Horticultural Crops Production

Level III

Learning Guide –93

Unit of Competence: Apply Quality Control

Module Title: Applying Quality Control

LG Code: AGR HCP3 M19LO1- 93

TTLM Code: AGR HCP3 TTLM 0120V1

LO1:- Established quality standards.

Instruction sheet 1	Learning Guide 93

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

- Acquiring and confirming agreed quality standard and procedures.
- Introducing standard procedures.
- Providing quality standard and procedures documents.
- Revising / updating standard 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:

- Acquire and confirm agreed quality standard and procedures.
- Introduce standard procedures.
- Provide quality standard and procedures documents.
- Revise / update standard procedures.

Learning Instructions

1. Read the specific objectives of this Learning Guide.
2. Follow the instructions described below 3 to 4.
3. Read the information written in the information “Sheet 1, Sheet 2, Sheet 3 and Sheet 4”.
4. Accomplish the “Self-check 1, Self-check t 2, Self-check 3 and Self-check 4” **in page 5, 10, 13 and 16** respectively.

Information Sheet-1	Acquiring and confirming agreed quality standard and procedures.

1.1. Definition of quality: -

it is relative term which have no inversely definition.

It is characteristics property that defines the apparent individual nature of something.

It is the degree of goodness or badness.

A 'standard' is a result of a particular standardization effect, approved by the recognized authority. It may take the form of a document containing a set of conditions to be fulfilled, a fundamental unit or physical constituent or an object for physical comparison.

There are different levels of standards, which may be listed as:

- An Individual Standard
- A Company Standard
- An Association Standard
- A National Standard
- An International Standard

The level is determined by the specific interests involved in creating and using the standard in day-to-day operations.

There are various benefits to standardization. To mention a few briefly; the following are listed:

1. To the Producer— Rationalization of manufacturing processes, improved control of processes, high rate of production, reduction of inventories ultimate increase in sales and profits.

2. To the Consumer—Assurance of quality of products and services purchased, better value for money spent.

3. To the Trade— Minimization of delays, workable basis for acceptance or rejection of goods, opening of larger markets, reduction in cost of handling transactions.

4.To the Technologist— increased knowledge of properties, possibilities of application of materials, accepted methods of tests and procedures, guidance for formulation of R & D programs.

Defining work and standard is not our ultimately a common task rather our aim is how do you assess complete work against work place standard. So based on aspect of standard and procedures you can check our complete work.

Standardization is the process of formulating and applying the rules for an orderly approach to a specific activity - for the benefit of all - with the co-operation of all concerned and in particular for the promotion of optimum overall economy, taking due account of functional conditions and safety requirements.

Standardization is based on the consolidated results of science, technology and experience. It determines not only the basis for the present but also for future development and it should keep pace with advances.

Procedure: procedure is a set of written instructions that identifies the health and safety issues that may happen from the jobs and tasks that make up a system of work.

1.2. Developing Quality standard procedures

The development of sustainable management systems is a high priority globally as social and environmental aspects of horticulture become increasingly important to both consumers and producers. Good practices at farm level with regard to horticulture crop production, management, post-harvest handling and the environment are essential tools to ensure that both the needs of the food industry. . A safe and hygienic working environment must be provided, and occupational health and safety practices which prevent accidents and injury must be promoted. This includes protection from fire, accidents and toxic substances. Lighting, heating and ventilation systems must be adequate. Employees must have access at all expectations of consumers are met.

To enable good horticultural products quality and safety at farm level, all levels of production chain and agronomic practice have to be properly managed i.e. Quality assurance of fruit production through: criteria pertaining to the accommodation and care of fruit.

, they have slow response, allow small sample size to work with, and they delay in the release of food.

Self-Check 1	Written Test

Name: _____ Date: _____

Directions: Answer all the questions listed below. Illustrations may be necessary to aid some explanations/answers.

1. Define quality? (5 points)
2. Define standard? (5pts)
3. What Is Standardization? (5points)

Note: Satisfactory rating -15 points and Unsatisfactory – below 15 points

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

You can ask your teacher for the copy of the correct answers

Information Sheet-2	Introducing standard procedures.

Definition

A Standard Operating Procedure is a document which describes the regularly recurring operations relevant to the quality of the investigation. The purpose of a SOP is to carry out the operations correctly and always in the same manner. A SOP should be available at the place where the work is done

An important aspect of a quality system is to work according to unambiguous Standard Operating Procedures (SOPs). In fact the whole process from sampling to the filing of the analytical result should be described by a continuous series of SOPs.

A SOP for a laboratory can be defined as follows:

A SOP is a compulsory instruction. If deviations from this instruction are allowed, the conditions for these should be documented including who can give permission for this and what exactly the complete procedure will be. The original should rest at a secure place while working copies should be authenticated with stamps and/or signatures of authorized persons.

Several categories and types of SOPs can be distinguished. The name "SOP" may not always be appropriate, e.g., the description of situations or other matters may better designated protocols, instructions o simply registration forms. Also worksheets belonging to an analytical procedure have to be standardized (to avoid jotting down readings and calculations on odd pieces of paper).

- **A number of important SOP types are:**
    - **Fundamental SOPs**. These give instructions how to make SOPs of the other categories.
    - **Methodic SOPs**. These describe a complete testing system or method of investigation.
    - **SOPs for safety precautions**. Standard procedures for operating instruments, apparatus and other equipment.
    - **SOPs for analytical methods**. Sops for the preparation of reagents.

- **SOPs for receiving and registration of samples**. SOPs for Quality Assurance.
- SOPs for archiving and how to deal with complaints

The following are common procedures for checking the quality of completed work against work place standards;

1) Select work product to be evaluated based on documented work place standards
   Note; work products can include services produced by a process whether the recipient of the service is internal or external to the organization.
2) Establish and maintain clearly stated criteria for the evaluation of selected work products.
   The intent of the above procedure is to provide criteria, based on business needs, such as the following;
   - What will be evaluated during the evaluation of a work product
   - When or how often a work product will be evaluated
   - How the evaluation will be conducted
   - Who must be involved in the evaluation
3) Use the stated criteria during the evaluations of selected work products
4) Evaluate selected work products before they are delivered to the customer
5) Evaluate work products at selected time intervals
6) Identify each cases of noncompliance found during the evaluations
   After setting (establishing) quality standards for organization/company/. The new established quality standards should be introducing to organization staff and also if it is necessary, the new standard procedures should be updating.

To establish that the Quality (Management) System is achieving the expected results and meeting the Company's requirements, continuing to conform to the Standard, continuing to satisfy the customer' needs and expectations, and functioning in accordance with the established Operating Procedures.

a) To expose irregularities or defects in the System, identify weaknesses and evaluate possible improvements.

b) To review the effectiveness of previous corrective actions, and to review the adequacy and suitability of the management system for current and future operations of the Company.

c) To review any complaints received, identify the cause and recommend corrective action if required.

d) To review the finding of internal/ external audits and identify any areas of recurring problems or potential improvements.

e) To review the reports of nonconforming items and trend information to identify possible improvements.

Internal audits of the Quality System are undertaken at least once per annum to confirm that the function concerned is adhering to the Company's Procedures. A comprehensive Audit Program is compiled at least a year in advance however, should particular needs be identified, and the frequency of audit may be increased at the discretion of the Quality Manager.

