, less repeated work & warranty costs.
- Errors rectification at the earliest stage & not repeated.
- Continuous improvement, increase productivity.
- Increase profits and company growth.

#### **External Benefits**

- Easy access to international market through demonstration of competence and improving competiveness.
- Improved customer satisfaction
- Consistency in quality of products and service.
- Customer confidence (reduce the amount of inspection).

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Self-Check -1

**Directions:** Answer all the questions listed below. Use the Answer sheet provided in the next page:

- 1. What is Quality?
- 2. List down Benefits of implementing quality management system

Score = \_\_\_\_\_

Rating: \_\_\_\_\_

*Note:* Satisfactory rating – 3 points

**Unsatisfactory - below 3 points** 

You can ask you teacher for the copy of the correct answers.

Name:			

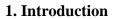
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Short Answer Questions

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**Information Sheet-2** 



**A Deviation** is a departure from standard procedures or specifications resulting in nonconforming material and/or processes or where there have been unusual or unexplained events which have the potential to impact on product quality, system integrity or personal safety.

#### **1.2.** Types of Deviations

Following are some examples of deviations raised from different functional areas of business:

- **Production Deviation** usually raised during the manufacture of a batch production.
- **Quality Improvement Deviation** may be raised if a potential weakness has been identified and the implementation will require project approval.
- Audit Deviation raised to flag non-conformance identified during internal, external, supplier or corporate audits.
- **Customer Service Deviation** rose to track implementation measures related to customer complaints.
- **Technical Deviation** can be raised for validation discrepancies. For example: changes in Manufacturing Instruction.
- **Material Complaint** rose to document any issues with regards to non-conforming, superseded or obsolete raw materials/components, packaging or imported finished goods.
- System Routing Deviation raised to track changes made to Bill of materials as a result of an Artwork change.

#### When to Report Deviation:

A Deviation should be raised when there is a deviation from methods or controls specified in manufacturing documents, material control documents, standard operating procedure for products and confirmed out of specification results and from the occurrence of an event and observation suggesting the existence of a real or potential quality related problems.

A deviation should be reported if a trend is noticed that requires further investigation. All batch production deviations (planned or unintended) covering all manufacturing facilities, equipment's, operations, distribution, procedures, systems and record keeping must be reported and investigated for corrective and preventative action.

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Reporting deviation is required regardless of final batch disposition. If a batch is rejected a deviation reporting is still required.

Self-Check -2	Written Test
Self-Check -2	vviitten rest

**Directions:** Answer all the questions listed below. Use the Answer sheet provided in the next page:

1. What is a Deviation?

2. Write Types of Deviations?

Score = \_\_\_\_\_

Rating: \_\_\_\_\_

*Note:* Satisfactory rating – 4 points

**Unsatisfactory - below 3 points** 

You can ask you teacher for the copy of the correct answers.

Name: \_\_\_\_\_

Date: \_\_\_\_\_

**Short Answer Questions** 



**Information Sheet-3** 



**Recording and Reporting Procedures** 

#### 3. Recording basic information on the quality performance

Basic information on the quality performance is recorded in accordance with workplace procedures, whereas Record of work quality is maintained according to the requirements of the company.

#### **Final product against workplace**

Technological advances have made computers an important part of every workplace. Many companies store valuable data on computer systems, databases and networks, and most workplace communication are done using computers and networks.

#### Benefits

Because most data is stored on computers and almost all communication is done on an organization's computer network, the security of the data is crucial for the success of an organization. Monitoring workplace computers can be done using a variety of software products that monitor computer networks. This software can also be used to monitor or track employee activity and productivity as well.

#### Effects

Monitoring workplace computers can secure data stored on computer systems, as well as ensure employees are using workplace computers for business purposes. Some monitoring software comes highly recommended at a reasonable cost and can be customized to an organization's needs. This requires some additional efforts by management or information technology staff, but proves it's a valuable tool to ensure the security of business data and integrity.

#### Considerations

When considering using computer monitoring software in the workplace, do extensive research on different products and services. Although some software is costly, it may be worth the investment to protect the integrity of a business. If an organization decides to use this software--inform employees. Allow employees to see the software and its capabilities by demonstrating its features in a group setting.

