# APPLY QUALITY CONTROL

## NTQF LEVEL -III

# LEARNING GUIDE -61

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| UNIT OF COMPETENCE: - | APPLY QUALITY CONTROL |
| MODULE TITLE: - | APPLYING QUALITY CONTROL |
| LG CODE: | HLT MLT M012 LO4-LG-61 |
| TTLM CODE: | HLT MLT TTLM 0919V1 |

# LO4: **Study causes of quality deviations**

| **Instruction Sheet** | **Learning Guide 61** |
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This learning guide is developed to provide you the necessary information

regarding the following content coverage and topics –

- Cause of deviation and report accordance with organizational procedures

- Preventive action based on organizational quality

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 cause of deviation and report in accordance with organization procedures.
- Recommend suitable preventave action based on organization quality standards and identified causes of deviation from specified quality standards of final service or output.

**Learning Instructions**

1. Read the information written in the “Information Sheets”.
2. If you earned a satisfactory evaluation proceed to next module. However, if your rating is unsatisfactory, see your teacher for further instructions.
3. Read the “Operation Sheet” and try to understand the procedures discussed.
4. Practice the steps or procedures as illustrated in the operation sheet. Go to your teacher if you need clarification or you want answers to your questions or you need assistance in understanding a particular step or procedure
5. **Do the “LAP test” (if you are ready). Request your teacher to evaluate your performance and outputs. Your teacher will give you feedback and the evaluation will be either satisfactory or unsatisfactory. If unsatisfactory, your teacher shall advice you on additional work. But if satisfactory you can proceed to the next Learning Guide.**

| **Information sheet 11** | **Study causes of quality deviations** |
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## 4.1. Investigating and reporting causes of deviations from final outputs or services.

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. For compliance to GMP and the sake of continuous improvement, these deviations are recorded in the form of Deviation Report (DR).

**Types of Deviations:**

Following are some examples of deviations raised from different functional

areas of business:

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

**When to Report Deviation:**

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 mustbe 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. If a critical or serious deviation leads to a CFI, corrective and preventive actions should be determined and follow up tasks should be assigned to area representatives. Follow up tasks should be completed within 30 business days of the observation of deviation. If a deviation with CFI can not be completed within 30 business days, an interim report should be generated detailing the reason for the delay and the progress so far. After successful completion of the Follow up tasks Deviation should be completed and attached with the Batch Report /Audit report/ Product complaint report /Safety investigation report as appropriate.

### 4.1.1 investigation and report

The purpose of this guidance document is intended to provide information on the management and documentation of deviations from SOPs and study protocols under the direction of the University of Texas Medical Branch-Galveston (UTMB-Galveston) personnel participating in Good Laboratory Practices (GLP) facility operations and studies. Individual laboratories may establish internal business operations to handle
such deviations, but the minimum requirements are stated within this document.

| **Self check 11** | **Mcq** |
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**Chose the best answer for the following questions**

1. After receiving the Deviation information, the director should

    A. Identify the root cause of the deviation
    B. Identify the scope of the deviation
    C. Assess the impact of the deviation on the GLP study.
    D. All

2. Which one of the following is correct about the time in which deviation is reported?

A. When there is a deviation from methods or controls specified in manufacturing documents
B. when there is a deviation from standard operating procedure
C. If a trend is noticed that requires further investigation
D. All

**Answer Sheet**

**Score = _____**

**Rating: _____**

Name: _____Date: _____

I- Enumeration:

1. _____
2. _____

| **Information sheet 12** | **Recommending suitable preventive action**. |
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## 4.2 Recommending suitable preventive action.

Quality professionals frequently express confusion as to the difference between corrective and preventive action. A corrective action deals with a nonconformity that has occurred, and a preventive action addresses the potential for a nonconformity to occur. Many ISO 9000 registrar auditors tell their clients to use separate procedures

and forms to document each type of action. Nothing in the standard says this must be done, but p. 13 includes the word “prevent” in the clauses on corrective and preventive action.

**Common Misconceptions**

There are three common misconceptions about corrective and preventive action:

- The standard calls for documenting every occurrence of a nonconformity.
- A preventive action is really just calling a corrective action something different.
- The major reengineering of a process, product or service, or the introduction of a new process or equipment, is not a candidate for preventive action documentation.

One way to dispel these is by separating situations into what I call a patch (a single occurrence of a nonconformity that involves little risk and needs not be recorded), a corrective action (a more serious nonconformity involving some risk that requires action to prevent recurrence and must be recorded), a preventive action (a process that can be improved to prevent occurrence of a nonconformity and is to be documented) or a developmental action (a planned change to introduce a new process or product in response to strategic objectives, documented as a preventive action). Consider the examples in Table 1. (Go to www.asq.org, and click on the cover of Quality Progress.)