Audits are undertaken by auditors who are trained in auditing and not directly responsible for the functions being audited within that Company. Nonconformance observed is brought to the attention of the person responsible, and is recorded, documented and subject to timely corrective action to ensure full rectification. Demonstrating how the work activities are completed Identifying final products or faulty pieces and isolating them. Recording and reporting faults

General guidance on specifying user and organizational requirements and objectives is provided.

The following should be documented within the specification:

- Identification of the range of relevant users and other stakeholders
- Clear statement of design goals
- The requirements with an indication their priority levels

- Measurable benchmarks against which the emerging design can be tested
- Evidence of acceptance of the requirements by the stakeholders
- Acknowledgement of statutory or legislative requirements

. It is also important to manage changing

A requirement as the system develops.

Procedures shall be documented, implemented and maintained to confirm the following:

- demonstrate packaging complies with relevant food safety / product legislation and suitability for use
- Where packaging materials pose a product safety risk, special handling procedures shall be in place to prevent product contamination or spoilage. Records shall be maintained of packaging failures and appropriate corrective actions
- Where modified atmosphere is utilized in product packaging the suitability of the gas mix shall be validated for the shelf life of the product and appropriate control systems shall be in place to manage the delivery of food grade gas to each pack. Seal effectiveness shall also be monitored
- Any partially used packaging materials transferred from production lines shall be effectively protected prior to being returned to storage. Product contact liners, work in progress contact liners or raw material contact liners shall be appropriately colored and of sufficient gauge to prevent accidental product contamination

self-check 2	written test

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

1. What is A Standard Operating Procedure? (5 point)
2. List number of important SOP types? (5 points)

Note: **Satisfactory rating - 10 points** **Unsatisfactory - below 10 points**

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

Answer Sheet

Score = _____

Rating: _____

Name: _____ Date: _____

Information Sheet-3	Providing quality standard and procedures documents.

What is quality standards?

Quality management standards are details of requirements, specifications, guidelines and characteristics that products, services and processes should consistently meet in order to ensure:

Quality management standards establish a framework for how a business manages its key activities. They identify an agreed way of doing something, either making a product, managing a process or delivering a service.

Elements of Quality standards

- their quality matches expectations
- they are fit for purpose
- they meet the needs of their users

Quality standards are designed to ensure companies meet the minimum requirements to become an integral part of almost every industry from products.

1.3. Documentation of quality standard procedures

.Policy on marketing of horticultural products, and the broad national policies and strategies such as Liberalization, Privatization, Decentralization policy (Local Government Act); the Poverty Eradication Action Plan (PEAP), Plan for Modernization of Agriculture (PMA) and the National Agricultural Advisory Services (NAADS). Perishable fruit products should be preserved according to OHS requirements System which identifies a specific hazard throughout the food chain i.e. from primary production fruit products till it reaches the consumer. With increasing demand for horticultural products worldwide, it is necessary for every fruit industry to adopt hazard analysis critical control point in order to give quality assurance to consumers.

A hazard is any aspect of the production chain that is unacceptable because it is a potential cause of harm or hazard such as a biological, chemical or physical agent in food with the potential to cause an adverse health effect in humans, whether or not it causes disease in crops.

Control points are points in food production starting from the raw state through processing and shipping to consumption by consumers, where the loss of control does not lead to an unacceptable health hazard

Raw and end-products may be tested for the presence, level, or absence of micro-organisms. Traditionally these practices were used to reduce manufacturing defects in fruit products and ensure compliance with specifications and regulations, however, they have many drawbacks e.g. they are destructive and time-consuming

self-check 3	written test

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

1. What is quality standards? (5point)
2. What is the purpose of establish Quality standards? (5 points)

3. Main elements Quality standards? (5 points)

Note: **Satisfactory rating - 15 points** **Unsatisfactory - below 15 points**

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

Answer Sheet

Score = _____

Rating: _____

Name: _____ Date: _____

Information Sheet-4	Revising / updating standard procedures.

How to Change a Standard Operating Procedure (SOPs).

Changes to Standard Operating Procedures (SOPs) follow a specific method that a company's Quality and Regulatory Affairs department establishes. Start documenting requested changes to an SOP as soon as relevant personnel consider the revision. Keep a list of conversations regarding these changes by date and participants.

Then, include this record as part of your initial request to change an SOP.

- Identify in writing the need for a change to the SOP.
- Forward this document to the supervisor of the department that the change affects and to the document control department.
- Complete a change request form.
- Decide whether the change requested is administrative or clerical.
- Administrative changes seek to revise a process the company follows.
- Clerical changes seek to revise the existing SOP's spelling, grammar, format and clarity.
- Prepare an explanation of the requested change.
- If possible, copy the existing SOP and make red line revisions showing the requested changes.
- Sign and date the change request form.
- Submit it to the document control department.
- Forward a copy of the change request form to the human resources department. Explain whether the department must train employees because of the requested change and which employees the change affects.
- Require human resources to document the training by date, employees, trainer and subject matter.
- Submit the training completion data to the document control department. Request that they add it to the original change request form.
- Distribute the approved change request form to all employees of the company. Identify the form by its control authorization number.
- Tell employees how to access the form.

Updating standard procedure

SOPs should be reviewed by all staff, department supervisors and the director at least once each year, and suggestions from staff should always be considered for changes of process. The consequences of not having SOPs in good working order are far more serious than the inconvenience of keeping them updated.

Part I of this series explains why SOPs matter and presents strategies for creating them. These strategies are also useful for updating existing SOPS.

Part II discusses ways to implement SOPs in your organization.

Organizations need to develop a comprehensive system to ensure that all policies, procedures and training programs are continually reviewed and updated, in practice as well as in writing. Making such a review part of supervisor job descriptions, and making time for it on the calendar help ensure that your organization keeps the information current and functional

STAFF AWARENESS

- Where are the SOPs kept? Is the "centralized" copy really still available?
- Does everyone have a copy? Do new staff get a copy right away? Is there someone responsible for assuring this?
- Do all of the staff know—more than vaguely—what you are talking about when you ask about policies

self-check 4	written test

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

1. Discuss on How to Change a Standard Operating Procedure (SOPs)? (5 point)

2. List the record as part of your initial request to change an SOP.? (5 points)

Note: **Satisfactory rating - 10 points** **Unsatisfactory - below 10 points**

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

Answer Sheet

Score = _____

Rating: _____

Name: _____ Date: _____

Reference

1. https://www.researchgate.net/publication/311271355
2. ISO, “ISO 9001:2015 Quality management systems - Requirements,” Vernier, Geneva, Switzerland, 2015.

3. O. Boiral, “Managing with ISO Systems: Lessons from Practice,” *Long Range Plann.*, vol. 44, no. 3, pp. 197–220, 2011.
4. ISO, “ISO 9001:2015 Quality management systems - Requirements,” Vernier, Geneva, Switzerland, 2015.
5. S. Urbonavicius, “ISO system implementation in small and medium companies from new EU member countries: A tool of managerial and marketing benefits development,” *Res. Int. Bus. Financ.*, vol. 19, no. 3, pp. 412–426, 2005.
6. www.swismedic.ch

Horticultural Crops Production

Level III

Learning Guide –94

Unit of Competence: Apply Quality Control

Module Title: Applying Quality Control

LG Code: AGR HCP3 M19LO2- 94

TTLM Code: AGR HCP3 TTLM 0120V1

LO2. Assess quality of service delivered.

