Ethiopian TVET-System

BASIC ELECTRICAL/ELECTRONIC

EQUIPMENT SERVICING Level I

Based on May 2011 Occupational standards

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Module Title: Applying Quality Standards

TTLM Code: EEL BEE1 TTLM 1019v1

This module includes the following Learning Guides

LG19: Assess own work

LG Code: EEL BEE1 M06 LO1LG-19

LG20: Assess quality of service rendered

LG Code: EEL BEE1 M06LO2-LG-20

LG21: Record information

LG Code: EEL BEE1 M06LO3-LG-2

LG22: Study causes of quality deviations

LG Code: EEL BEE1 M06LO4-LG-22

LG23: Complete documentation

LG Code: EEL BEE1 M06LO5-LG-23

Instruction Sheet	LG19: Assess own work

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

- Checking completed work
- Demonstrating work activities
- Identifying and isolating faulty service
- Recording and reporting faults and any identified causes

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 completed work
- Demonstrate work activities
- Identify and isolate faulty service
- Record and report faults and identified causes

Learning Instructions:

1. Read the specific objectives of this Learning Guide.
2. Follow the instructions described below
3. Read the information written in the “Information Sheets 1, 2, 3 and 4”. Try to understand what are being discussed. Ask you teacher for assistance if you have hard time understanding them.
4. Accomplish the “Self-checks” in each information sheets on pages 5, 9, 13 & 19.
5. Ask from your teacher the key to correction (key answers) or you can request your teacher to correct your work. (You are to get the key answer only after you finished answering the Self-checks).
6. If you earned a satisfactory evaluation proceed to “Operation sheets 1, 2 & 3 on pages 21-23 and do the LAP Test on page 24”. However, if your rating is unsatisfactory, see your teacher for further instructions or go back to Learning Activity.
7. After you accomplish Operation sheets and LAP Tests, ensure you have a formative assessment and get a satisfactory result.
8. Then proceed to the next LG.

Information Sheet-1	Checking completed work

1.1. Introduction to standards

A standard is an agreed way of doing something. It could be about making a product, managing a process, delivering a service or supplying materials – standards can cover a huge range of activities undertaken by organizations and used by their customers.

Standards facilitate everyday life. They increase safety and can be used to rationalize operations. Standardization ensures that products, services and methods are appropriate for their intended use. It ensures that products and systems are compatible and interoperable.

Standards provide people and organizations with a basis for mutual understanding, and are used as tools to facilitate communication, measurement, commerce and manufacturing. Standards are everywhere and play an important role in the economy, by: facilitating business interaction.

Standards are documents, specifications, guidelines or characteristics that can be used consistently to ensure that materials, products, processes and services are fit for their purpose.

1.2. Organizational Standards

Organizational standards are the specification of principles and procedures by which the institution assures that it provides an appropriate learning and research environment. Organizational standards outline the way in which business is to be conducted and govern what is deemed as acceptable behavior in the workplace. Organizational requirements are: the organization's vision, goals, objectives and priorities.

Example: The phone will be answered within three rings.

Generally a company will establish and communicate standards in relation to:

- Customer Service
- Code of Conduct
- Human Resource Issues
- Quality Assurance
- Dress and Corporate Presentation
- Legislative Issues

- Marketing Material and Communication
- Customer Service

1.2.1. Documenting Standards

Standards will usually be represented in the following resources:

- Mission, Vision and Charter Statements
- Workplace Policy and Procedure Manuals
- Industry Legislation Guidelines
- Implementation or Delivery Guidelines
- Terms and Conditions Brochures

It is important that standards are communicated and easily accessible to both employees and customers. By establishing, communicating and monitoring standards a company or organization has more input into how their staff undertake tasks and service customers. From a customer perspective, standards are a guideline against which service can be measured. When a company is able to consistently reach a set measure customer loyalty is increased.

1.3. Standards of completed work

Completed work are products that have completed the manufacturing process but have not yet been sold or distributed to the end user.

Are materials or products which have received the final increments of value through manufacturing or processing operations, and which are being held in inventory for delivery, sale, or use could also be considered as completed works.

Standard work is the practice of setting, communicating, following, and improving standards. Establishing standard work begins with creating, clarifying, and sharing information about the most efficient method to perform a task that is currently known with everyone performing that process

The three components of standard work are:

- Tact time, which is the rate at which products must be produced to meet customer demand. It is not cycle time.
- The work sequence operators perform within tact time.
- The inventory required to keep the process operating smoothly.

N.B: The standard of completed work should be similar to that of organizational standard.

Self-Check -1	Written Test

Direction I: Short answer item

Instruction: Give short answer for the following questions.

1. What is a standard?(1 point)
2. How standards are documented? (2 point)
3. How do we state standards of completed work? (3 point)
4. What are the three components of standard work? (2 point)

Note: **Satisfactory rating - 4 points and above** **Unsatisfactory - below 4 points**

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

Answer Sheet

Score = _____

Rating: _____

Name: _____ Date: _____

Information Sheet- 2	Demonstrating work activities

2.1. Work activities

Activities are measurable amount of work performed to convert inputs into outputs. Work activities are the tasks employees must complete in order for a business or organization to operate successfully. This might include taking inventory, preparing orders, designing or building products, or communicating with current and potential clients.

Work activities are the systemic entity of purposeful, cooperative human action, where several actors work in an organized way upon a shared object of work to transform it into an intended outcome, by using different kinds of means of work and means of cooperation and coordination. The intended outcome forms the purpose (motive) of the activity. Information entities, information tools, and information systems are used within work activities alongside with other means of work and means of cooperation and coordination.

2.2. Work activities (SOP) Vs completed work

Quality Control refers to the activities and techniques to verify that the developed product is in conformance with the requirements. The ultimate output of both processes is to deliver a quality product.

A standard operating procedure (SOP) is a set of step-by-step instructions compiled by an organization to help workers carry out complex routine operations. SOPs aim to achieve efficiency, quality output and uniformity of performance, while reducing miscommunication and failure to comply with industry regulations.

Standard Operating Procedure (SOP) plays an important role in your business. SOPs are policies, procedures and standards you need within your business to ensure success. These can create: efficiencies, and therefore profitability.

A Procedure is more detailed than a process, but less detailed than a work instruction. ... A Work Instruction is the most detailed description of a task. It's sole purpose is to explain step When employees follow the SOP for a particular job, they produce a product that is consistent by step how to do a specific task.

and predictable. However, if your goal is to produce the same product over the long term and increase your business productivity, the implementation of SOPs can have many benefits.

The following points are bused to measure one's own work against SOP

- Check your attitude
- Be reflective
- Assess your performance against the job specifications
- Keep a file
- Find out the supervisor's expectations
- Get feedback from others
- Be a team player
- Plan ahead

Self-Check -2	Written Test

Direction I: Short answer item

Instruction: Give short answer for the following questions .

1. What are work activities?(3 points)
2. What is standard operating procedure (SOP) ?
3. Discuss on how to measure your own work against SOP? (3 points)

Note: **Satisfactory rating - 3 points and above Unsatisfactory - below 3 points**

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

Answer Sheet-2

Score = _____

Rating: _____

Name: _____ Date: _____

Information Sheet-3	Identifying and isolating faulty services

3.1. Faulty services/products

The Consumer Guarantees Act (CGA) says services must meet these requirements — also known as guarantees:

- Done with reasonable care and skill.
- Fit for a particular purpose.
- Cost a reasonable price if the price wasn't set beforehand.
- Completed in a reasonable time if the timeframe wasn't set beforehand.

If your services fail to meet any of these four guarantees, your customers can seek a remedy from you. The remedy depends on how bad the problem is. You may also be responsible for paying for any damage or loss caused by the problem. You and your customer might have different opinions on how serious it is and whether it can be fixed.

3.2. Identification of faulty services/products

A "fault" is another word for a problem. A "root cause" fault is a fundamental, underlying problem that may lead to other problems and observable symptoms. (It might not be directly observable). A root cause is also generally associated with procedures for repair.

A "fault" or "problem does not have to be the result of a complete failure of a piece of equipment, or even involve specific hardware. For instance, a problem might be defined as non-optimal operation or off-spec product. In a process plant, root causes of non-optimal operation might be hardware failures, but problems might also be caused by poor choice of operating targets, poor feedstock quality, poor controller tuning, partial loss of catalyst activity, buildup of coke, low steam system pressure, sensor calibration errors, or human error.

Is monitoring a system, identifying when a fault has occurred, and pinpointing the type of fault and its location. Two approaches can be distinguished: A direct pattern recognition of sensor readings that indicate a fault and an analysis of the discrepancy between the sensor readings and expected values, derived from some model. In the latter case, it is typical that a fault is said to be detected if the discrepancy or residual goes above a certain threshold. It is then the task of fault isolation to categorize the type of fault and its location in the machinery.

3.3. Isolation of faulty services/products

3.3.1. Remedies for minor problems

If the problem or fault with the service is minor and can be fixed, you must:

- fix the problem or do extra work at no extra cost
- act within a reasonable time.

How fast you must act depends on the nature of the problem and what's involved in fixing it. Sometimes a reasonable time will mean within a few hours, eg a window won't open after a house is painted. In other cases, it might be a few days, eg a new roof is leaking.

The customer must give you the chance to fix minor problems first. If they complain after getting a minor fault fixed elsewhere, you do not have to pay the repair bill. Nor do you have to give a refund or replacement. By not coming to you first, the customer has lost their right to a remedy.

3.3.2. Remedies for serious problems

A problem or fault with a service is considered serious if:

- The customer who knew what would go wrong would not have had the job done.
  - For example, getting a jacket dry cleaned, but the dye runs and the jacket is streaked.
- The work done is unfit for its normal purpose and can't easily be put right, or it can't be put right within a reasonable time.
  - For example, bald patches left on a carpet after it's been professionally cleaned.
- A customer tells you of a specific purpose or result they want. The work does not achieve this, and can't easily or within a reasonable time be made to do so.
  - For example, a large family hire a station wagon for a weekend trip to visit relatives. It breaks down and repairs will take two days. But the hire company doesn't have a replacement vehicle that's large enough.
- The work done produces an unsafe result.
  - For example, an electrician wires a wall socket incorrectly and the customer gets an electric shock.

3.3.3. Remedies for damage or loss

Sometimes the work you do causes damage to a customer's belongings or property, known as consequential loss. If this happens, you must: Pay for any damage or other losses you caused.

