Ethiopian TVET-System

INFORMATION TECHNOLOGY SUPPORT SERVICE

Level I

LEARNING GUIDE #17

Unit of Competence:	Apply Quality Standards
Module Title:	Applying Quality Standards
LG Code:	ICT ITS1 M06 L04 LG-17
TTLM Code:	ICT ITS1 TTLM07 1019v1

LO4: Study Causes of Quality Deviations

Instruction Sheet	Learning Guide # 25

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

- Causes of deviations from final products with workplace 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 –

- Investigate and report causes of deviations from final products in accordance with workplace procedures
- Recommend suitable preventive action based on workplace quality standards and identified causes of deviation from specified quality standards of materials or final product

Learning Instructions:

1. Read the specific objectives of this Learning Guide.
2. Follow the instructions described below 3 to 6.
3. Read the information written in the information “Sheet 1, Sheet 2, Sheet 3 and Sheet 4, Sheet 5 ” in page 3, 22, 29, 33 and 35 respectively.
4. Accomplish the “Self-check 1, Self-check t 2, Self-check 3 and Self-check 4, Self-check 5 in page 16, 27, 32, 34 and 37 respectively.
5. If you earned a satisfactory evaluation from the “Self-check” proceed to “Operation Sheet 1 in page 18.
6. Do the “LAP test” in page 20, 28.

Information Sheet 1	Quality performance in workplaces

- **A Standard Procedure for Quality Assurance Deviation Management**
  - ✓ **What is a Deviation?**

    A Deviation is a departure from standard procedures or specifications resulting in non-conforming 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.

  - ✓ **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, equipments, operations, distribution, procedures, systems

and record keeping must be reported and investigated for corrective and preventative action.

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

- **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 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.

- **Workplace Prevention and Response**
  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**

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 1	Written Test

Name: _____ Date: _____

Instruction*:* Answer all the questions listed below, if you have some clarifications- feel free to ask your teacher.

Experts

The development of this Learning Gide for the TVET Program Information technology support service Level I.

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