Instruction sheet	Learning Guide 94

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

- Checking Quality standards and specifications
- Evaluating service delivered using quality parameters.
- Identifying causes of any faults and Taking corrective actions.

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 Quality standards and specifications
- Evaluate service delivered using quality parameters.
- Identify causes of any faults and Take corrective actions.

Learning Instructions

1. Read the specific objectives of this Learning Guide.
2. Follow the instructions described below 3 to 4.
3. Read the information written in the information “Sheet 1, Sheet 2 and Sheet 3”.
4. Accomplish the “Self-check 1, Self-check 2 and Self-check 3” **in page -24, 28 and 33 respectively**.

Information Sheet-1	**Checking Quality standards and specifications**

1.1. Checking the delivered services against quality standards

I. Understanding of quality

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

II. **Feature of Quality**

In a manufacturing or service environment, there are major categories of quality, quality of design, quality of conformance and quality of use. A poorly designed product will not function properly regardless of how well it meets its specifications. Conversely a product that does not conform to excellent design specifications will not properly perform its intended function.

a) **Design quality**

In general, design quality refers to the ability of a design to exactly address the design inputs, such as, intended purpose, regulatory requirements and designer own idea. This includes:

- Identification of the customers
- Identification of the real needs of the customers and other requirements
- Converting the customer needs in to technical language
- Verifying that the technical language reflects the customer needs

b) **Conformance quality**

Conformance quality may be defined as the degree of adherence of the product characteristics to the design drawings and specifications. The objective of a quality program is to have a system that will measure and control the degree of product and process conformance in the most economical way.

The producer uses the design to develop a product or provide a service with the available:

- Personnel
- Equipment and material
- Working procedure
- Working environment

If the design quality does not reflect the intended purpose and other requirements or the organization has no adequate arrangements to convert the design in to the product the final output will not be fit for the intended use/purpose.

III. Quality Determination and Control

The Determinants of Service Quality

Through interviews with business executives and customer focus group, Berry et al have identified the ten determinants of service quality. They are:

1) **Reliability:** consistency of performance and dependability; performing the right service right first time; honoring promises; accuracy.

2) **Responsiveness**: Willingness or readiness of employees to provide service; timeliness.

3) **Competence:** possession of the skill and knowledge required to perform the service.

4) **Access:** approachability and ease of access; waiting time; hours of operation.

5) **Courtesy**: politeness, respect, consideration and friendliness of contact personnel.

6) **Communication:** keeping customers informed in language they can understand; listening customers; adjusting language to different needs of different customers; explaining the service itself, how much it will cost, and how problems will be handled.

7) **Credibility**: trustworthiness, believability, honesty; company reputation; personal characteristics of personnel.

8) **Security:** freedom from danger, risk, or doubt; physical safety; financial security; confidentiality.

9) **Understanding the customer**: making the effort to understand the customer's needs; learning the customer's specific requirements; providing individualized attention; recognizing the regular customer

10**) Tangible:** physical evidence of the service; physical facilities; appearance of personnel; tools or equipment used to provide service; physical representation of the service, such as a plastic credit card or a bank statement; other customers in the service facility

2 Checking the delivered services against organizational specifications

What is a specification?

In a purchasing context, a specification can be defined as a statement of needs. It defines what the purchaser wants to buy and, consequently, what the supplier is required to provide. The success of the purchasing activity relies on the specification being a true and accurate statement of the buyer's requirements.

A Good Specification Should:

- State the requirement clearly, concisely and logically in functional and performance terms unless specific technical requirements are needed;
- For goods, state what the item will be used for;
- Contain enough information for offertory to decide and cost the goods or services they will offer and at what level of quality;
- Permit offered goods or services to be evaluated against defined criteria by examination, trial, test or documentation;
- State the criteria for acceptance of goods or services by examination, trial, test or documentation;
- Provide equal opportunity for all potential suppliers to offer goods or services which satisfies the needs of the user, including goods or services incorporating alternative solutions;
- Form the fundamental basis of the contract between buyer and seller;

Types of specifications

There are three types of specifications:

a) Functional specifications

These are specifications that define the function, duty or role of the goods or services.

b) Performance specifications

Performance specifications define the task or desired result by focusing on what is to be achieved. They do not describe the method of achieving the desired result. This enables suppliers to provide solutions to defined problems.

c) Technical specifications

These are specifications that define the technical and physical characteristics and/or measurements of a product, such as physical aspects (for example, dimensions, color, and surface finish), design details, material properties, energy requirements, processes, maintenance requirements and operational requirements. They are used when functional and performance characteristics are insufficient to define the requirement.

self-check 1	written test

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

1. What is Responsiveness? (5 point)
2. List Feature of Quality? (5 points)
3. Write types of specifications? (5 points)

Note: **Satisfactory rating - 15 points** **Unsatisfactory - below 15 points**

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

Answer Sheet

Score = _____

Rating: _____

Name: _____ Date: _____

Information Sheet-2	Evaluating service delivered using quality parameters.

2.1. Evaluating the Services or Final Products against Standards

Before the final service delivered to the end user it should be evaluate to do so there is method of quality evaluation. Those methods are:

- Against the designed standards
- Against the specification
- By visual inspection

⌖ **Why inspection?**

By “inspection” it is usually meant that, at certain stages in the course of production, a comparison is made between what has actually been produced and what should have been produced.

Different forms of inspection

According to production flow, the inspection may be divided into:

A. Incoming inspection concerns goods upon delivery from vendors and/or suppliers. It consists of inspection of raw materials, components, sub-assemblies and so on.

B. . **In-process inspection**: In-process inspection aims to prevent products of unacceptable quality from being manufactured. It provides data for making decisions on the product (accept or rework or reject), as well as on the process (run or stop).

Final inspection: final inspection and/or testing is done after manufacture has been completed, with the object of making sure that the goods concerned are satisfactory for dispatch to the customer or maybe to another department for the next operation

3 Ways to Evaluate Your Services

The first important step for evaluating your services is determining what you want to evaluate. After you determine this, you need a system to capture the necessary data to allow you to analyze the results to make a final evaluation.

Surprisingly, there are three types of evaluation options. Each type of evaluation is unique to the type of information required to judge the results.

1. **Goals-based Evaluation:** Let's say your organization decides to implement peak-end theory with every patient encounter. The goals for your department are to reduce the no show rate to 6% or less, to increase word of mouth referrals to 45% and to increase satisfaction to a consistent 98% or better on average. These goals are to be met within 6 months of implementation and maintained for another 6 months.
2. **Process-based Evaluation:** Although this type of evaluation does not immediately seem to be relevant to evaluating service, it has merit. Let's pretend that your organization has begun having a substantial increase in

Medicare denials. The reason for the denials is because functional limitation codes and modifiers are not being included on claims. The types of questions you'll be asking revolve around processes within the organization.

- Are patients completing patient reported outcomes at the appropriate times?
- What reminders or tasks have been created to ensure patients complete the measures?
- Are staff adequately trained to retrieve reminders or tasks?
- Are all clinicians in the organization negligent in including the codes and modifiers on claims?
- Is there a way for front office personnel to be involved in ensuring each patient completes outcome measures?
- When is the denial occurring: initial, 10th visit/30-day point in time or discharge?
- After a patient completes an outcome measure, how are the functional limitation codes and modifiers determined?