- For example, costs to clean up paint spilled on a driveway or repair scratches on tiles caused by moving an appliance. Pay any extra costs directly related to the problem you caused.
- For example, costs of panel-beating and temporary transport if a builder drops roofing materials on a customer's car.

Self-Check -3	Written Test

Direction I: Short answer item

Instruction: Give short answer for the following questions.

1. What are the three requirements that services should meet?(3 points)
2. What do we mean by fault? (1 point)
3. Mention the remedies for: (2 points each)
   i. minor problems
   ii. serious problems
   iii. damage or loss

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

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

Answer Sheet-3

Score = _____

Rating: _____

Name: _____ Date: _____

Information Sheet-4	Recording and reporting any identified causes of faults

4.1. Causes of faults in service or output

The major causes of poor service delivery are councilor interference and political manipulation, corruption and lack of accountability and transparency, inadequate citizen participation, poor human resource policy, failure to manage change, lack of employee capacity, poor planning, and poor .

Bad customer service is caused by a number of factors which include; very unhelpful and impolite staffs, poor after sales service, poorly trained staff members who lack knowledge and skills to perform various tasks and poor products or services.

Solutions to customer services experiencing limited improvement:

- Establish a knowledge foundation
- Empower your customers
- Empower your frontline employees
- Offer multichannel choice
- Create streamlined experiences
- Measure your performance and continuously improve

Reasons for defective out puts:

- Design defects.
- Improper labeling or failure to warn.
- Manufacturing defects.
- Strict liability.
- Warranty breach.
- General negligence.

Defective Product is an imperfection in a product that has a manufacturing or design defect, or is faulty because of inadequate instructions or warnings. A product is in a defective condition if it is unreasonably dangerous to the user or to consumer who purchases the product and causes physical harm.

There are three types of product defects that can result in product liability cases: Design defects, Manufacturing defects, and Marketing defects.

A. Defective design

Design defects are inherent flaws in the design of a product, such that even if a product is assembled and produced perfectly, it will always come out of the factory in dangerous condition. For example, an automobile that will explode upon impact, as was the case with the Ford Pinto, would be considered to have a design defect.

Some products possess design flaws that make them dangerous for consumers even when they are manufactured properly and used in accordance with the manufacturer's guidelines. These flaws are not due to an isolated mistake or error and will typically affect the entire line of products. Design defects should be detected during the testing process. However, in some cases, these products are released onto the market.

Examples of design defects include:

- Cell phones with batteries that may explode, space heaters that might catch fire, and tires with inherently poor traction.
- A ladder is constructed of lightweight aluminum, which can bend, or cause the ladder to tip with little force. Even if every such ladder is assembled correctly, it will still create a dangerous situation for users of the ladders. Such a ladder is considered to have a design defect. Design defects also apply to the way products are packaged.
- If an insect poison is sold in a bottle that is prone to leaking, or requires a user's hands to come in contact with the poison, the manufacturer could be liable for injuries which result from the defective design. Much of today's product liability litigation consists of design defect cases, and this field is broad enough to cover such claims as asbestos litigation, vaccine and other drug litigation, flammable fabric litigation, dangerous power tool or appliance litigation, defective medical implant litigation (including breast implants), and any other area in which a product's design makes it unreasonably dangerous for its intended use, thereby causing injury.

B. Manufacturing defects

Manufacturing defects are defects that typically occur in a relatively low number of units of a given product, since the defects occur during the manufacturing process of a product. Any number of problems can occur during production and assembly of complex products — a screw may not be adequately tightened, a bolt may be missing, wires may be crossed, or pieces may be incorrectly soldered. As a result, the product comes off the assembly line in defective condition.

Example: A transistor is improperly installed into a hair dryer, causing the unit to smoke and eventually burn up. The manufacturing defect poses a risk of electrical shock, as well as a fire hazard. If it causes a shock or a fire in your home, the manufacturer will be liable for injury and damages which result.

C. Failure to provide instructions or warnings

All products must include adequate instructions for proper use and maintenance, as well as warnings for any side effects, illnesses or injuries that the product could cause. If these warnings are not included in the product's literature, the manufacturer of the product may be liable for injuries or damage the product causes. Examples of products that are defective for this reason include medications with undisclosed side effects, or even electric blankets that can electrocute the user.

If you have purchased a faulty or defective product that caused illness, injury or property damage, you may be entitled to compensation from the product's manufacturer. In order to qualify for compensation, the illness, injury or damage must have been a direct result of the product's defect or lack of warning.

Inadequate instructions and warnings are also a basis by which a product can be determined to be defective. Inadequate warnings generally are those which fail to prevent the improper use or assembly of a product. Product manufacturers have a responsibility to provide consumers with clear and complete instructions to ensure the safe use of a product. This is particularly important where the product is "intrinsically dangerous," i.e., of such a character to be harmful in its ordinary use absent proper caution (chemicals, drugs, machinery, etc.). In that case, the manufacturer must adequately warn consumers of the potential dangers, and the alert must be explicit and written in language that is easily comprehensible to the average person. Failure to adequately and properly warn, with regard to use, handling, dangers, and other effects of a product, is a common basis for product liability lawsuits. An otherwise useful product carrying inherent risks may be determined to be unreasonably dangerous for its intended use solely due to the absence of an adequate warning alerting the user to the danger.

4.2. Record keeping

A quality record is a document recording specific information that relates to a procedure or work instruction. Quality records are proof that an organization is complying with its procedures and policies.

Recordkeeping is the process of recording transactions and events in an accounting system. Since the principles of accounting rely on accurate and thorough records, record keeping is the foundation accounting.

4.2.1. Types of records

Usually, it includes documents such as quality policy, quality manual, procedures, work instructions, quality plans, and records

There are five types of records to be kept.

- Accounting records: Accounting records document your business's transactions
- Bank statements : Bank statements are records of all your accounts with the bank
- Legal documents
- Permits and Licenses
- Insurance documents

Organizing information for retrieval when needed. Protecting records that are essential to mission-critical business operations. Ensuring compliance with legal and regulatory recordkeeping requirements, thereby avoiding costly fines or other penalties.

The essence of good record keeping is good bookkeeping. Efficient bookkeeping will save you time and money in the long run. Proper business record keeping provides the business a real advantage over the competition in different ways. It helps you to manage your accounts, interests, taxes and working costs effectively.

4.3. Reporting

Fault Reporting is a maintenance concept that increases operational availability and that reduces operating cost through three mechanisms. Fault reporting is used to:

- Reduce labor-intensive diagnostic evaluation
- Eliminate diagnostic testing down-time
- Provide notification to management for degraded operation

Self-Check -4	Written Test

Direction I: Short answer item

Instruction: Give short answer for the following questions .

1. What are the solutions you recommend to customer services experiencing limited improvement?(3 points)
2. What are the main reasons for defective out puts?(2 points)
3. Give examples of design defects (3 point each)
4. Define what record keeping mean(1point)
5. List types of records(3 points)

Note: **Satisfactory rating - 3 points and above** **Unsatisfactory - below 3 points**

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

Answer Sheet-4

Score = _____

Rating: _____

Name: _____ Date: _____

Operation Sheet -1	Technique of documenting workplace records

Procedures

Step 1: Describe the detailed instructions for the work. Identify roles and responsibilities.

Step 2: Give each activity its own title

Step 3: One role activities

Step 4: Number each step

Step 5: Use consistent formatting

Step 6: Document control-Version number, Date ,Documeent, name, Detail of change, Review date, etc

Operation Sheet -2	Techniques of preparing work instruction

Procedures

Step 1: Know exactly how to do the task.

Step 2: Plan how to write steps in order.

Step 3: Write instructions beginning with a verb.

Step 4: Write each step as a small piece.

Step 5: Include warnings as pre-steps.

Step 6: Write the steps in logical order.

Step 7: Review and edit instructions carefully.

Step 8: Express steps in the positive.

Step 9: Avoid expressing opinions, preferences, or choices.

Operation Sheet -3	Techniques of fixing customer product problems

procedures

Step 1: Assess the situation

Step 2: Ask for the customer's needs and preferences

Step 3: Offer a solution and give options whenever possible

Step 4: Deliver the solution

Step 5: Follow up with the customer

Step 6: Address the issue within the company

LAP Test	Practical Demonstration

Name: _____ Date: _____

Time started: _____ Time finished: _____

Instructions: Given necessary templates, tools and materials you are required to perform the following tasks within 12 hours.

Task 1: Perform documentation of workplace records

Task 2: Prepare work instruction

Task 3: Perform fixing of customer product problems

N.B: *You can ask your instructor for all necessary tools, equipments and other supplies including diagrams and drawings.*

Instruction Sheet	LG20: Assess quality of service rendered

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

- Checking quality
  - Visual inspection
  - Physical measurements
  - Checking against specifications/preferences
- . Evaluating service rendered
- Identifying and correcting Causes of any fault
- Taking corrective action

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

- Check quality
- Evaluate service render
- Identify and correct Causes of any fault
- Take corrective action

Learning Instructions:

1. Read the specific objectives of this Learning Guide.
2. Follow the instructions described below
3. Read the information written in the “Information Sheets 1, 2 & 3”. Try to understand what are being discussed. Ask you teacher for assistance if you have hard time understanding them.
4. Accomplish the “Self-checks" in each information sheets on pages 7, 14 & 21.
5. Ask from your teacher the key to correction (key answers) or you can request your teacher to correct your work. (You are to get the key answer only after you finished answering the Self-checks).
6. If you earned a satisfactory evaluation proceed to “Operation sheets 1-5 on pages 25-29 and do the LAP Test on page 30”. However, if your rating is unsatisfactory, see your teacher for further instructions or go back to Learning Activity.

7. After You accomplish Operation sheets and LAP Tests, ensure you have a formative assessment and get a satisfactory result;
8. Then proceed to the next LG.

Information Sheet-1	Checking quality

1.1. Quality checks

Used to ensure that a manufactured product or performed service adheres to a defined set of quality criteria or meets the requirements of the client or customer.

It involves testing of units and determining if they are within the specifications for the final product. The purpose of the testing is to determine any needs for corrective actions in the manufacturing process. Good quality control helps companies meet consumer demands for better products.

The quality of services or products delivered to customers could be checked using the following three methods.