#### Instructions

• Make a space plan and measure the area where the desk will sit to ensure the right fit. Decide whether the desk will be straight or a corner unit, and how the desk will be supported, and plan

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accordingly. Straight desks are a simpler project, but corner units afford more workspace and often allow for the best use of the available area.

- Purchase supplies for the project, including counter tops, support system, and any brackets that may be required. Counter top can be cut at the time of purchase, or ordered to fit, so be certain to have exact measurements to ensure a correct fit without further cutting. Collect all tools needed for the project before beginning.
- Prepare your support system before assembling your desk. The simplest support solution is to use kitchen cabinets, metal filing cabinets, or sturdy plastic or medal drawers. This will make your desk both sturdy and easy to move and requires no tools, cutting, or drilling. This support solution is particularly idea for granite, metal, or stone counter top materials which are difficult to cut or drill.
- Install the chosen support system, ensuring that it is both the proper height, and level, before applying counter tops. If you've chosen cabinets or other form of freestanding support, be certain they're positioned at appropriate intervals to support the weight of the counter top.
- Affix the counter top to the support system one section at a time. If your counter is a heavy material, such as granite or stone, be certain the support system is sufficient to harbor the weight before applying the next section of counter. Once all sections of counter are installed, use a level to check that there the desk is even and level.
- Apply the end cap finishing kit where necessary and add any brackets that might be required to anchor the counter top. This step is optional but may be necessary to ensure your desk is both attractive and stable.

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Self-Check -3

**Directions:** Answer all the questions listed below. Use the Answer sheet provided in the next page:

- 1. Define quality Performance?
- 2. Write the Final product against workplace?

Score =	:

Rating: \_\_\_\_\_

*Note:* Satisfactory rating – 3 points

**Unsatisfactory - below 3 points** 

You can ask you teacher for the copy of the correct answers.

Name: \_\_\_\_\_

Date:	
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#### **Instruction Sheet**

This learning guide is developed to provide you the necessary information regarding the following content coverage and topics:

- Characteristics of Materials/Articles
- Quality Checks

This guide will also assist you to attain the learning outcome stated in the cover page. Specifically, upon completion of this Learning Guide, you will be able to:

- Identified Impact of the materials or component in final outcomes.
- Check materials, final products with quality standards and specifications.

#### **Learning Instructions:**

1. Read the specific objectives of this Learning Guide.

2. Follow the instructions described below 3 to 5.

3. Read the information written in the information "Sheet 1, Sheet 2,". Try to understand what are being discussed. Ask you teacher for assistance if you have hard time understanding them.

4. Accomplish the "Self-check 1, Self-check 2," in page \_\_\_, and \_\_\_\_\_ respectively.

5. Ask from your teacher the key to correction (key answers) or you can request your teacher to correct your work. (You are to get the key answer only after you finished answering the Self-check

6. If you earned a satisfactory evaluation from the "Self-check" proceed to "Information Sheet 2"
in page \_\_\_\_\_. However, if your rating is unsatisfactory, see your teacher for further instructions or go back to Learning Activity #1.

7. Submit your accomplished Self-check. This will form part of your training portfolio.

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**Information Sheet-1** 



#### 1. Materials

Material is the matter from which something can be made. Material can include but is not limited to raw and processed material, components or parts.

A quality characteristics or response is the performance characteristics of a product that is most critical to customers and often reflects the product quality. Selecting the right quality characteristics is critical to success of any industrial designed experiment.

Self-Check -1	Written Test

**Directions:** Answer all the questions listed below. Use the Answer sheet provided in the next page:

1. Define material?

Score = \_\_\_\_\_

Rating: \_\_\_\_\_

*Note:* Satisfactory rating – 2 points

**Unsatisfactory - below 2 points** 

You can ask you teacher for the copy of the correct answers.

Name: \_\_\_\_\_

Date:	
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**Short Answer Questions** 





**Quality Checks** 

#### **2.1 Visual Inspection**

Visual inspection is a common method of quality control, **data acquisition**, and **data analysis** Visual Inspection, used in maintenance of facilities, mean inspection of equipment and structures using human senses such as vision, hearing, touch and smell or any non-specialized inspection equipment.