As you can see, a process-based evaluation feels more qualitative in nature. It focuses on who, what, when, and how. In a process-based evaluation the focus is mapping out a process and determining how well the process is working or where the process breaks down leading to failure. When the problem is identified, the goal is to change the process.

3. **Outcome-based Evaluation:** This type of evaluation answers the question, "are my services making a difference in the lives of my customers?" In the rehabilitation world, one of the best ways to determine this is to learn how much functional change happens as a result of your services. To most accurately know, you need a system that risk adjusts for patient factors that affect outcomes.
    - Do you capture level of function prior to beginning services?
    - Does your system risk adjust?

- As a bonus feature, do you have a system that can predict the final outcome?
- Do you capture level of function prior to discontinuing an episode of care?
- Does your system have the capability for benchmark reporting?

An outcome-based evaluation will focus on what functional change happens in your patients' lives. A great system will combine both the effectiveness and efficiency of your services. Outcome-based evaluations are key in the ever-changing health care environment. When the predominant fee-for-service payment model changes toward a value based payment model, you will need to perform outcome-based evaluations at least quarterly.

self-check 2	written test

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

1. What is inspection? (2 point)
2. List Different forms of inspection? (5 points)
3. List types of evaluation? (5 points)

Note: **Satisfactory rating - 15 points** **Unsatisfactory - below 15 points**

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

Answer Sheet

Score = _____

Rating: _____

Name: _____ Date: _____

Information Sheet-3	Identifying causes of any faults and Taking corrective actions.

3.1. Some of common causes of faults include:

Hurried work – when teams are in a hurry to complete their work it increases the chances of making mistakes

Changes to scope and specification – when specs and/or the size of the project changes midstream, workers and teams can make mistakes while trying to adjust to the changes, especially if those changes are poorly communicated

Complexity – technical tasks and complex processes invite people to make errors

Upstream errors – some errors can be passed-down from one team to another, and if undiscovered, they can continue to be passed along until later stages of the project or until the customer receives the product

Hand-offs – having to hand work off to other teams/departments can introduce errors

Communication issues – lacking a system to notify downstream teams of important product information or issues can cause people to make mistakes

Staff turnover – new staff are more prone to making mistakes as they're coming up-to-speed

Misunderstood specification – inheriting a specification that is difficult to understand or left open to interpretation can introduce errors, and those errors can be compounded as other teams work from the same specification Process improvement is specifically aimed at alleviating the causes of a quality problem, and thereby increasing schedule performance and increasing customer satisfaction on projects.

3.2. Identifying and isolating faults and taking corrective actions

The standard requires you to have ways to identify a product or service nonconformity and to decide what to do about it. It might be necessary to keep it separate from acceptable products and services.

For instance, where customer complaints on nonconformities are infrequent, the entire history of the complaint, its investigation and the corrective action taken can be recorded in a correspondence file.

The following are **internal sources** to show up problems of product or service;

- Verification of purchased product
- Production and service provision
- Monitoring and measurement

The following are the most common **external indications**, which enable you to target where attention is needed;

- Customer complaints
- guarantee claims

Where applicable the organization shall deal with nonconforming product by one or more of the following ways:

- By taking actions to eliminate the detected nonconformity;
- By authorizing its use , realize or acceptance under concession by a relevant authority and where applicable, by the customer;
- By taking action to preclude its original intended use or application;
- By taking action appropriate to its effect, or potential effects, of nonconformity when nonconforming product is detected after delivery or use has started

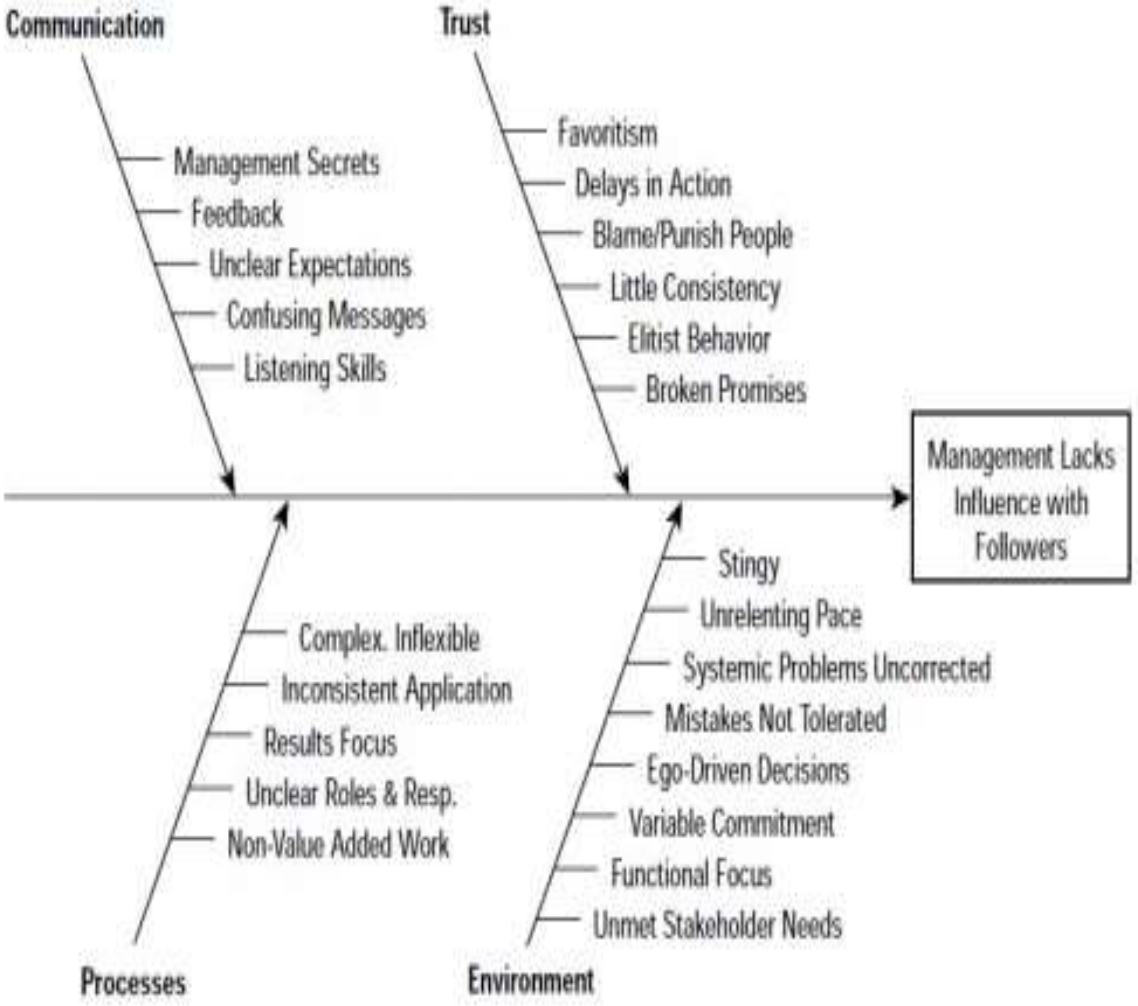


Figure 1 cause of failure

Corrective action: Action taken to eliminate the causes of non-conformities or other undesirable situations. Preventive action: Action taken to prevent further reoccurrence of such non-conformities.

self-check 3	written test

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

1. What is Corrective action? (2 point)
2. List some of common causes of faults**?** (5 points)

Note: **Satisfactory rating - 10points** **Unsatisfactory - below 10 points**

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

Answer Sheet

Score = _____

Rating: _____

Name: _____ Date: _____

Reference

7. https://www.researchgate.net/publication/311271355
8. ISO, “ISO 9001:2015 Quality management systems - Requirements,” Vernier, Geneva, Switzerland, 2015.
9. O. Boiral, “Managing with ISO Systems: Lessons from Practice,” *Long Range Plann.*, vol. 44, no. 3, pp. 197–220, 2011.
10. ISO, “ISO 9001:2015 Quality management systems - Requirements,” Vernier, Geneva, Switzerland, 2015.