- Visual inspection
- Physical measurements
- Check against specifications/preferences

Quality inspection are measures aimed at checking, measuring, or testing of one or more product characteristics and to relate the results to the requirements to confirm compliance. This task is usually performed by specialized personnel and does not fall within the responsibility of production workers. There are different types of quality checks. The following are the common types:

- Company Quality Check Policy
- Prototype quality testing
- Failure or stress testing
- Manufacturing quality inspections

Company Quality Check Policy: One of the best overall quality control methods is to institute a company-wide quality control policy. This policy should make it clear that product quality is a high priority, and should assign employees tasks for checking product quality at all stages, from design to manufacture and finishing. Giving employees a convenient means of reporting quality

problems or defects can lead to early detection and can save money in the long term. After all, it is far more inexpensive to fix a problem with a design at the design stage than repairing or fully discarding completed products with a built-in design.

Prototype quality testing: Testing prototypes is a quality checking method that relies on real-world testing by employees and their families, or by potential customers selected from the general public. Prototype products should be as close as possible to production versions, and users should be asked to fill out surveys or report problems with the product.

For example, if you own a shoe company and want to ensure that your shoes will hold up to real world conditions, you can send employees home with pairs for themselves and their families. After a set period, for example, a month or three months, ask them to bring the shoes back in and answer some survey questions about how often they wore them, what activities they performed in them and how comfortable and supportive they found the shoes.

Failure or stress testing: Failure testing, or stress testing, is one of the most common quality check methods for industrial products. Factories often contain a special area for failure testing, where products are subjected to repeated use and misuse until they fail in some way.

This testing can include subjecting the products to extreme temperatures, submerging electronic devices in water, and crushing or dropping products. Mattress testing, for example, involves repeatedly pressing weights on the mattress to see how it will hold up to wear after a long period.

Failure testing not only gives manufacturers an idea of how much a product can endure, but also gives them knowledge about what the form the failure will take and whether or not the broken product will represent a safety risk.

Manufacturing quality inspections: Continuous quality checking should also occur at the point of manufacturing. Employees who perform quality checks in a factory may look for defects at several stages of production, or check random samplings of products at the end of the process. Measuring tools can serve to check whether products meet certain quality standards in terms of size or shape, and a simple visual inspection can ensure that no severely flawed products leave the factory.

1.2. Factors affecting quality of services or products

The quality of a product may be defined as the sum of number of related characteristics, such as shape, dissension composition, strength, workmanship, adjustment, finish and color.

It is sum-total of features of a product which influence its capacity to satisfy a given need. Quality of a product consists of the following attributes:

(a) Appearance of the product

(b) Product design or planned quality

(c) Suitability from customer's viewpoint

(d) Reliability

(e) Durability

(f) Degree to which it conforms to the product specifications

(g) Its marketing and service, etc.

Quality characteristics may be directly measurable, e.g., diameter , volt-age, weight, etc. But some quality features are non-measurable, e.g. blow holes, cracks, dents, etc. Quality is of two types :

(a) **Quality of design** refers to the manufacturing specification of the product. It consists of appearance, life, safety, maintenance and other features of product design.

(b) **Quality of conformance** implies the degree to which the product actually conforms to the design specification. Quality of conformance is measured by the level of defects in the finished product. Usually, higher quality of design means higher cost while higher quality of conformance means lower total cost. Perfection in any type of quality is rarely possible and it may mean infinite cost Moreover, exceptionally high quality product may not be accepted in the market unless sufficient number of customers can pay for it.

All business concerns exist to provide goods and services to society. They can be profitable and successful only when the products and services are for use and meet the needs of consumers. Such 'fitness for use' of product is known as quality. While deciding the quality of his products, a manufacturer has to reconcile two conflicting trends, viz., customer satisfaction and cost of production.

Higher is the quality greater is the satisfaction of customer. But every improvement in quality means additional costs. It is the responsibility management to build a quality level which provides reasonable customer satisfaction at economical cost. The level of quality ultimately depends upon the type of market (level of customer wants and the price he is willing to pay for). Within a certain range quality level is a management decision taken on the basis of costs and profits.

For example, it may be more profitable to supply a medium-quality item at a low price which people can buy rather than to supply a top quality at a price so high that very few people can afford. Thus, the level of quality has direct relation with customer's purchasing power. This is the economics of quality.

Quality of a product or service depends upon the following factors

(i) Market. Customer demand, his needs and purchasing power are the main determinants of quality level.

(ii) Materials. The availability of right type of materials is essential for maintaining quality level of finished products. A wide variety of materials may be available but material with right specification has to be used.

(iii) Technology. Nature of technology and machinery used has a direct bearing on product quality. Modem technology, methods and equipment have led to improvements in product quality level.

(iv) Labour. The knowledge and experience of people who design and produce products exercise significant influence on quality level. Competent and trained people can design and manufacture better quality products.

(v) Cost. Cost of quality maintenance and improvement has increased significantly. Increasing competition, growing mechanization and decreasing profit margins may not permit greater expenditure on quality improvements. Scrap and rework losses have become serious.

(vi) Management. The attitude and policy of management towards product quality is important Some managers tend to be more quality conscious than others.

Self-Check -1	Written Test

Direction I: Short answer item

Instruction: Give short answer for the following questions.

1. What are quality checks(2 points).
2. List different types of quality checks(5 points).
3. What are the factors affecting quality of services or products(5 points).
4. What are the attributes of quality? (5 points).

Note: **Satisfactory rating – 8.5 points and above** **Unsatisfactory - below 8.5 points**

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

Answer Sheet-1

Score = _____

Rating: _____

Name: _____ Date: _____

Information Sheet- 2	Evaluating service rendered

2.1 Introduction to evaluation of quality

Evaluation (of quality or standards) is the process of examining and passing a judgment on the appropriateness or level of quality or standards. Quality evaluation may be undertaken internally or externally. External evaluation is a process for undertaking an independent evaluation.

Evaluation is a systematic process of determining to what extent instructional objectives has been achieved. Therefore evaluation process must be carried out with effective techniques.

When you evaluate something, you're making a judgment, one that most likely results from some degree of analysis.

There are three main types of evaluation:

- Planning,
- Formative and
- Summative

2.2. Evaluation Techniques

I. **Formative Evaluations:** Formative evaluations are evaluations that occur during the process

II. **Summative Evaluations:** The summative evaluation occurs at the end of the program. The various instruments that can be used to collect the data for a summative evaluation include questionnaires, surveys, interviews, observations, and testing.

III. **Process Evaluation:** Process evaluations focuses on how a program was implemented and how it operates.

IV. Impact Evaluation.

V. Outcome Evaluations.

2.3 Evaluation of quality of service delivered

Measuring service quality is absolutely crucial. An assessment of how well a delivered service conforms to the client's expectations should be made to satisfy the customers. Service business operators often assess the service quality provided to their customers in order to improve their service, to quickly identify problems, and to better assess client satisfaction.

Here are 9 practical techniques and metrics for measuring your service quality.

1. SERVQUAL: This is the most common method for measuring the subjective elements of service quality. Through a survey, you ask your customers to rate the delivered service compared to their expectations. In this method, service quality is measured as:

Reliability - the ability to deliver the promised service in a consistent and accurate manner.

Assurance - the knowledge level and politeness of the employees and to what extent they create trust and confidence.

Tangibles - the appearance; of e.g. the building, website, equipment and employees.

Empathy - to what extend the employees care and give individual attention.

Responsiveness - how willing the employees are to offer a speedy service.

Mystery Shopping: This is a popular technique used for retail stores, hotels, and restaurants, but works for any other service as well. It consists of hiring an "undercover customer" to test your service quality – or putting on a fake moustache and going yourself, of course.

Post Service Rating: This is the practice of asking customers to rate the service right after it's been delivered.

Different scales can be used for the post service rating. Many make use of a number rating from 1 – 10. There's possible ambiguity here, though, because cultures differ in how they rate their experiences .

People from individualistic cultures, for example, tend to choose the extreme sides of the scale much more often than those from collectivistic cultures. In line with stereotypes, Americans are more likely to rate a service as "amazing" or "terrible," while the Japanese will hardly ever go beyond "fine" or "not so good." It's important to be aware of when you have an international audience.

Simpler scales are more robust to cultural differences and more suited for capturing service quality. Customers don't generally make a sophisticated estimation of service quality.

"Was it a 7 or an 8...? Well...I did get my answer quickly... On the other hand, the service agent did sound a bit hurried…" No. They think the service was "Fine," "Great!" or "Crap!".

Follow-Up Survey: With this method you ask your customers to rate your service quality through an email survey – for example via Google Forms . It has a couple advantages over the post-service rating.

In-App Survey: With an in-app survey, the questions are asked while the visitor is on the website or in the app, instead of after the service or via email. It can be one simple question – e.g. "how would you rate our service" – or it could be a couple of questions.

Customer Effort Score (CES): This metric was proposed in an influential Harvard Business Review article. In it, they argue that while many companies aim to "delight" the customer – to exceed service expectations – it's more likely for a customer to punish companies for bad service than it is for them to reward companies for good service .

Social Media Monitoring: This method has been gaining momentum with the rise of social media. For many people, social media serve as an outlet. A place where they can unleash their frustrations and be heard.

Documentation Analysis: With this qualitative approach you read or listen to your respectively written or recorded service records. You'll definitely want to go through the documentation of low-rated service deliveries, but it can also be interesting to read through the documentation of service agents that always rank high.

2.4 Ways to Improving and Maintain Quality Customer Service

Improving, or at least maintaining, the quality of services, products, workplace and marketing practices is always to be the first plan for any business success. Often many business managers/owners wonder they provide the same product/service to customers as their competitor do, but the competitor is winning and they are losing. This is just because they lack something called 'dedication for quality'; although the difference will be very minute but it is the deciding factor. Here are some tips to improving the quality of products and services.

- Create a long-term plan for quality improvement, break it in to small steps, and then make changes to achieve goals of each step. Give supreme priority of quality in every plans and procedures. Remember, adjusting quality with time, cost or labor can provide temporary benefits but permanently destroy the future.
- Talk often with your clients. Investigate why they like you, why they are tempting to go to your competitors or what else they expect from you.

- Talk politely with your employees, especially sales persons, what do they and their clients expect from the company and why company fail to deliver so.
- Frequently compare your product with your competitors and find out where you are winning and where you are losing.
- Always look for possibilities to improve your product and service. Carefully analyze every technical/social developments and think how that can help you in your business.