#### **2.2 Physical Measurements**

#### Using appropriate measuring instruments

If you've shopped around for just the right desk for your space, but haven't found exactly what you're looking for, consider building your own. Counter top desks are a unique way to modify your work area. Whether starting with a brand new section counter top, or repurposing old counters after a remodel, counter top desks make a sturdy addition to your office furnishings. A moderately simple do-it-yourself project, building a counter top desk is considerably less expensive than having a custom desk built, and requires less than one day's work to complete from start to finish.

#### Instructions

Make a space plan and measure the area where the desk will sit to ensure the right fit. Decide whether the desk will be straight or a corner unit, and how the desk will be supported, and plan accordingly. Straight desks are a simpler project, but corner units afford more workspace and often allow for the best use of the available area.

Purchase supplies for the project, including counter tops, support system, and any brackets that may be required. Counter top can be cut at the time of purchase, or ordered to fit, so be certain to have exact measurements to ensure a correct fit without further cutting. Collect all tools needed for the project before beginning.

Prepare your support system before assembling your desk. The simplest support solution is to use kitchen cabinets, metal filing cabinets, or sturdy plastic or medal drawers. This will make your desk both sturdy and easy to move and requires no tools, cutting, or drilling. This support





solution is particularly idea for granite, metal, or stone counter top materials which are difficult to cut or drill.

Install the chosen support system, ensuring that it is both the proper height, and level, before applying counter tops. If you've chosen cabinets or other form of freestanding support, be certain they're positioned at appropriate intervals to support the weight of the counter top.Affix the counter top to the support system one section at a time. If your counter is a heavy material, such as granite or stone, be certain the support system is sufficient to harbor the weight before applying the next section of counter. Once all sections of counter are installed, use a level to check that there the desk is even and level.

Apply the end cap finishing kit where necessary and add any brackets that might be required to anchor the counter top. This step is optional but may be necessary to ensure your desk is both attractive and stable.

#### 2.3 Check against Design/Specifications

#### **Standard specifications**

Standard specification is a precisely defined specification, established through a standardization process and meant to be used for all purchases of a particular item.

Self-Check -2 Written Test
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**Directions:** Answer all the questions listed below. Use the Answer sheet provided in the next

page:

- 1. What is Visual Inspection?
- 2. Define Standard specification?

Score = \_\_\_\_\_

Rating: \_\_\_\_\_

#### *Note:* Satisfactory rating – 3 points Unsatisfactory - below 3 points

You can ask you teacher for the copy of the correct answers.

Name: \_\_\_\_\_

Date: \_\_\_\_\_





#### **Instruction Sheet**

## LG32:-Study causes of quality deviations

This learning guide is developed to provide you the necessary information regarding the following **content coverage** and topics:

- Analyses on Quality Deviation's
- Preventive Action

This guide will also assist you to attain the learning outcome stated in the cover page. Specifically, upon completion of this Learning Guide, you will be able to:

- Investigate and report causes of deviations from final products in workplace procedures.
- Recommend suitable preventive action in workplace *quality standards*.

#### **Learning Instructions:**

1. Read the specific objectives of this Learning Guide.

2. Follow the instructions described below 3 to 5.

3. Read the information written in the information "Sheet 1, Sheet 2,". Try to understand what are being discussed. Ask you teacher for assistance if you have hard time understanding them.

4. Accomplish the "Self-check 1, Self-check 2," in page \_\_, \_\_, \_\_ and \_\_\_\_ respectively.

5. Ask from your teacher the key to correction (key answers) or you can request your teacher to correct your work. (You are to get the key answer only after you finished answering the Self-check

6. If you earned a satisfactory evaluation from the "Self-check" proceed to "Information Sheet 2"
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7. Submit your accomplished Self-check. This will form part of your training portfolio.

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**Information Sheet-1** 



#### A Standard Procedure for Quality Assurance Deviation Management

Causes of deviations from final products with workplace procedures

#### **Different Levels of Deviation Risks:**

For the ease of assessing risk any deviation can be classified into one of the three levels 1, 2 & 3 based on the magnitude and seriousness of a deviation.