11. S. Urbonavicius, “ISO system implementation in small and medium companies from new EU member countries: A tool of managerial and marketing benefits development,” *Res. Int. Bus. Financ.*, vol. 19, no. 3, pp. 412–426, 2005.
12. www.swismedic.ch

Horticultural Crops Production

Level III

Learning Guide –95

Unit of Competence: Apply Quality Control

Module Title: Applying Quality Control

LG Code: AGR HCP3 M19LO3- 95

TTLM Code: AGR HCP3 TTLM 0120V1

LO3. Record information

Instruction sheet	Learning Guide 95

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

- Recording basic information on the quality performance.
- Maintaining records of work 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:

- Record basic information on the quality performance.
- Maintain records of work quality.

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 and Sheet 2”.
4. Accomplish the “Self-check 1 and Self-check 2” **in page -40 and 46,** respectively.

Information Sheet-1	Recording basic information on the quality performance.

1.1. Recording Information on Quality Performance

Records established to provide evidence of conformity to requirements and of the effective operation of the quality management system shall be controlled. The organization shall establish a documented procedure to define the controls needed for the identification, storage, protection, retrieval, retention and disposition of records. Records shall remain legible, readily identifiable and retrievable.

For example, these may include physical, chemical and nutritional characteristics of the final food product.

A. **Physical characteristics**.

The physical characteristics of a product include:

- Freedom from foreign matter
- Size and shape
- Color of the product
- Flavor
- Consistency
- Healthiness

B. Chemical composition

The chemical composition of product such as water, proteins, fat and mineral should be recorded. The products should be free from unwanted chemical residue

C. Nutrient composition

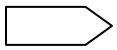
The type of amino acids present in protein, the fatty acids available in fat, and vitamins should be listed and recorded on the product

1.2. Recording production processes & outcomes:

The usually way of recording facts is to write them down but to describe in writing even a simple process can be very tedious. It is often hard to picture the whole process from a written record. Consequently, symbols are used to combine a short hand system with a system analysis. Five basic types of event in to which all work can be classified, are represented by the symbols in figure 5.1

◯ Operation - produces or accomplishes


Inspection - verifies


Transport - moves


- Delay or interferes


Storage -holds or keeps

Fig.1.1.process chart symbols

Principles of record

- More specifically, you should always try to ensure that you:

- Make sure your entries are dated and timed as close to the actual time of the events as possible
- Record events accurately and clearly – remember that the patient/client may wish to see the record at some point, so make sure you write in language that he or she will understand
- Focus on facts, not speculation
- avoid unnecessary abbreviations – as you'll find, the health care system uses many abbreviations, but not all workplaces use the same definitions: for instance, 'DNA' means 'deoxyribonucleic acid' in some places, but 'Did Not Attend' (meaning a patient/client who does not show up for an appointment) in others – avoid abbreviations if you can!
- Record how the patient/client is contributing to his or her care, and quote anything he or she has said that you think might be significant
- Do not change or alter anything someone else has written, or change anything you have written previously; if you do need to amend something you have written, make sure you draw a clear line through it and sign and date the changes
- Never write anything about a patient/client or colleague that is insulting or derogatory.

Self-Check -1	Written Test

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

1. What type of physical characteristic of the products are recorded to evaluate the performance of quality work? (2pts.)
2. List the information to be record? (3pts)
   a._____
   b. _____
   c. _____
   d. _____

Note: **Satisfactory rating - 5 points** **Unsatisfactory - below 5 points**

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

Answer Sheet

Score = _____
Rating: _____

Name: _____ Date: _____

Short Answer Questions

Information Sheet-2	Maintaining records of work quality

1.1. Maintain quality performance

It require some particular commitment and action

a. Institutional dynamism

An organization need to dynamic always moving and seeking continued improvement and to institutionalize its dynamic character:

- Dynamism needs to be part of the organizational culture
- Encourage and providing support
- Listing to and carefully evaluating

- Encourage openness to change and experimentation with ideas and strategies
- Never being complacent
- Incorporating constant reevaluation including feedback
- Always being aware of the original mission

b. Long-range strategic planning

To maintain quality, an organization needs to continually look at itself over the long term

c. SWAT analysis

SWOT stands for strength weakness, opportunities and threats

- Strengths and weaknesses may be trends, rather than specifics. A level of service that is currently appropriate, for example, is not strength if it is more or less than will be needed in a year. A new program that's not ready to implement yet is not a weakness if it's unready because the developers are taking the time necessary to make it effective.
- Opportunities :
  - An organization may be able to meet other needs with its current structure
  - It may be possible to expand into other areas of service, or into a larger arena (another town, another county, national instead of just one state).
  - Increased funding may be available from new sources, or because of changed circumstances.
  - Collaboration with other groups, leading to increased resources, may become a prospect.
  - Invitations or awards offered to your organization or staff members or good press may lead to your organization being viewed as more "legitimate". Eg. Good government agricultural policy, suitable climate for horticultural crop production land and human resources

Taking advantage of any opportunity can have both positive and negative consequences for your organization, so it's important to analyze the situation carefully before committing yourself.

- **Threats (challenges):** Some of the challenges that go along with any opportunity can be truly daunting if they're not thought through carefully. Many of the opportunities above require some sort of organizational restructuring or growth, processes that are always difficult, and require a lot of planning. In becoming larger or more accepted, for instance, an organization may forget its roots or its guiding principles, and lose much of its effectiveness.

E.g. High Rf. flood, natural hazard, disease, insect, weed, market and climate change, availability of resource

Other threats may come unaccompanied by opportunity. Your organization may experience difficulty finding -- and keeping -- ongoing funding and other resources.

 Applying SWOT analysis to all the areas your organization has to deal with makes it easier both to anticipate and prepare for the negative, and to remember to identify and build on the positive.

D. Keeping at it

The single most important thing to understand about maintaining quality performance -- or maintaining an organization, for that matter is that you can never stop working at it. No effort at maintaining quality will work any longer than it is applied. No matter how institutionalized dynamism becomes, no matter how good your planning process is, they take constant care.

1.2. Maintaining Records of Work Quality

It is essential to maintain quality records not only to conform to the regulations but to also aid management in reviewing the effectiveness of our quality system and making decisions on how to improve it. The records that are maintained also demonstrate that products were manufactured to specifications and standards.

1.2.1. The quality records that are maintained include:

- Quality System documentation

- Device Master Records
- Device History Records
- Document Change Requests
- Calibration and maintenance records
- Internal Audit Reports and Management Reviews
- Customer Complaints
- Vendor Qualifications
- Purchase Orders
- Customer Orders and Contracts
- Personnel Records/Training records
- Design History Files (Validation Data)
- Field Notifications and Recalls

All records are stored in conditions to facilitate their preservation and ready access by appropriate personnel.