Customer service may be maintained through providing :

- Value: Let your clients know they are so much more than a number to you.
- Inform: A client comes to you because you have a set of skills that they do not.
- Respond: Ensure you provide a timely response to email correspondence, let your customer know they have been heard.
- Expectation
- Convenience
- Consistency

2.5 Evaluation of Products

The quality of a product or service refers to the perception of the degree to which the product or service meets the customer's expectations. Quality has no specific meaning unless related to a specific function and/or object.

Product quality evaluation is usually based on customer's product expectation and product perception. If the products provided by enterprises can meet the customer lowest needs, the customer will be satisfied with the product quality.

The customer's satisfaction is based on the product itself. A manufactured product has established specifications, whether appearance or performance, that can be measured directly. Measures of quality for manufactured goods are also tangible. So, managing quality is crucial for small businesses. Quality products help to maintain customer satisfaction and loyalty and reduce the risk and cost of replacing faulty goods. Companies can build a reputation for quality by gaining accreditation with a recognized quality standard.

Products and services that meet or exceed customer expectations result in customer satisfaction. Quality is a function of how the customer views the product/service that he or she receives.

2.6. Characteristics of service standards

Service standards are usually defined in terms of:

- timeliness
- accuracy
- appropriateness

Customer expectations

Accuracy: Customers expect accurate information and accurate deliveries – only 100% is acceptable as a standard under this heading. 'We got most of your order right' is a response that is not appreciated by a customer.

Examples of service standards reflecting the accuracy of a service are 'the information quoted in a telephone conversation is 100% accurate' or 'the parcel received by the customer contained all the goods ordered by the customer'.

Appropriateness: How often do you hear the exclamation 'they didn't answer the question!' It happens often when politicians are being interviewed on TV but it shouldn't happen in the commercial world. Appropriateness is about ensuring that the customers' expectations have been met, particularly in an enquiry situation.

Example:

A customer writes to an organization with a three-part enquiry. The customer receives a response that is on time, totally correct in what it says – but fails to address one of the three topics in the original enquiry. Such a response would fail the appropriateness standard – again based on a 100% expectation. '100% of the customer's questions were addressed' would be a good starting point for such a standard.

There are at least seven potential sources of information to help define the service standards for an organization:

- Management
- Employees
- Existing customers
- Potential customers
- Lost or former customers
- Competitors
- Regulatory authorities

Self-Check -2	Written Test

Direction I: Short answer item

Instruction: Give short answer for the following questions .

- Define what evaluation mean(2 points).
- List different evaluation techniques(4 points).
- What are the different ways to improving and maintain quality customer service? (4 points).
- List characteristics of service standards (2 points)

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

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

Answer Sheet-2

Score = _____

Rating: _____

Name: _____ Date: _____

Information Sheet-3	Identifying and correcting Causes of any fault

3.1. Identification of causes of faults

Defect /fault is an imperfection or shortcoming, especially in a part that is essential to the operation or safety of a product .

Fault is an identified deviation from reasonable efforts to prevent a failure or to mitigate the severity of a failure. Thus, it is the lack of reasonableness that is the key for the engineer in identifying the defect. Furthermore, using lack of reasonableness in identifying defects will serve to go beyond the frequently applied superficial (wrong) analyses that assert that the occurrence of a failure is prima facie evidence that there was a defect. The defect is the lack of reasonableness that existed prior to the failure and that resulted in the circumstances that led to the failure. However, it should be noted that a defect can exist that is not causal. As discussed later in this article, the defect (or lack of reasonableness) must have resulted in the failure to then allow the engineer to assert that the responsible person or entity caused the failure. Defect identification then allows the engineer to proceed with efforts to protect the public.

To correctly identify a fault, you must first figure out which block is the footwall and which is the hanging wall. Then you determine the relative motion between the hanging wall and footwall. Every fault tilted from the vertical has a hanging wall and footwall.

3.2. Root Cause analysis

A root cause is defined as a factor that caused a nonconformance and should be permanently eliminated through process improvement. Root cause analysis is a collective term that describes a wide range of approaches, tools, and techniques used to uncover causes of problems.

Root Cause Analysis (RCA) is the process of identifying factors that cause defects or quality deviations in the manufactured product. Common examples of root cause analysis in manufacturing include methodologies such as the “Fishbone” diagram and the “5 Whys”.

Root cause analysis is a process for identifying the basic or causal factors that underlie variation in performance, including the occurrence or possible occurrence of a sentinel event. A root cause analysis focuses primarily on systems and processes, not individual performance.

The key to successful problem resolution is the ability to identify the problem, use the appropriate tools based on the nature of the problem, and communicate the solution quickly to others. Inexperienced personnel might do best by starting with the Pareto chart and the cause and effect diagram before tackling the use of the other tools. Those two tools are used most widely by quality improvement teams.

PARETO DIAGRAMS

The Pareto diagram is named after Vilfredo Pareto, a 19th-century Italian economist. are caused by 20% of the potential sources.

A Pareto diagram puts data in a hierarchical order (Figure 3.1), which allows the most significant problems to be corrected first. The Pareto analysis technique is used primarily to identify and evaluate nonconformities, although it can summarize all types of data. It is perhaps the diagram most often used in management presentations. To create a Pareto diagram, the operator collects random data, regroups the categories in order of frequency, and creates a bar graph based on the results.

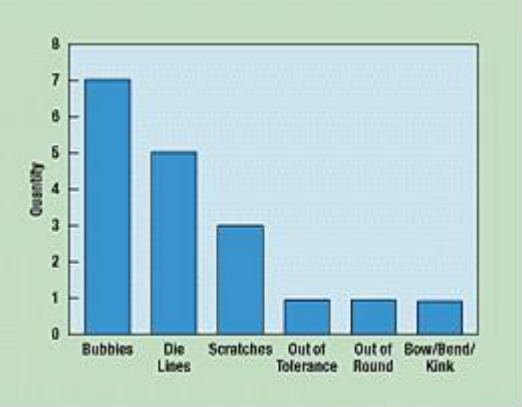

Figure 3.1 *By rearranging random data, a Pareto diagram identifies and ranks nonconformities in the quality process in descending order.*

CAUSE AND EFFECT DIAGRAMS

The cause and effect diagram is sometimes called an Ishikawa diagram after its inventor. It is also known as a fish bone diagram because of its shape. A cause and effect diagram describes a relationship between variables. The undesirable outcome is shown as effect, and related causes are shown leading to, the said effect. This popular tool has one severe limitation,

however, in that users can overlook important, complex interactions between causes. Thus, if a problem is caused by a combination of factors, it is difficult to use this tool to depict and solve it.

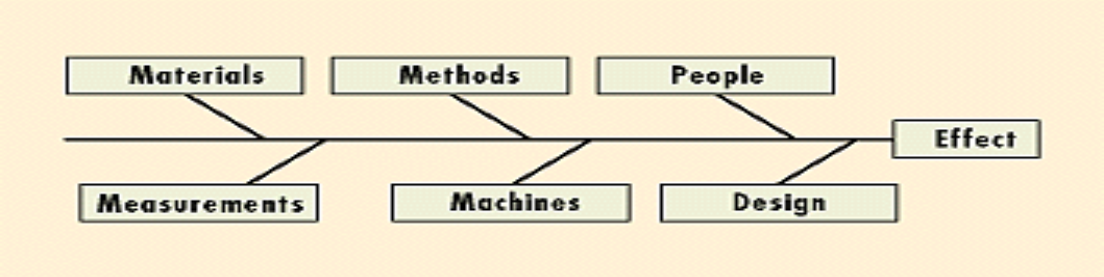

Figure 3.2 Fish bone diagrams display the various possible causes of the final effect.

A fish bone diagram displays all contributing factors and their relationships to the outcome to identify areas where data should be collected and analyzed. The major areas of potential causes are shown as the main bones, Later, the sub-areas are depicted. Thorough analysis of each cause can eliminate causes one by one, and the most probable root cause can be selected for corrective action. Quantitative information can also be used to prioritize means for improvement, whether it be to machine, design, or operator.

Self-Check -3	Written Test

Direction I: Short answer item

Instruction: Give short answer for the following questions.

1. What is the use of fish bone diagram? (4 points)
2. What is service/product defect? (3 points)
3. What do you mean by **root cause**? (3 points)
4. What is the use of Pareto diagram ? (4 points)

Note: **Satisfactory rating - 7 points and above** **Unsatisfactory - below 7 points**

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

Answer Sheet-3

Score = _____

Rating: _____

Name: _____ Date: _____

Information Sheet-4	Taking corrective action

4.1 Corrective actions

Corrective action is the action taken to eliminate the causes of an existing nonconformity, defect or other undesirable situation in order to prevent recurrence. It deals with a nonconformity that has occurred. 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. It must be systematically implemented and observed for its ability to eliminate further recurrence of non-conformation. Non-conformance may be a market complaint or customer complaint or a failure of a machinery or a quality management system, or misinterpretation of written instructions to carry out a work.

Corrective action is an aspect of quality management that aims to rectify a task, process, product, or even a person's behavior when any of these factors produce errors or have deviated from an intended plan. Corrective actions can be thought of as improvements to an organization to eliminate undesirable effects. Corrective actions can apply to an entire project when the deliverables, whether tangible or service, deviate from the required output. In HR for higher education institutions in particular, corrective action also applies to individual employees and functions to communicate to the individual what aspects of attendance, unacceptable behavior, or performance require improvement.

A company's ability to rapidly correct existing problems and implement controls to prevent potential problems is essential to ensure customer satisfaction and achieve operational success. A corrective action process must meet the necessary industry compliance requirements, it must also be effective. Taking corrective action requires identifying the problem and implementing a potential solution.

4.2 Advantages and disadvantages of Corrective actions

Benefits:

- It walks you through the process, so there's no need to reinvent the problem-solving wheel.
- The corrective action document helps detail steps for solving a particular problem.
- The corrective benefits process adds transparency to the activity and empowers teams.

- It captures experience and changes for future events and development.

Drawbacks:

- If implemented poorly, corrective action becomes a bureaucratic exercise in which corrective action requests are sometimes filled out for minor incidents.
- Corrective action also runs the risk of focusing on symptoms rather than root causes.
- In addition, a team may perceive it as a non-vital activity to be conducted by one or two team members during their ever-elusive “free time.”