#### Level 1: Critical Deviation

Deviation from Company Standards and/or current regulatory expectations that provide immediate and significant risk to product quality, patient safety or data integrity or a combination/repetition of major deficiencies that indicate a critical failure of systems

#### Level 2: Serious Deviation

Deviation from Company Standards and/or current regulatory expectations that provide a potentially significant risk to product quality, patient safety or data integrity or could potentially result in significant observations from a regulatory agency or a combination/repetition of "other" deficiencies that indicate a failure of system(s).

#### Level 3: Standard Deviation

Observations of a less serious or isolated nature that are not deemed Critical or Major, but require correction or suggestions given on how to improve systems or procedures that may be compliant but would benefit from improvement (e.g. incorrect data entry).

#### How to Manage Reported Deviation:

The department Manager or delegate should initiate the deviation report by using a standard deviation form as soon as a deviation is found. Write a short description of the fact with a title in the table on the form and notify the Quality Assurance department within one business day to identify the investigation.

QA has to evaluate the deviation and assess the potential impact to the product quality, validation and regulatory requirement. All completed deviation investigations are to be approved by QA Manager or

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delegate. QA Manger has to justify wither the deviation is a Critical, Serious or Standard in nature. For a deviation of either critical or serious nature QA delegate has to arrange a Cross Functional Investigation.

For a standard type deviation a Cross functional Investigation (CFI) is not necessary. Immediate corrective actions have to be completed before the final disposition of a batch. Final batch disposition is the responsibility of Quality Assurance Department

Self-Check -1	Written Test

**Directions:** Answer all the questions listed below. Use the Answer sheet provided in the next page:

1. List and explains levels of Deviation Risks

Score = \_\_\_\_\_

Rating: \_\_\_\_\_

#### *Note:* Satisfactory rating –3 point

Unsatisfactory –below 3 points

You can ask you teacher for the copy of the correct answers.

Name:	

Date: \_\_\_\_\_

**Short Answer Questions** 

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#### 2. Workplace Prevention and Response

#### Workplace Violence

Workplace violence can be any act of physical violence, threats of physical violence, harassment, pressure, or other threatening, disruptive behavior that occurs at the work site. Workplace violence can affect or involve employees, visitors, contractors, and other non-Federal employees.

#### Responsibilities

It is up to each employee to help make a safe workplace for all of us. The expectation is that each employee will treat all other employees, as well as customers and potential customers, with dignity and respect. You can and should expect management to care about your safety and to provide as safe a working environment as possible by having preventive measures in place and, if necessary, by dealing immediately with threatening or potentially violent situations which occur.

#### • Prevention of Workplace Violence

A sound prevention plan is the most important and, in the long run, the least costly portion of any agency's workplace violence program.

#### • Identifying Potentially Violent Situations

If you ever have concerns about a situation which may turn violent, alert your supervisor immediately and follow the specific reporting procedures provided by your agency. It is better to err on the side of safety than to risk having a situation escalate.

#### • Responding to Violent Incidents

No matter how effective agencies' policies and plans are in detecting and preventing incidents, there are no guarantees against workplace violence. Even the most responsive employers face this issue. When a violent incident does occur, it is essential the response be timely, appropriate to the situation, and carried out with the recognition that employees are traumatized and that the incident's aftermath has just begun.

#### • Disclosure of Information

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Disclosing information obtained from employees without their written consent. An exception to this prohibition however, is if an employee specifically threatens another person

Self-Check -2	Written Test

**Directions:** Answer all the questions listed below. Use the Answer sheet provided in the next page:

1. What are the six Workplace Prevention procedures?

Score = \_\_\_\_\_

Rating: \_\_\_\_\_

*Note:* Satisfactory rating –5 point Unsatisfactory – below 5 point

You can ask you teacher for the copy of the correct answers.

Name:
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Date: \_\_\_\_\_

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# Instruction Sheet LG33:-Complete documentation

This learning guide is developed to provide you the necessary information regarding the following **content coverage** and topics:

- Quality Performance Indicators
- Documentation Procedures

This guide will also assist you to attain the learning outcome stated in the cover page. Specifically, upon completion of this Learning Guide, you will be able to:

- Records Information on quality and other indicators of production performance
- Records production processes and outcomes.

#### **Learning Instructions:**

1. Read the specific objectives of this Learning Guide.

2. Follow the instructions described below 3 to 5.

3. Read the information written in the information "Sheet 1, Sheet 2,". Try to understand what are being discussed. Ask you teacher for assistance if you have hard time understanding them.