**TABLE 1** Four Types of Action

| Situation | Frequency | Suggested action | Type | Comment |
|---|---|---|---|---|
| Final inspection returns part to operator to correct. Corrected part returned to original lot. | Single occurrence before shipment. | Rework, repair. | Patch. | May not need to record; depends on magnitude of risk and frequency. |
| Item or work unusable. | Single occurrence before shipment. | Scrap. | Patch. | May not need to record; depends on magnitude of risk and frequency. |
| Item or service does not meet customer requirements. | Serious. Occurred more than once and after shipment. | Assign for action (and contact customer, as appropriate):<br>• Find root cause.<br>• Correct.<br>• Document.<br>• Evaluate effectiveness. | Corrective action. | |
| Situation that could potentially affect process, product or service is found. | Nothing has occurred, yet. | Assign for action:<br>• Analyze what ifs.<br>• Evaluate potential effects of failure.<br>• Identify solution.<br>• Implement solution.<br>• Document.<br>• Evaluate effectiveness. | Preventive action. | May require long-term follow-up to ensure effectiveness. |
| Desire to improve the process, product or service for reasons other than nonconformance. | No nonconformance exists, and no potential for one is detected. | Assign project:<br>• Analyze present process.<br>• Reengineer process.<br>• Document process.<br>• Evaluate effectiveness of reengineered process. | Developmental action. Use preventive action system with project management. | Organizations frequently forget to take credit for this type of breakthrough project. |

Table 1: preventive Action

## Corrective Action Process

Locate and document the root cause of the nonconformity.Scan the entire system to ensure no other similar nonconformity could occur.Analyze the effect such a nonconformity may have had on a product or service produced before the nonconformity was discovered, and take action appropriate to the severity of the situation by either recalling the product, notifying the customer, downgrading or scrapping product.

Establish thorough follow-up to ensure the correction is effective and recurrence has been prevented.Preventive Action Processtake proactive steps to ensure a potential nonconformity does not occur.Employ process and system analysis to determine how to build in safeguards and process changes to prevent nonconformance. For example, use a failure mode and effects analysis to identify risks and potential deficiencies and to set priorities for improvement.Developmental Action Process (Treated as Preventive Actions)

Initiate an improvement project, with project plans, justification for planned expenditures, resource controls and evaluation.Contain a related series of actions, often separated by long periods so you can wait and see progress and results.
Use a variety of appropriate disciplines at different times during the project.
Establish a means for communicating what has been done and what has to be done to facilitate communication about changes to project team members.
Include a clear trail of actions taken and decisions made to substantiate the decision to proceed, document lessons learned and avoid needless reinvention on future similar projects.Documenting and controlling corrective and preventive actions ensure appropriate action is taken within a reasonable timeframe and the resulting changes work.

| Self check 13 | Written test |
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## Answer the following question

1. What is Deviation?
2. Write down the three Levels of Deviation Risks?
3. How do we Manage Reported Deviation?
4. What are the main causes of quality deviation?

**Answer Sheet**

**Score = _____**

**Rating: _____**

Name: _____Date: _____

I- short answer

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| Information sheet 14 | Identifying causes of deviation from specific quality standards |
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## 4.3. Identifying causes of deviation from specific quality standards

Causes of poor quality may be grouped in six main categories:

Simply **5 M and environment**

- M- man
- M-materials
- M-machine
- M-method
- M-management

If these all criteria are fulfilled, can lead to good quality standards

**Machine**

Machines can cause poor quality or may cause deviation from quality standard in different ways:

- Lack of capability
- Lack of maintenance
- Non availability of spares
- Wear and tear
- Improper setup/calibration
- Outdated technology

**Material**

Machines can cause poor quality or may cause deviation from quality standard in different ways:

- Low grade material
- Unspecified material
- Variation

**Management**
Machines can cause poor quality or may cause deviation from quality standard in different ways:

- Lack of vision, mission, value system
- Failing to identify/understand customer needs/requirements
- Short term planning
- Inadequate/poor planning
- Flawed/Mistaken incentives and indicators
- Favoritism/unfairly generous treatment of one person or group
- Lack of supervision/monitoring
- Low Attitude towards change
- Lack of decision making and communication skills
- Lack of process understanding
- Lack of fact based decision making

**Method**
Machines can cause poor quality or may cause deviation from quality standard in different ways:

- Lack of procedures
- Procedures not followed
- Conflicting requirements
- Procedures not communicated
- Too rigid or too relaxed requirements

**Environment**
Poor quality can also be cause by the environment deviation in:

- temperature
- humidity
- hour of the day (light conditions)

| Self-Check | Mcq |
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**Chose the best answer for the following questions**

1. which one of the following item can cause poor quality standard or deviation from specific quality standards?
   A. Material
   B. Machine
   C. Method
   D. All
2. Which one of the following environmental factor cause poor quality standard?
   A. Humidity
   B. Lack of supervision/monitoring
   C. Lack of process understanding
   D. Lack of procedures

3. Which one of the following management factor cause poor quality standard?

   A. Lack of procedures
   B. Lack of fact based decision making
   C. Temperature
   D. All
4. Which one of the following machine factor cause poor quality standard?

   A. Lack of process understanding
   B. Lack of fact based decision making
   C. Short term planning
   D. Non availability of spares

**Answer Sheet**

**Score = _____**

**Rating: _____**

Name: _____Date: _____

I- Enumeration:

1. _____
2. _____
3. _____
4. _____

**References and Manuals**

1.Claire capon (2000) **understanding organizational context**, Pearson education.

2.Elizabeth Chell. (2001) **Entrepreneurship: globalization, innovation and development.** homson learning.

3.**Trainer guide manual**, (Micro enterprise creation, small business management, business growthstrategies), 2002.