4.3 Corrective measures

Corrective measures are a documented way of fixing repetitive problems or conditions in which critical or high levels of nonconformance appear. You may identify problems through a variety of means, including statistical analysis.

Even among quality management professionals, confusion over the differences between corrective and preventive actions often persists, as people sometimes consider the two actions to be the same. Some of the confusion arose because ISO 9000 originally listed the two actions adjacent to each other, with corrective actions listed first. The revision of ISO 9000:2015 indicates that preventive actions are more of a culture and part of day-to-day good practice. Some organizations also mistake every instance of nonconformity for something that requires documentation — one way to create never-ending paperwork.

4.4. A corrective action plan (CAP):

Is a step by step plan of action that is developed to achieve targeted outcomes for resolution of identified errors in an effort to identify the most cost-effective actions that can be implemented to correct error causes.

A corrective action plan (CAP) describes, step by step, how you plan to resolve a problem or nonconformity. A CAP details the resources needed to correct the causes of a problem in the most cost-effective and cost-efficient way. The plan’s objectives and benefits include the following:

- It provides a standard way to address deficiencies.
- It offers premade templates that describe what types of information you need in your plan.

- It provides a process to start, research, implement, and close out a corrective action program.
- It clarifies team member or contractor responsibilities.
- It specifies what types of issues require a corrective action plan.

A corrective action plan should be very specific, such as when you're detailing a problem in a particular part in a production line. But it may also be general: For instance, you'll need to speak in broader terms when providing detailed guidelines for addressing different severities of hazardous waste sites throughout the country and generating the paperwork required for permitting construction in such conditions. A plan or the template for dealing with troubles may detail interim measures to mitigate problems before you find a more comprehensive solution. Deadlines also apply to the creation of corrective action plans. For example, regulatory entities may impose longer lead times, whereas issues in factories may require shorter turnaround times.

A corrective action plan may also include the following information:

- Stakeholders
- Resources available to solve the problem
- Constraints
- Due dates
- Metrics for completion
- Progress updates

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.

4.5 Preventive Action

An action taken to eliminate the cause of a potential nonconformity, defect, or other undesirable situation in order to prevent occurrence. 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 both include stages for investigation, action, review, and further action if required. It can be seen that both fit into the PDCA (plan-do-check-act) philosophy as determined by the Deming-Shewhart cycle.

Preventive Action Process

- Take 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.

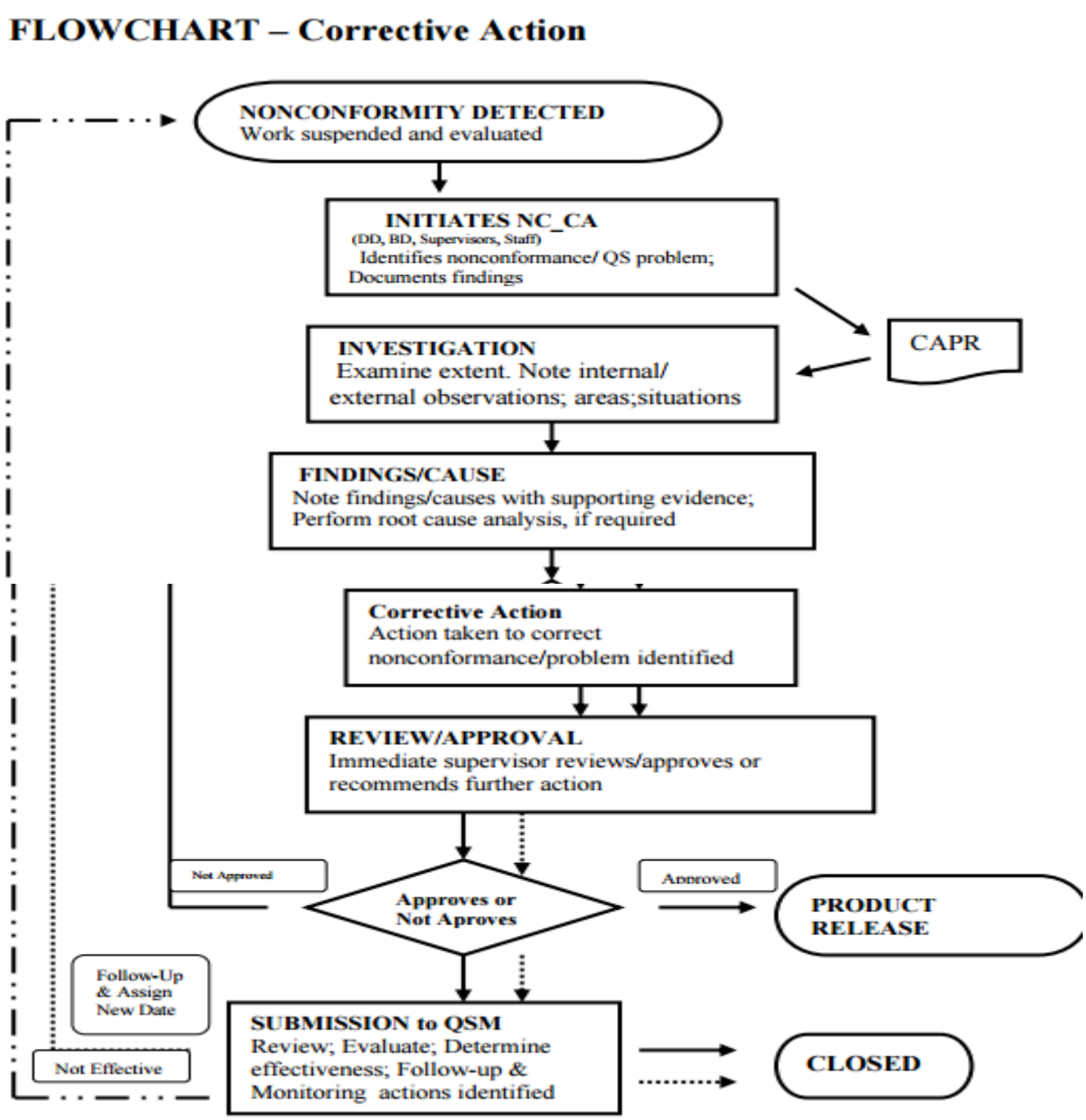

Figure 3.2: Corrective action flow chart

Self-Check -4	Written Test

Direction I: Short answer item

Instruction: Give short answer for the following questions

1. Define the following:(2 points each)
    - Preventive action

- Corrective measures
- A corrective action plan (CAP):

2. What are Advantages and disadvantages of Corrective actions(4 points)
3. Mention all information that should be included in the corrective action plan? (4 points)
4. What do we mean by non-conforming service? (2 points)

Note: **Satisfactory rating - 8 points and above** **Unsatisfactory - below 8 points**

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

Answer Sheet-3

Score = _____

Rating: _____

Name: _____ Date: _____

Operation Sheet -1	**Techniques of carrying out performance evaluation**

Necessary Steps in Process Of Performance Appraisal.

Step 1: Establish performance expectations and standards.

Step 2: Providing regular feedback.

Step 3: Measure actual performance.

Step 4: Compare actual performance with standards.

Operation Sheet -2	Techniques of preparing root cause analysis for faults

Procedures

Step 1: Identify Possible Causal Factors

Step 2: Identify the Root Causes

Step 3: Identify Communication Challenges

Step 4: Prioritize the causes and their challenges

Step 4: recommend to solve the problem

Operation Sheet -3	Techniques of creating effective action plan

Steps

Step 1: Choose an appropriate goal and clearly define your objective.
Step 2: Use a team to create your action plan.
Step 3: Choose action steps that are concrete, measurable and attainable.
Step 4: Identify who is responsible for each action step and who will be supporting them

Operation Sheet -4	Techniques of maintaining service standards

Procedures

Step 1: Write a vision statement for your business.
Step 2: Develop a strategy for service quality.
Step 3: Understand your customers' needs.
Step 4: Hire staff that provide quality service.
Step 5: Implement systems and standards for service quality.
Step 6: Measure and manage service quality

Operation Sheet -5	Strategies of reducing Defects of products

Steps

Step 1: Inspect the problems related to the quality of the products

Step 2: Take preventative measures to the identified problems/faults

Step 3: Control the quality of the product

Step 4: Communicate the findings with all the stake holders

LAP Test	Practical Demonstration

Name: _____ Date: _____

Time started: _____ Time finished: _____

Instructions: Given necessary templates, tools and materials you are required to perform the following tasks within 5hours.

Task 1: Carry out performance evaluation at your work place

Task 2: Prepare root cause analysis for identified faults

Task 3: Prepare effective action plan to solve problems

Task 4: Maintain service standards at your work place

Task 5: Perform reduction of defects of products at the work place

N.B: *You can ask your instructor for all necessary tools, equipments and other supplies including diagrams and drawings .*

Instruction Sheet	LG21: Record information

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. Read the information written in the “Information Sheets 1 & 2”. Try to understand what are being discussed. Ask you teacher for assistance if you have hard time understanding them.
4. Accomplish the “Self-checks" in each information sheets on pages 7 & 10.
5. Ask from your teacher the key to correction (key answers) or you can request your teacher to correct your work. (You are to get the key answer only after you finished answering the Self-checks).
6. If you earned a satisfactory evaluation proceed to “Operation sheets 1-5 on pages 12-16 and do the LAP Test on page 17”. However, if your rating is unsatisfactory, see your teacher for further instructions or go back to Learning Activity.
7. After You accomplish Operation sheets and LAP Tests, ensure you have a formative assessment and get a satisfactory result;
8. Then proceed to the next LG.

Information Sheet-1	Recording basic information on the quality performance

1.1. Concepts of quality performance

Performance is understood as achievement of the organization in relation with its set goals. It includes outcomes achieved, or accomplished through contribution of individuals or teams to the organization's strategic goals. The term performance encompasses economic as well as behavioral outcomes.

Quality conformance is the ability of a product, service, or process to meet its design specifications. Design specifications are an interpretation of what the customer needs.

Quality performance is a numerical measurement of the performance of an organization, division, or process. Quality of performance can be accessed through measurements of physical products, statistical sampling of the output of processes, or through surveys of purchasers of goods or services.

Quality performance could be maintained by:

- Stopping to depend on inspection to achieve quality.
- Building in quality from the start.
- Stopping awarding of contracts based on low bids.
- Improving the system of production and services to enhance quality and productivity, and thus constantly to reduce costs.