4. Accomplish the "Self-check 1, Self-check 2," in page \_\_\_\_, \_\_\_\_ and \_\_\_\_\_ respectively.

5. Ask from your teacher the key to correction (key answers) or you can request your teacher to correct your work. (You are to get the key answer only after you finished answering the Self-check

6. If you earned a satisfactory evaluation from the "Self-check" proceed to "Information Sheet 2"
in page \_\_\_\_\_. However, if your rating is unsatisfactory, see your teacher for further instructions or go back to Learning Activity #1.

7. Submit your accomplished Self-check. This will form part of your training portfolio.

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**Information Sheet-1** 



#### **1. Quality Performance**

Performance measures designed to move associates toward business goals can be a powerful method for action. Because "you get what you measure," it is important to think through how and what you measure so you can achieve the desired results. And measuring profitability is attractive because it goes straight to the heart of every builder's existence.

Performance measures of profitable builders are as varied as their business strategies. A good place to start is examining your own business goals and tune-up your measures at the company level. Then proceed to create department measures that align with company goals. Your organization will be the winner.

#### 1.2 The Six-Factor Model of Personality in the Workplace

The following are the six-factor model with job performance and other job-related activities. Motivation, deviation, absences, and job satisfaction are related to the five factors.

#### **1.2.1** Motivation in the Workplace

Motivation is the driving force by which humans achieve their goals. Motivation is said to be intrinsic or extrinsic. The term is generally used for humans but it can also be used to describe the causes for animal behavior as well. According to various theories, motivation may be rooted in a basic need to minimize physical pain and maximize pleasure, or it may include specific needs such as eating and resting, or a desired object, goal, state of being, ideal, or it may be attributed to less-apparent reasons such as selfishness, morality, or avoiding morality.

#### 1.2.2 Job Satisfaction

Job satisfaction has been defined as a pleasurable emotional state resulting from the consideration of one's job; an affective reaction to one's job; and an attitude towards one's job. Weiss (2002) has argued that job satisfaction is an attitude but points out that researchers should clearly distinguish the objects of cognitive evaluation which are affect (emotion), beliefs and behaviors.

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#### **1.2.3 Departure in the Workplace**

Workplace deviance occurs when an employee voluntarily pursues a course of action that pressures the well-being of the individual or the organization.

Employees who had a positive perception of their workplace were less likely to pursue deviant behavior. Research indicates that personality acts as a moderating factor: workplace deviance was more likely to be endorsed with respect to an individual when both the perception of the workplace was negative and emotional stability.

#### **1.2.4 Performance in the Workplace**

The five factors, the single factor of carefulness is the most predictive of job performance.

#### 1.2.5 Absences

Job absence is very much a part of job performance: employees are not performing effectively if they do not even come to work. Shy, careful employees are much less likely to be absent from work, as opposed to extraverted employees who are low on carefulness.

#### 1.2.6 Teamwork

Oftentimes in the workplace the ability to be a team player is valued and is critical to job performance. Although this strengthen the case that job performance is related to the five-factor model via increased cooperativeness among coworkers, the role of personality by implying that actual job performance (task performance) is related to cognitive ability and not to personality.

#### Using 5S to Increase Performance in the Workplace

5S is the name of a workplace organization methodology that uses a list of five Japanese words which are **seiri** (Sorting), **seiton** (Straightening or setting in order / stabilize), **seiso** (Sweeping or shining or cleanliness / systematic cleaning), **seiketsu** (Standardizing) and **shitsuke** (Sustaining the discipline or self-discipline). Translated into English, they all start with the letter "S". The list describes how to organize a work space for efficiency and effectiveness by identifying and storing the items used, maintaining the area and items, and sustaining the new order. The decision-making process usually comes from a dialogue about standardization which builds a clear understanding among employees of how work should be done. It also instills ownership of the process in each employee.

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The QCDSM program ensures this will happen on a daily basis. In addition to QCDSM, members of senior management must carry out periodic inspections of each target area. One common error by senior management is never being visible on the factory floor.