1.2.2. Work Areas for maintain products quality

Handling, storage, and packaging of products shall be clean, safe, and organized to ensure that they do not adversely affect quality or personnel performance. Applicable for components and products susceptible to electrostatic discharge (ESD) damage. Consider components and products such as: integrated circuits, printed wiring board assemblies, magnetic tapes and/or disks, and other media used for software or data storage.

A. Handling

The producer shall provide methods of handling product that prevent damage or deterioration.

B. Storage

The producer shall use designated storage areas or stock rooms to prevent damage or deterioration of product, pending use or delivery.

C. **Deterioration** - Where the possibility of deterioration exists, materials in storage shall be controlled (i.e., date stamped/coded) and materials with expired dates shall not be used.

D. Packaging

The producer shall control packing, packaging, and marking processes (including materials used) to the extent necessary to ensure conformance to specified requirements.

E. Preserving

The producer shall apply appropriate methods for preservation and segregation of product when the product is under the supplier's control.

F. Documentation - The producer shall establish and maintain methods to ensure that all documentation required to describe, test, install, and apply a patch has been verified and delivered.

Quality Records and six procedures as listed below as mandatory documentation:

1. Control of Documents
2. Control of Records
3. Internal Audit
4. Control of Nonconforming Product
5. Corrective Action
6. Preventive Action

Self-Check -2	Written Test

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

1. Discuss how do you maintain quality performance?(2pts)
2. Explain clearly SWOT analysis? (2pts)
3. List the records which will be maintained? (2pts)

Note: **Satisfactory rating - 6 points** **Unsatisfactory - below 6points**

Answer Sheet

Score = _____

Rating: _____

Name: _____ Date: _____

Reference

13. https://www.researchgate.net/publication/311271355
14. ISO, “ISO 9001:2015 Quality management systems - Requirements,” Vernier, Geneva, Switzerland, 2015.
15. O. Boiral, “Managing with ISO Systems: Lessons from Practice,” *Long Range Plann.*, vol. 44, no. 3, pp. 197–220, 2011.
16. ISO, “ISO 9001:2015 Quality management systems - Requirements,” Vernier, Geneva, Switzerland, 2015.
17. S. Urbonavicius, “ISO system implementation in small and medium companies from new EU member countries: A tool of managerial and marketing benefits development,” *Res. Int. Bus. Financ.*, vol. 19, no. 3, pp. 412–426, 2005.
18. www.swismedic.ch

Horticultural Crops Production

Level III

Learning Guide –96

Unit of Competence: Apply Quality Control

Module Title: Applying Quality Control

LG Code: AGR HCP3 M19LO4- 96

TTLM Code: AGR HCP3 TTLM 0120V1

LO4. Study causes of quality deviations.

Instruction sheet	Learning Guide 96

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

- Investigating and reporting causes of deviations from final outputs or services.
- Recommending suitable preventive action.
- Identifying causes of deviation from specific quality standards

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 outputs or services.
- Recommend suitable preventive action.
- Identify causes of deviation from specific quality standards

Learning Instructions

1. Read the specific objectives of this Learning Guide.
2. Follow the instructions described below 3 to 4.
3. Read the information written in the information “Sheet 1, Sheet 2, Sheet 3 and Sheet 4”.
4. Accomplish the “Self-check 1, Self-check 2, and Self-check 3” **in page -53, 57, and 63** respectively.

Information Sheet-1	Investigating and reporting causes of deviations from final outputs or services.

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

Types of Deviations:

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

- **Production Deviation** - usually raised during the manufacture of a batch production.

  EHS Deviation - raised due to an environmental, health and safety hazards.

- **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** - raised to track implementation measures related to customer complaints.
- **Technical Deviation** - can be raised for validation discrepancies. For example: changes in Manufacturing Instruction.
- **Material Complaint** - raised 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.

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.

Level1: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

Level2:Serious 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).

Level3: 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.

What to Check during the Deviation Assessment:

QA delegate has to conduct a primary Investigation on the deviation reported and evaluate the following information

- Scope of the deviation - batch affected (both in-process and previously released)
- Trends relating to (but limited to) similar products, materials, equipment and testing processes, product complaints, previous deviations, annual product reviews, and /or returned goods etc where appropriate.
- A review of similar causes.
- Potential quality impact.
- Regulatory commitment impact.
- Other batches potentially affected.

Self –CHECK-1	written test

Name ----------ID NO----------

1. Write Levels of Deviation Risks? (5points)
2. Write types of Deviation? (5points)

Note: **Satisfactory rating - 10 points** **Unsatisfactory - below 10 points**

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

Answer Sheet

Score = _____

Rating: _____

Name: _____ Date: _____

Information Sheet-2	Recommending suitable preventive action.

2.1. Corrective and preventive actions

Corrective and preventive action (CAPA, also called corrective action/preventive action or simply corrective action) consists of improvements to an organization's processes taken to eliminate causes of Non-conformities or other undesirable situations. It is usually a set of actions that laws or regulations require an organization to take in manufacturing, documentation, procedures, or systems to rectify and eliminate recurring nonperformance. Non-conformance is identified after systematic evaluation and analysis of the root cause of the non-conformance.

Non-conformance may be a market complaint or customer complaint or failure of machinery or a quality management system, or misinterpretation of written instructions to carry out work. The corrective and preventive action is designed by a team that includes quality assurance personnel and personnel involved in the actual

observation point of nonconformance. It must be systematically implemented and observed for its ability to eliminate further recurrence of such non-conformation.

Corrective action: Action taken to eliminate the causes of non-conformities or other undesirable situations. Preventive action: Action taken to prevent further reoccurrence of such non-conformities.

CAPA is used to bring about improvements to an organization's processes, and is often undertaken to eliminate causes of non-conformities or other undesirable situations.[3] CAPA is a concept within good manufacturing practice (GMP), Hazard Analysis and Critical Control Points/Hazard Analysis and Risk-based Preventive Controls (HACCP/HARPC) and numerous business standards. It focuses on the systematic investigation of the root causes of identified problems or identified risks in an attempt to prevent their recurrence (for corrective action) or to prevent occurrence (for preventive action).

Preventive action is any proactive methodology used to determine potential discrepancies before they occur and to ensure that they do not happen (thereby including, for example, preventive maintenance, management review or other common forms of risk avoidance). Corrective and preventive actions include stages for investigation, action, review, and further action is required. It can be seen that both fit into the PDCA (plan-do-check-act) philosophy as determined by the Deming-Shewhart cycle.

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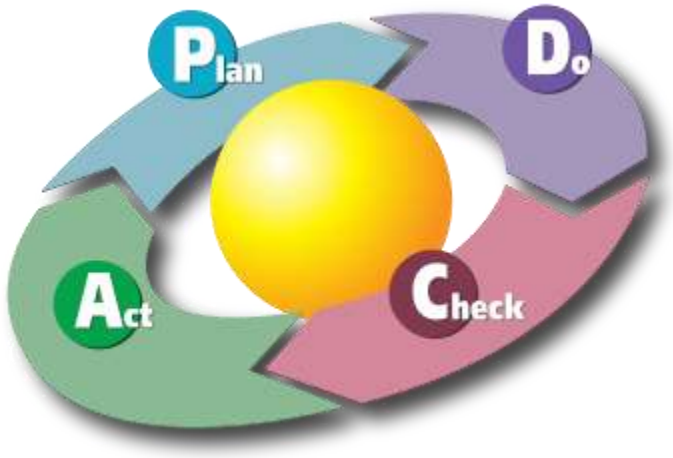

The PDCA cycle[4]

Investigations to root cause may conclude that no corrective or preventive actions are required, and additionally may suggest simple corrections to a problem with no identified systemic root cause. When multiple investigations end in no corrective action, a new problem statement with expanded scope may be generated, and a more thorough investigation to root cause performed.