Quality of performance can be accessed through measurements of physical products, statistical sampling of the output of processes, or through surveys of purchasers of goods or services. Also referred to as quality of service.

1.2. Performance management

Performance management is a way of systematically managing people for innovation, goal focus, productivity and satisfaction. Its main objective is to ensure success to all managees i.e., all task teams who believe in its process, its approach and implementation with sincerity and commitment. It is a means of getting better results from the organizations, teams and individuals by understanding and managing performance within the agreed framework of planned goals and competency requirements. It is a process for establishing shared

understanding about what is to be achieved and an approach to managing and developing people. Its basic principles include:

- **Transparency:** Decisions relating to performance improvement and measurement such as planning, work allocation, guidance and counseling and monitoring, performance review etc., should be effectively communicated to the managees and other members in the organization.
- **Employee development and empowerment:** Effective participation of employees managees (individuals and teams) in the decision – making process and treating them as partners in the enterprise. Recognizing employees/managees of their merit, talent and capabilities, rewarding and giving more authority and responsibility etc., come under the umbrella this principle.
- **Values:** A fair treatment and ensuring due satisfaction to the stakeholders of the organization, empathy and trust and treating people as human beings rather than as mere employees form the basic foundation, apart from others. 4. Congenial work environment : The management need to create a conducive and congenial work culture and climate that would help people to share their experience knowledge and information to fulfill the managees aspirations and achieve organizational goals. The managees/employees should be well informed about the organizational mission, objectives, values and the framework for managing and developing individuals and teams for better performance.
- External environment: Effective and contextual management of external environment to overcome the obstacles and impediments in the way of effective managerial performance.

1.2.1. Importance of measuring organizational performance

Managers measure and control organizational performance because it leads to better asset management, to an increased ability to provide customer value, and to improved measures of organizational knowledge. In addition, measures of organizational performance do have an impact on an organization's reputation. Increased Ability to Provide Customer Value providing value to customers is important for organizations. If customers aren't receiving something of value from their interactions with organizations, they'll look elsewhere. Managers should monitor how well they're providing customer value, and they can do that when they measure performance.

The following are what to be measured in measuring organizational performance

1. Productivity
2. Organizational Effectiveness

3. Organizational Ranking.

1.2.2. Improving performance

Here are ways you can take control, improve your reputation and performance at work, and reach new skill levels and professional development.

1) Organize & Prioritize: Create a daily schedule and follow it. Identify the top three or four critical projects that need to be completed. Ensure your task list is manageable, adds value, and benefits your firm.

2) Stop Multitasking: Multitasking lowers IQ, lowers EQ (emotional intelligence), slows you down, increases stress levels, and causes mistakes. Master unit asking instead.

3) Avoid Distractions: Did you know that *focus* is a fundamental quality of productive people? Our brains are wired to work best when we focus on a single task. Practice staying focused and strive to complete one task before diving into another.

4) Manage Interruptions: It's easy to minimize or forget how many times we're interrupted during the day. Interruptions can come in all forms: co-workers, bosses, family, etc. Here's a great trick to manage your interruptions.

5) Be a Great Finisher: Many of us are great starters but we fall short on finishing. Think about how many times you've started something new: a project, a New Year's resolution, or a letter and end up adding it back on your to-do list. Keep a journal of completed projects and reflect on it to demonstrate your contributions and accomplishments.

6) Set Milestones: The road to completing a big project may seem overwhelming. Don't let that stop you from taking time to celebrate interim achievement. Break large projects into blocks of mini-tasks and set individual success metrics to keep your morale and energy levels high. Record your progress, reward yourself, and share your progression with the team.

7) Wear the Bosses Shoes: Put yourself in your boss's shoes. Think about the big picture and look at goals from his/her perspective.

8) Get a Mentor/Be a Mentor: Enhance your skills with a mentor. A mentor can offer new insight, perspective, and vision. Working with a mentor will stretch your thinking and supply you with a stream of self-development ideas related to your unique skills and talent.

9) Simply Listen: Listening is vital to effective communication. Spend time thinking about how you listen. Do you interrupt others? Mature listening skills lead to increased productivity with fewer mistakes, innovative growth, and higher client satisfaction rates.

10) Aim for Clarity: Clarity provides confidence. Ask questions if you are not 100 percent sure of your responsibilities. Schedule time quarterly to re-evaluate firm goals, how your

responsibilities fulfill those goals, and how you can better partner with team members to reach each goal.

11) Research: Take time to research. Don't waste other's time; do your homework before taking on a new task. You'll be better prepared to present strategies to reach each objective.

12) Write a Letter to Your Future Self: Where do you see yourself in 1 year, 3 years, or even 5 years? What will be the same? What will be different? Write a letter to yourself and work hard to become that person.

13) Identify Your Blind Spots: Blind spots are areas we are unaware of about ourselves and may cause good intentions to be perceived in a negative way. Blind spots can hold you back and prevent professional development. To identify blind spots you must be willing to look at yourself honestly, ask others for feedback, and be willing to make changes. Reach out to your peers and ask how you are perceived; you may discover behaviors that hinder your influence as well as strengths you're not aware of. View feedback as an asset rather than a judgment; which will allow you to make adjustments to align your reputation with your ideal self.

14) Simplify Something: Often we do things because *"that's the way we've always done it"* even if it's complicated or messy. Find something each week to simplify or automate: a difficult system or process, a messy office, daily tasks, or email. Your efficiency will increase by keeping things simple.

15) Ask Questions: Constantly challenge yourself by asking, *"Is there a more effective way to achieve the same results?"* Brainstorm to determine if you are working as efficiently as possible. Always believe that things can be improved.

16) Know Your Competition: Know and observe your competition. Identify what they're doing right and use it as a learning opportunity to implement something new at your firm.

17) Acknowledge Others: Help others excel, express gratitude, and give credit where credit is due. You'll be surprised how much encouragement and motivation a simple, *"Great job!"* provides. Your team is bound to grow and rise together.

18) Read: Read at least one personal development or industry related article each day. Start a journal to record your notes, identify what you learned, and determine how you can apply your findings personally or in the workplace. Share your information with others to establish expertise.

19) Give Yourself Down Time: Vacation time is critical to professional development. Without it, stress and burn out levels increase and productivity declines. Schedule time away from the office to expand your horizons, re-energize, and maintain a healthy work-life balance.

20) Practice Humility: Avoid self-promotion and practice humility. Encourage team members and hold a high respect for their unique skill set and contributions to success.

Self-Check -1	Written Test

Direction I: Short answer item

Instruction: Give short answer for the following questions.

1. Compare and contrast quality performance with performance management(4 points)
2. List basic principles of performance management(4 points)
3. How performance could be improved? (4 points)
4. List the importance of measuring organizational performance(4 points)

Note: **Satisfactory rating - 8 points and above** **Unsatisfactory - below 8 points**

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

Answer Sheet-1

Score = _____

Rating: _____

Name: _____ Date: _____

Information Sheet- 2	Maintaining records of work quality

2.1 Concepts of work quality

Work quality is the value of work delivered by an individual, team or organization. This can include the quality of task completion, interactions and deliverables. Work quality is a common consideration in managing the performance of programs, projects, vendors and individuals.

Quality work means consistently achieving expectations while having a positive, ethical working environment. It means putting your best foot forward every day to ensure the success of the organization.

2.2 Maintaining records of work quality

Record keeping is fundamental in any quality-management system. Usually, it includes documents such as quality policy, quality manual, procedures, work instructions, quality plans, and records.

Quality records are the documented evidence that the processes are executed according to the quality systems' plans and requirements. This includes, but not limited to, inspection results, audit results, calibration data, data sheets, etc.

In maintaining records of work quality, the following should be included.

- Quality of work (accuracy, thoroughness, competence)
- Quantity of work (productivity level, time management, ability to meet deadlines)
- Job knowledge (skills and understanding of the work)
- Working relationships (ability to work with others, communication skills)
- Achievements

There are six ways to maintain quality customer service.

- Value: Let your clients know they are so much more than a number to you. ...
- Inform: A client comes to you because you have a set of skills that they do not
- Respond: Ensure you provide a timely response to email correspondence, let your customer know they have been heard
- Expectation
- Convenience
- Consistency

Self-Check -2	Written Test

Direction I: Short answer item

Instruction: Give short answer for the following questions.

1. In maintaining records of work quality, what should be included? (3 points)
2. What is quality work? (3 points)
3. Mention the 6 ways which are used to maintain quality customer service.(5points)

Note: **Satisfactory rating – 5.5 points and above Unsatisfactory - below 5.5 points**

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

Answer Sheet-2

Score = _____

Rating: _____

Name: _____ Date: _____

Operation Sheet -1	Measuring organizational performance using performance improvement model

Procedures

Step 1: Establish the Transformation Improvement Process Management and Cultural Environment

Step 2: Define the Mission

Step 3: Set Performance Improvement Goals

Step 4: Establish Improvement Projects and Action Plans

Step 5: Implement Projects with Performance Tools and Methodologies

Step 6: Evaluate

Step 7: Review and Recycle

Operation Sheet -2	*Techniques of maintaining organizational records*

Steps

Step 1: Determining Responsibility

Step 2: Standardize Company Document Creation

Step 3: Implement Filing Systems

Step 4: Management of Physical Files

Step 5: Storage of Records

Operation Sheet -3	*Techniques of preparing job specification*

Steps

Step 1: Job Title. Make your job titles specific. Avoid internal jargon that may confuse the job seeker

Step 1: Job Summary. Open with a strong, attention-grabbing summary

Step 1: Responsibilities and Duties. Outline the core responsibilities of the position

Step 1: Qualifications and Skills. Include a list of hard and soft skills.

Operation Sheet -4	*Techniques of managing records in office*

Steps

Here is the 10-step records management plan for your office.

Step 1. Determine who will be responsible and what resources will be needed.

Step 2. Identify records needed to document the activities and functions of your office.

Step 3. Establish your procedures (recordkeeping requirements).

Step 4. Match your records to the records schedules.

Step 5. Prepare a "file plan."

Step 6. Document your recordkeeping requirements and procedures.

Step 7. Clean out records which are beyond the approved retention periods.

Step 8. Organize your records.

Step 9. Maintain your records on an on-going basis.