5S provides the foundation for improving performance through continuous improvement. It focuses on:

- Increasing quality by removing waste from the workplace.
- Provide reduction in operating costs by reducing non value added activities.
- Improving delivery by simplifying processes and removing obstacles
- Improving safety through improved housekeeping and identification of hazards

Provide an environment where continuous improvement is embraced through workers problem solving and suggestions, thereby improving morale.

Simply put, 5S works best if the implementation of the program is based on the 5S Performance Improvement Formula:

#### P=Q+C+D+S+M

Where;

- **P** Increase productivity.
- **Q** Improve product quality.
- **C** Reduce manufacturing costs.
- **D** Ensure on-time delivery.
- S Provide a safety working environment
- M Increase worker moral

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Self-Check -1

**Directions:** Answer all the questions listed below. Use the Answer sheet provided in the next page:

- 1. Write the Six-Factor Model of Personality in the Workplace?
- 2. Define the job Absences?
- 3. Define the Motivation?

Score = \_\_\_\_\_

Rating: \_\_\_\_\_

*Note:* Satisfactory rating – 5 point Unsatisfactory – below 5 point

You can ask you teacher for the copy of the correct answers.

Name: \_\_\_\_\_

Date: \_\_\_\_\_

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**Information Sheet-2** 

**Documentation Procedures** 



#### 2. Procedures

A **procedure** is step-by-step sequence of activates, work instruction or course of action that must be followed in the same order to correctly perform a task. Repetitive procedures are called routines.

A procedure is a section of a program that performs a specific task.

A procedure is a series of steps, taken together, to achieve a desired result. It is a particular way of accomplishing something as in a repetitive approach or cycle to accomplish an end result.

#### **Quality system procedures**

- Develop and implement quality system procedures that are consistent with your quality policy
- Develop your procedures for all areas of your quality system.
- Document your procedures, and keep them up to date.

Each procedure should:

- Specify its purpose and scope.
- Describe how an activity should be carried out.
- Describe who should carry out the activity.
- Explain why the activity is important to quality.
- Describe when and where it should be carried out.
- Explain what tools and equipment should be used.
- Explain what supplies and materials should be used.
- Explain what documents and records should be kept.

Procedures may also refer to detailed work instructions that explain exactly how the work should be done.

#### **Production process**

The production process is concerned with transforming a range of inputs into those outputs that are required by the market.

The transforming resources include the buildings, machinery, computers, and people that carry out the transforming processes. The transformed resources are the raw materials and components

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that are transformed into end products.

Any production process involves a series of links in a production chain. At each stage value is added in the course of production. Adding value involves making a product more desirable to a consumer so that they will pay more for it. Adding value therefore is not just about manufacturing, but includes the marketing process including advertising, promotion and distribution that make the final product more desirable.

It is very important for businesses to identify the processes that add value, so that they can enhance these processes to the ongoing benefit of the business.

#### **Types of process**

There are three main types of process: job, batch and flow production.

#### • Job production

Job or \'make complete\' production is the creation of single items by either one operative or a team of operative\'s. Job production is unique in the fact that the project is considered to be a single operation, which requires the complete attention of the operative before he or she passes on to the next job. Examples from the service industries include cutting hair, and processing a customer's\' order in a store.

#### Batch production

The term batch refers to a specific group of components, which go through a production process together. As one batch finishes, the next one starts. For example on Monday, Machine A produces a type 1 engine part, on Tuesday it produces a type 2 engine part, on Wednesday a type 3 and so on. All engine parts will then go forward to the final assembly of different categories of engine parts.

#### • Flow production

Batch production is described as \'intermittent\' production and is characterized by irregularity. If the rest period in batch production disappeared it would then become flow production. Flow production is therefore a continuous process of parts and sub-assemblies passing on from one stage to another until completion.

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Self-Check -2

**Directions:** Answer all the questions listed below. Use the Answer sheet provided in the next page:

- 1. Define Procedures?
- 2. Define the production process?
- 3. Write the Types of production process?

Score = \_\_\_\_\_

Rating: \_\_\_\_\_

*Note:* Satisfactory rating – 4 point Unsatisfactory – below 4 point

You can ask you teacher for the copy of the correct answers.

Name: \_\_\_\_\_

Date:	
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**Short Answer Questions** 

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