Implementation of corrective and preventive actions is the path towards improvement and effectiveness of Quality Management Systems. Corrective actions are nothing but action/actions based on problem identification. The problem or a non-conformance can be identified internally through staff suggestions, management reviews, document reviews or internal audits. External leads to finding the root cause of the problem can include Customer complaints/suggestions; customer rejections; non-conformities raised in customer/third-party audits; recommendations by auditors.

A root cause is the identification of the source of the problem where the person(s), system, process, or external factor is identified as the cause of the nonconformity.

Examples of corrective actions

- Error Proofing
- Visible or Audible Alarms
- Process Redesign

- Product Redesign
- Training or enhancement/ modification of existing training programs
- Improvements to maintenance schedules
- Improvements to material handling or storage

Self-Check -3	**Written Test**

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

2. What are the purpose of preventive and corrective actions? (**5 points**)
3. List out the cause of identified faults? (**5 points**)

a. _____
b. _____
c. _____
d. _____

4. What are the common corrective actions? (5pts.)

Note: **Satisfactory rating – 15 points** **Unsatisfactory - below 15points**

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

Answer Sheet

Score = _____

Rating: _____

Name: _____ Date: _____

Short Answer Questions

Information Sheet-3	Identifying causes of deviation from specific quality standards

3.1. Study Causes of Quality Deviation

3.1.1. Investigating and reporting cause of deviations

Some of the most challenging quality problems are those which are connected with defect investigation in spite of careful planning and proper process control, certain defects may still be revealed during assembly or in final inspection. To prevent these defects from recurring, they have to be investigated to find the underlying causes, so that efforts can be made for its elimination. The causes of certain defects are fairly obvious and can directly be identified. In fact ,the 'analysis' element in any process

control system is a form of defect investigation ,in the sense that based on the defects observed ,the causative factor is identified ,which in turn gives a clue to the corrective action required . However, there are other defects which cannot be readily explained. There may be so many possible causes that it may be difficult to spot with any degree of certainty the factor which has caused a particular defect. In such cases, formal defect studies may be carried out to find the real cause and the remedial measures required. An organized method of defect investigation is discussed in this topic.

Types of quality deviation

Following are some example of deviation raised from different functional areas of business

1) Production deviation usually raised during the manufacture of a batch production

2) Quality improvement deviation may be raised if a potential weakness has been identified and the implementation will require project approval

3) Customer service deviation: - rose to track implementation measure related to customer complaints.

4) Technical deviation:- can be raised for validation discrepancies example change in manufacturing instructions

5) Materials complaint: - rose to document any issues with regarding to nonconforming, superseded or obsolete (out of date) raw materials components, packaging or imported finished goods.

Causes of Quality Deviations

1. **Design and Specification**

    a) Vague or insufficient manufacturing particulars or illegible drawing prints

    b) Impracticable design or incompatible component and assembly tolerance.

c) Obsolete drawing being used.

2. Machinery and equipment

a) Inadequate process capability

b) Incorrectly designed tooling

c) Worn tools

d) Non-availability of measuring equipment

e) Poor maintenance of machines

f) Equipment affected by environment condition such as temperature, humidity etc;

3. Materials

a) Use of untested materials.

b) Mix-up of materials

c) Substandard material accepted on concession because of the non-availability of correct material

4. Operating and supervisory staff

a) Operator does not possess adequate skill for operating the process equipment.

b) Operator does not understand the manufacturing drawing or instructions relating to the process.

c) Machine setter does not know how to correctly set the machine.

d) Careless operator and inadequate supervision

e) Undue rush by the operator to achieve quantity targets

5. Process control and inspection

a. Inadequate process controls

b. Non availability of proper test equipment

c. Test equipment out of calibration

d. Vague inspection /testing instructions

e. Inspectors do not possess the necessary skill

3.1.2. Which defects should be investigated?

A quality enthusiast may say that every single defect must be investigated to assure defect –free production. Unfortunately, this may not be practicable or economically desirable. Defect studies cost money in the form of the time of engineers and technicians, test facilities and then products destroyed in testing, and therefore, unless the expected benefits from the prevention of defects are likely to exceed the cost of the defect study, it will not be economically justifiable. Further, the resources at the disposal of the quality manager will normally be limited; therefore, he will have to undertake defect studies on a selective basis. The defects may be broadly grouped into two classes, namely, **sporadic** and **chronic**. A **sporadic defect** generally signifies that some new factor has entered into the process, and unless this factor is identified and eliminated, the process will remain out of control. Therefore, such defects have to be investigated on priority. On the other hand, **chronic defects** are the various types of defects which have been occurring in a certain percentage of the product, due to unknown causes. As these defects also cause losses to the company, their incidence has to be minimized, where possible. Generally, chronic defects comprise a large number of different types of defects of varying magnitude. Since all of these cannot be taken up for investigation simultaneously, it is advisable to concentrate on the' vital few' rather than the 'trivial many'. To identify the 'vital few' the resultant losses due to different defects may be evaluated. The defects showing highest losses merit first attention. There may be certain defects which result in serious failures of equipment in service. Though direct losses (such as warranty claims) due to these defects may not be appreciable, the loss in customer good will may be considerable. Therefore, the quality manager

should be on the alert for such defect which will not figure as major defects in a purely financial analysis.

3.1.3. Defining Responsibility and conducting a defect study

A defect study, like any other activity, requires proper planning and organization to be fruitful. The object of a defect study and its responsibility should be clearly defined. The task is generally entrusted to a team rather than an individual. The team may be composed of personnel from quality control, engineering production, or wherever expertise is available. For proper direction and coordination, a study coordinator is also named who coordinates the activities of the team and keeps the management informed about the progress of the study.

Once then study team is formed and the objective of defect study has been explained to them, the first question which arises is how to go about it and where to start? Although there is no cut and dried method of defect investigation, which will be valued for all situations the general approach to the organized study of defects in different products and processes is more less the same. The main steps of this approach are discussed below.

1. **Study of the products**
2. **Data collection**
3. **Identification of defective component/process**

3.2. Recommending suitable preventive action

Preventive action is an important activity. It seeks to prevent the occurrence of potential problems that could have a negative effect on your business results, products, processes, quality management system, or customer satisfaction.

Preventive action can take two forms.

The first is the elimination of potential failure modes. This technique should be deployed in the advanced quality planning stage of new product or process development.

The second form of preventive action **is the elimination of potential failure modes** when information from processes, systems, work operations, process capability studies, yield analyses, deviations, concessions, quality records, audit reports, service reports, or customer complaints suggests a nonconformance may occur. Steps shall be taken according to documented procedures to eliminate potential nonconformance. The minimum, preventive action process should include, but not be limited to:

- Determining the steps needed to verify or deny the potential nonconformance;
- Gathering and analyzing the required data;
- Determining the effectiveness of the implemented containment actions;
- Applying controls to ensure the solution is effective in resolving the problem at an acceptable level corresponding to the risks encountered;
- Reviewing preventive action activities by management for trends and impact on procedures, products, processes, and systems

Self-Check 3	Written Test

Directions: Answer all the questions listed below. Illustrations may be necessary to aid some explanations/answers.