Operation Sheet -5	Procedures of maintaining records

Procedures

Step 1: File new materials on a regular basis (e.g., weekly).

Step 2: Protect records containing confidential information such as confidential business information (CBI) or personal information.

Step 3: Establish a check-out system (e.g., "out" cards) to track the location of your records so you always know where they are.

Step 4: Clean out inactive materials on a regular basis, usually at the end of the year (as per your written procedures).

Step 5: Retire eligible records to the FRC.

Step 6: Clean out superseded or obsolete reference materials.

LAP Test	Practical Demonstration

Name: _____ Date: _____

Time started: _____ Time finished: _____

Instructions: Given necessary templates, tools and materials you are required to perform the following tasks within 12 hours.

Task 1: Measure organizational performance using performance improvement model

Task 2: Maintain organizational records

Task 3: Prepare job specification

Task 4: Manage records in office

Task 5: Maintain records

N.B: *You can ask your instructor for all necessary tools, equipments and other supplies .*

Instruction Sheet	LG22: Study causes of quality deviations

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 output/service
- Recommending suitable preventive action
- Identifying quality standards and causes of deviation
    - Materials
    - Service
    - output and processes/procedures

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

- Investigate and report causes of deviations from final output/service
- Recommend preventive action
- Identify quality standards and causes of deviation

Learning Instructions:

1. Read the specific objectives of this Learning Guide.
2. Follow the instructions described below
3. Read the information written in the “Information Sheets 1 & 2”. Try to understand what are being discussed. Ask you teacher for assistance if you have hard time understanding them.
4. Accomplish the “Self-checks" in each information sheets on pages 9 & 15.
5. Ask from your teacher the key to correction (key answers) or you can request your teacher to correct your work. (You are to get the key answer only after you finished answering the Self-checks).
6. If you earned a satisfactory evaluation proceed to “Operation sheets 1 on pages 17 and do the LAP Test on page 20”. However, if your rating is unsatisfactory, see your teacher for further instructions or go back to Learning Activity.
7. After You accomplish Operation sheets and LAP Tests, ensure you have a formative assessment and get a satisfactory result;
8. Then proceed to the next LG.

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

1.1 Introduction to Quality Deviation

Quality deviation is departure from an agreed-upon course, design, mean, or method. The act of deviating; a wandering from the way; variation from the common way, from an established rule, etc.; departure, as from the right course or the path of duty.

It 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.

In manufacturing, a deviation is a notable statistical different in the units being produced. It typically means that there is an increase in product defects or a notable change in product quality that is the same throughout several batches but not in accordance with product designs. Deviations typically present serious problems for manufacturers in terms of both profit and safety. Deviation processes help businesses quickly deal with such issues as effectively as possible.

Deviation can quickly ruin batches that the manufacturer creates. Sometimes the product units that have deviated from the planned model can be recycled, but in many cases the products lead directly to profit losses and increased costs. But having deviation processes in place, manufacturers can use both software warning systems and planned emergency actions for employees to quickly stop production and examine the problem when it appears that a deviation is occurring.

Some deviations are subtle and manufacturers discover them only after looking carefully at past periods and production results. In this case, it can be very difficult to discover what is causing the deviation. It could be equipment malfunctions or a single part that needs to be oiled or maintained. It could be the quality of new hydraulic fluid, or the quality of the latest shipment of raw materials. By have a deviation process in place, the business can move through steps designed to pinpoint the exact cause quickly and accurately.

A deviation process will also often include deviation accounts to store a certain expected loss from deviation, which allows the business to keep more accurate books and analyze production more effectively. Of course, sometimes a business also needs to plan for a deviation, if a supplier wants a batch of products with a particular difference. The process will also make room for these plans.

1.2 Causes of Quality Deviation

Minor Deviations

When the deviation does not affect any quality attribute, a critical process parameter, or an equipment or instrument critical for process or control, it would be categorized as Minor, and treated as such by the applicable procedure. Possible examples of minor deviations (*) are given below:

- Skip of FEFO principle (first expired-first out) in raw material handling.
- Balance out of tolerance used to determine gross weight of raw materials upon reception.
- Pressure differential out of established limits in class D washing area.
- Inadequately trained personnel to perform warehouse cleaning activities.

Major Deviations

When the deviation affects a quality attribute, a critical process parameter, an equipment or instrument critical for process or control, of which the impact to patients (or personnel/environment) is unlikely, the deviation is categorized as Major requiring immediate action, investigation, and documented as such by the appropriate SOP. Possible examples of major deviations (*) are given below:

- Use of unapproved reference standard to test an API or drug product.
- Inadequately trained personnel to perform sterility tests.
- Production started without line clearance.
- Filter integrity test has been carried out using equipment with no documented installation qualification completed.
- Gross misbehavior of staff in a critical aseptic process.
- Pressure differential out of established limits in aseptic fill areas.
- Operational parameter out of range for a parameter defined as non-critical.
- Untrained personnel responsible for segregating the approved and rejected raw material in the warehouse

Critical Deviations

When the deviation affects a quality attribute, a critical process parameter, an equipment or instrument critical for process or control, of which the impact to patients (or personnel or environment) is highly probable, including life threatening situation, the deviation is categorized as Critical requiring immediate action, investigated, and documented as such by the appropriate SOP.

Possible examples of critical deviations (*) are given below:

- Expired or rejected API component used.
- Sterilization record of product-contact material used in aseptic filling process not available or unacceptable.
- Incomplete inactivation stage of fermentation.
- Temperature out of control limit during detoxification stage.

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).

1.3 Types of Deviations

- 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

1.4 Investigation and reporting deviations

Deviation investigations are one of the most important quality activities in any GMP (good manufacturing practice) organization. Clearly, many organizations have room to improve in the writing and managing of **deviation investigations**.

What To Check During The Deviation Assessment:

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

1. Scope of the deviation - batch affected (both in-process and previously released)
2. 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.
- Market actions (i.e. recall etc)

The aim of the reporting process is to establish whether project objectives have been achieved, what resources have been expended, what problems have been encountered, and whether the project is expected to be completed on time and within budget. If performance is sufficient the project will receive payment from the programme for costs incurred, paid and reported.

1.5 Types of report forms

1) Start-up report: Some programmes use this to complement information needed for monitoring of project implementation. It mostly includes formal information about contact details and partnership organizations. Normally it doesn't require any formal approval and its data can be changed anytime.

2) Preparation costs report : Programmes for which preparation costs are eligible often have a separate report form for the reimbursement of preparation costs incurred prior to submission of project proposal. This report could be:

- a separate report form called preparation costs report;
- a part of the start-up report (if a programme is using it);
- a part of the first progress report.

3) Progress report: The progress report is a written document describing the activities that have taken place during the project implementation by project partners that conveys details such as what objectives have been achieved, what resources have been expended, what problems have been encountered, and whether the project is expected to be completed on time and within budget.

4) Final report : The last report submitted to the programme is in most cases called final report, but also terms such as Closure Report and Project End Report have been used. Different practices of the final report content and procedure were observed: • For some programmes a final report is the last regular project progress report with some additional questions or annexes related to the overall achievements of the project and its sustainability. It may also include feedback to the programme.

- Other programmes have split up their final reports into different parts. For example, they have one more technical part (similar to the project progress report or completely different) and another part which is more focused on the project's final achievements. The information collected in this part is sometimes intended to be published, e.g. on the programme website. • Most of the programmes, though, use specific final report form, which is neither very similar to the regular project progress report nor split up into several parts.
- Sometimes the final report replaces the last project progress report (or at least its activity related part); in other cases it is a complementing part of the project progress report.

5) Follow-up report: The use of follow-up report was observed in one programme. It's a report about sustainability of results which has to be submitted once a year for some years after project closure.

1.6 Relationship between customer satisfaction and service quality

Both customer satisfaction and service quality are considered as extensive and vast subjects of research and many studies related to customer satisfaction are conducted in the area of service settings. In marketing theory, the consumer satisfaction category has the main position. It is based on the premise that the profit is made through the process of satisfaction of consumers' demands. A further debate has considered whether service quality is a cause customer of satisfaction. It then helps to identify a link between both constructs.

For starters, the investigation report must be designed for the reader, providing information and evidence that fully support the findings, conclusions, and actions. The report should relate a story that can be clearly understood by a third party months or even years after the event and the investigation.

Reporting time of Deviation

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

A deviation should be reported if a trend is noticed that requires further investigation. All batch production deviations (planned or unintended) covering all manufacturing facilities, equipments, operations, distribution, procedures, systems and record keeping must be reported and investigated for corrective and preventative action. Reporting deviation is required regardless of final batch disposition. If a batch is rejected a deviation reporting is still required.

Techniques for managing 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.

Steps may be identified when handling events and possible deviations are:

- Event Detection
- Decision Making Process / Deviation Categorization

- Deviation Treatment
- Root cause investigation
- CAPA

Self-Check -1	Written Test

Direction I: Short answer item

Instruction I: Give short answer to the following questions .

1. What is quality deviation(2 points)
2. Mention causes of quality deviation (4 points)
3. List types of deviations(3 points)
4. Identify types of report forms (3 points)

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

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

Answer Sheet-1

Score = _____

Rating: _____

Name: _____ Date: _____

Information Sheet- 2	Recommending suitable preventive action

2.1 Introduction to quality standards

Quality standards are defined as documents that provide requirements, specifications, guidelines, or characteristics that can be used consistently to ensure that materials, products, processes and services are fit for their purpose.

A product is said to be of quality if it is free from any manufacturing defect deficiency or significant variation. In order to do so certain specific standards need to be set so that uniformity is achieved in the entire set of products being manufactured.

Quality management is the process for ensuring that all project activities necessary to design, plan and implement a project are effective and efficient with respect to the purpose of the objective and its performance.

2.2 Organizational quality standards

Organizations turn to standards for guidelines, definitions, and procedures that help them achieve objectives such as:

- Satisfying their customers' quality requirements
- Ensuring their products and services are safe
- Complying with regulations
- Meeting environmental objectives
- Protecting products against climatic or other adverse conditions
- Ensuring that internal processes are defined and controlled
- Use of quality standards is voluntary, but may be expected by certain groups of stakeholders.