1. What is quality deviation?(5 pts)
2. Write down types of quality deviation which arise from different functional areas of business? (5pts).
3. What are causes of quality deviation? (5pts)
4. Which defects should be investigated? (5 pts)
5. What is the difference between preventive action and corrective action? (5 pts)

`

Note: **Satisfactory rating - 25 points Unsatisfactory - below 25points**

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

Answer Sheet

Score = _____
Rating: _____

Name: _____ Date: _____

Reference

19. https://www.researchgate.net/publication/311271355
20. ISO, “ISO 9001:2015 Quality management systems - Requirements,” Vernier, Geneva, Switzerland, 2015.
21. O. Boiral, “Managing with ISO Systems: Lessons from Practice,” *Long Range Plann.*, vol. 44, no. 3, pp. 197–220, 2011.
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24. www.swismedic.ch

Horticultural Crops Production

Level III

Learning Guide –97

Unit of Competence: Apply Quality Control

Module Title: Applying Quality Control

LG Code: AGR HCP3 M19LO5- 97

TTLM Code: AGR HCP3 TTLM 0120V1

LO5. Complete documentation.

Instruction sheet	Learning Guide 97

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

- Recording information on quality and other indicators of service performance.
- Recording all service processes and outcomes.

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:

- Record information on quality and other indicators of service performance.
- Record all service processes and outcomes.

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 and Sheet 2”.
4. Accomplish the “Self-check 1 and Self-check 2” **in page -70 and 74, respectively**.

Information Sheet-1	Recording information on quality and other indicators of service performance.

1.1. Recording Information on Quality Performance

Records established to provide evidence of conformity to requirements and of the effective operation of the quality management system shall be controlled. The organization shall establish a documented procedure to define the controls needed for the identification, storage, protection, retrieval, retention and disposition of records. Records shall remain legible, readily identifiable and retrievable.

Records exist in all companies. These records can provide you with information to help your business effectively. You will need to show that you have actually done something, recorded certain information, or met a particular requirement. It is important that a small business does not burden itself with piles of paper that serve no purpose. You should decide;-

- What records are required in relation to your business?

- What is requiring by the standard.
- You should identify how long each type of records need to be kept where it will be found and how it is to be disposed of only keep what needs to be kept.
- Records should not be kept just to satisfy an auditor.

NB: In some instance, the retention period is dictated by statutory or regulatory requirements, financial requirements, and possible product liability claims or customers specifications. These details should be recorded or referenced in the documented procedure.

Some examples of what quality management system might generate as records (quality records) are:

- Design files, calculations
- Customers' orders, contract review,
- Meeting notes(management review)
- Internal audit reports
- Details of nonconformance(service failure reports, warranty claims, customer complaints)
- Corrective and preventive action reports
- Purchase orders
- Files on suppliers(evaluation of suppliers and their performance history)
- Process control details
- Calibration and verification reports
- Training details and
- Details of goods received and delivered

- Records indexing and filing may be in any appropriate form (hard copy or electronic).

- Storage will need to be appropriate for the medium and should be such that the risk of deterioration, damage or loss is minimized. It is useful to decide who has access to the records and how readily available these need to be.

If you use computer techniques to store records, be aware that developments and evolution of software programs can result in reading records made several years ago. It is also important that up-to-date anti-virus software is used. Back up of records stored electronically is also part of records management. After complete record and an organization have to maintain the work quality records from different damages

Service performance indicators

Key Performance Indicators are your friends. Each metric has its specific uses. It's down to you to employ these in a way that works best for your business.

Setting customer service KPIs

Key Performance Indicators help you measure performance versus set goals. They give the chance to understand the impacts.

For example, customer service insights show that increasing customer engagement by 50% leads to 80% improvement in customer retention. It might then be sensible to focus on setting customer engagement benchmarks to achieve higher retention rates.

Key Performance Indicators (KPIs) can identify issues in need of addressing. Measuring customer satisfaction across multiple touch-points may reveal phone users are the least satisfied, whereas those using live chat are extremely satisfied. Makes sense then to incorporate live chat across all possible touch-points and encourage phone users towards live chat where they are likely to have a better experience.

Self-Check 1	Written Test

Name _____ Date: _____

Directions: Answer all the questions listed below. Illustrations may be necessary to aid some explanations/answers.

1. Discuss recording information on quality performance? (5pts).
2. What information you record in relation to your business? (5 pts)

Note: **Satisfactory rating – 10points and above Unsatisfactory - below 10points**

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

Answer Sheet

Score = _____

Rating: _____

Name: _____ Date: _____

Information Sheet-2	Recording all service processes and outcome.

2.1. Record all service processes and outcomes

Documentation includes mandatory documented procedures as required by the standard and other documents such as specifications, records, etc. the important issue is that your people have the information they need to do their job. Some common terms used are:

- Work practices
- Operating practices, operating instructions or operating procedures
- Specifications and
- Drawings

Documentation should indicate, who does what, where, when, why, and how. It should not be a wish list of what you would like to happen in your business, but should clearly and accurately reflect what really happens. For example, it is not

necessary to have a formal document on how to open a door- simply putting “push” or “pull” on the door suffices.

2.1.1. Documentation requirements and Value of documentation

The quality management system documentation shall include

a) Documented statements of a quality policy and quality objectives

b) A quality manual

c) Documented procedures required by international standard

d) Documents needed by the organization to ensure the effective planning, operation and control of its processes

e) Records required by international standards

Documentation enables communication of intent and consistency of action. Its use contributes to

a) Achievement of conformity to customer requirements and quality improvement

b) Provision of appropriate training

c) Repeatability and traceability

d) Provision of objective evidence

e) Evaluation of the effectiveness and continuing suitability of the quality management system

2.1.2. Types of document used in quality management system

The following types of document are used in quality management system

a) Documents that provide consistent information, both internally and externally, about the organization’s quality management system: such documents are referred to as **quality manuals**;

b) Documents that describe how the quality management system is applied to a specific product, project or contract; such documents are referred to as **quality plans**;

c) Documents stating requirements; such documents are referred to as **specifications;**

d) Documents stating recommendations or suggestion; such documents are referred to as **guidelines;**

e) Documents that provide information about how to perform activities and processes consistently; such documents can include **documented procedures**, **work instructions** and **drawing;**

f) Documents that provide objective evidence of activities performed or results achieved; such documents are referred to as **records.**

2.2. Documenting quality standards

The following are common procedures for checking the quality of completed work against work place standards;

7) Select work product to be evaluated based on documented work place standards
8) Establish and maintain clearly stated criteria for the evaluation of selected work products.
9) Use the stated criteria during the evaluations of selected work products
10) Evaluate selected work products before they are delivered to the customer
11) Evaluate work products at selected time intervals
12) Identify each cases of noncompliance found during the evaluations

Self-Check 2	Written Test

Name: _____ **Date:** _____

Directions: Answer all the questions listed below. Illustrations may be necessary to aid some explanations/answers.

1. Define the term documentation? **5 points**
2. Write the common procedures for checking the quality of completed work against work place standard.. **- 10 points**

Note: **Satisfactory rating - 15 points Unsatisfactory - below 15 points**

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

Answer Sheet

Score = _____

Rating: _____

Name: _____ Date: _____

Reference

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