Additionally, some organizations or government agencies may require suppliers and partners to use a specific standard as a condition of doing business. Quality management ensures that an organization, product or service is consistent. It has four main components: quality planning, quality assurance, quality control and quality improvement. Quality management is focused not only on product and service quality, but also on the means to achieve it. Quality management, therefore, uses quality assurance and control of processes as well as products to achieve more consistent quality. What a customer wants and is willing to pay for it determines quality. It is written or unwritten commitment to a known or unknown

consumer in the market . Thus, quality can be defined as fitness for intended use or, in other words, how well the product performs its intended function.

2.3 Principles of Organizational quality standards

The International Standard for Quality management (ISO 9001:2015) adopts a number of management principles, that can be used by top management to guide their organizations towards improved performance.

Customer focus: The primary focus of quality management is to meet customer requirements and to strive to exceed customer expectations.

Rationale: Sustained success is achieved when an organization attracts and retains the confidence of customers and other interested parties on whom it depends. Every aspect of customer interaction provides an opportunity to create more value for the customer. Understanding current and future needs of customers and other interested parties contributes to sustained success of an organization.

Leadership; Leaders at all levels establish unity of purpose and direction and create conditions in which people are engaged in achieving the organization's quality objectives.

Engagement of people: Competent, empowered and engaged people at all levels throughout the organization are essential to enhance its capability to create and deliver value.

Process approach : Consistent and predictable results are achieved more effectively and efficiently when activities are understood and managed as interrelated processes that function as a coherent system.

Improvement: Successful organizations have an ongoing focus on improvement.

Improvement is essential for an organization to maintain current levels of performance, to react to changes in its internal and external conditions and to create new opportunities.[9]

Evidence based decision making : Decisions based on the analysis and evaluation of data and information are more likely to produce desired results.

Relationship management: For sustained success, an organization manages its relationships with interested parties, such as suppliers, retailers.

2.4 Recommendation of suitable preventive action

Preventive action is an action taken to reduce or eliminate the probability of specific undesirable events from happening in the future. It consists of improvements to an organization's processes taken to eliminate causes of non-conformities or other undesirable situations.

An action taken to reduce or eliminate the probability of specific undesirable events from happening in the future. Preventative actions are generally less costly than mitigating the effects of negative events after they occur, but may also be seen as a waste of resources if the predicted event does not take place.

A preventive action is a change implemented to address a weakness in a management system that is not yet responsible for causing nonconforming product or service.

After you identified the cause that would generate Nonconformity, you are required to initiate an action to eliminate it. Before executing the preventive action, it is required to consider cost effective of the preventive action.

Preventive actions are implemented in response to the identification of potential sources of non-conformity. To ensure that corrective and preventive actions are effective, the systematic investigation of the root causes of failure is pivotal.

Candidates for preventive action generally result from suggestions from customers or participants in the process but preventive action is a proactive process to identify opportunities for improvement rather than a simple reaction to identified problems or complaints. Apart from the review of the operational procedures, the preventive action might involve analysis of data, including trend and risk analyses and proficiency-testing results.

The focus for preventive actions is to avoid creating nonconformance, but also commonly includes improvements in efficiency. Preventive actions can address technical requirements related to the product or service supplied or to the internal management system.

Many organizations require that when opportunities to improve are identified or if preventive action is required, action plans are developed, implemented and monitored to reduce the likelihood of nonconformities and to take advantage of the opportunities for improvement. Additionally, a thorough preventive action process will include the application of controls to ensure that the preventive actions are effective.

Self-Check -2	Written Test

Direction I: Short answer item

Instruction: Give short answer for the following questions.

1. List items for which quality standards should be set(3 points)
2. What does (ISO 9001:2015) stand for? (2 points)
3. what is quality standard (2 points)
4. What are the most common organizational standard's principles? (5 points)

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

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

Answer Sheet-2

Name: _____ Date: _____

Information Sheet- 3	Identifying quality standards and causes of deviation

3.1. Introduction to quality standards

Quality standards are defined as documents that provide requirements, specifications, guidelines, or characteristics that can be used consistently to ensure that materials, products, processes and services are fit for their purpose.

A product is said to be of quality if it is free from any manufacturing defect deficiency or significant variation. In order to do so certain specific standards need to be set so that uniformity is achieved in the entire set of products being manufactured.

Quality management is the process for ensuring that all project activities necessary to design, plan and implement a project are effective and efficient with respect to the purpose of the objective and its performance.

Quality standards may include standards for:

Materials : Material standards are specifications that specify material properties. Typically quality standards or requirements, like surface finish or specific performance criteria.

Services: Service standards are important for customers, potential customers, employees and management of a business. They help to define what a customer can expect and to remind management and employees of the challenge and obligations that they face.

Output : The services provided must comply with the requirements of the Patents Act, and meet the expectations of its customers. The Product Quality Standards (PQS) are categorized according to the extent to which they affect the validity of the IP Right.

Processes/procedures : Process Quality Standards. Process quality standards protect the business owner from unnecessary costs in product repair or manufacturing rejects. These standards ensure that employees building products or providing services follow a specific procedure so that the results always meet the design quality standards.

3.2 Organizational quality standards

Organizations turn to standards for guidelines, definitions, and procedures that help them achieve objectives such as:

- Satisfying their customers' quality requirements

- Ensuring their products and services are safe
- Complying with regulations
- Meeting environmental objectives
- Protecting products against climatic or other adverse conditions
- Ensuring that internal processes are defined and controlled
- Use of quality standards is voluntary, but may be expected by certain groups of stakeholders.

Additionally, some organizations or government agencies may require suppliers and partners to use a specific standard as a condition of doing business. Quality management ensures that an organization, product or service is consistent. It has four main components: quality planning, quality assurance, quality control and quality improvement. Quality management is focused not only on product and service quality, but also on the means to achieve it. Quality management, therefore, uses quality assurance and control of processes as well as products to achieve more consistent quality. What a customer wants and is willing to pay for it determines quality. It is written or unwritten commitment to a known or unknown consumer in the market . Thus, quality can be defined as fitness for intended use or, in other words, how well the product performs its intended function.

3.3 Principles of Organizational quality standards

The International Standard for Quality management (ISO 9001:2015) adopts a number of management principles, that can be used by top management to guide their organizations towards improved performance.

Customer focus: The primary focus of quality management is to meet customer requirements and to strive to exceed customer expectations.

Rationale: Sustained success is achieved when an organization attracts and retains the confidence of customers and other interested parties on whom it depends. Every aspect of customer interaction provides an opportunity to create more value for the customer. Understanding current and future needs of customers and other interested parties contributes to sustained success of an organization.

Leadership; Leaders at all levels establish unity of purpose and direction and create conditions in which people are engaged in achieving the organization's quality objectives.

Engagement of people: Competent, empowered and engaged people at all levels throughout the organization are essential to enhance its capability to create and deliver value.

Process approach : Consistent and predictable results are achieved more effectively and efficiently when activities are understood and managed as interrelated processes that function as a coherent system.

Improvement: Successful organizations have an ongoing focus on improvement.

Improvement is essential for an organization to maintain current levels of performance, to react to changes in its internal and external conditions and to create new opportunities.[9]

Evidence based decision making : Decisions based on the analysis and evaluation of data and information are more likely to produce desired results.

Relationship management: For sustained success, an organization manages its relationships with interested parties, such as suppliers, retailers.

3.4 Recommendation of suitable preventive action

Preventive action is an action taken to reduce or eliminate the probability of specific undesirable events from happening in the future. It consists of improvements to an organization's processes taken to eliminate causes of non-conformities or other undesirable situations.

An action taken to reduce or eliminate the probability of specific undesirable events from happening in the future. Preventative actions are generally less costly than mitigating the effects of negative events after they occur, but may also be seen as a waste of resources if the predicted event does not take place.

A preventive action is a change implemented to address a weakness in a management system that is not yet responsible for causing nonconforming product or service.

After you identified the cause that would generate Nonconformity, you are required to initiate an action to eliminate it. Before executing the preventive action, it is required to consider cost effective of the preventive action.

Preventive actions are implemented in response to the identification of potential sources of non-conformity. To ensure that corrective and preventive actions are effective, the systematic investigation of the root causes of failure is pivotal.

Candidates for preventive action generally result from suggestions from customers or participants in the process but preventive action is a proactive process to identify opportunities for improvement rather than a simple reaction to identified problems or complaints. Apart from

the review of the operational procedures, the preventive action might involve analysis of data, including trend and risk analyses and proficiency-testing results.

The focus for preventive actions is to avoid creating nonconformance, but also commonly includes improvements in efficiency. Preventive actions can address technical requirements related to the product or service supplied or to the internal management system.

Many organizations require that when opportunities to improve are identified or if preventive action is required, action plans are developed, implemented and monitored to reduce the likelihood of nonconformities and to take advantage of the opportunities for improvement. Additionally, a thorough preventive action process will include the application of controls to ensure that the preventive actions are effective.

Self-Check -3	Written Test

Direction I: Short answer item

Instruction: Give short answer for the following questions .

1. what is preventive action ?(3 points)
2. Quality standards may include standards for: (1 point for each)

a----------

b----------

c----------

d----------

3. What are the most common organizational standard principles? (5 points)
4. What is quality standard? (2 points)

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

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

Answer Sheet-2

Name: _____ Date: _____

Operation Sheet -1	Procedure of investigating workplace

procedures

Step 1. Decide whether to investigate

Step 2. Take immediate action, if necessary

Step 3. Choose an investigator

Step 4. Plan the investigation

Step 5. Conduct interviews

Step 6. Gather documents and other evidence

Step 7. Evaluate the evidence

Step 8. Take action

Step 9. Document the investigation

Step 10. Follow up

LAP Test -1	Practical Demonstration

Name: _____ Date: _____

Time started: _____ Time finished: _____

Instruction I: Given necessary templates, tools and materials you are required to perform the following tasks within ***16 hours.***

Task 1: Investigate service quality of the work place

David Elder and Peter Smith (2012). *Regulation and Compliance: Deviation Investigations; Pharmaceutical Technology*, Vol. 36, No. 4, 2012, pp. 22-22.

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http://www.web-strategist.com/blog/2013/01/14/the-difference-between-strategy-and-tactics/

https://www.cdc.gov/healthcommunication/toolstemplates/entertainmented/tips/preventivehealth.html

https://www.nlm.nih.gov/medlineplus/ency/article/001921.htm

ISO 15504-4: (2005). *Information technology — process assessment — Part 4: Guidance on use for process improvement and process capability determination.*

ISO 9001 (2015). *A certified quality management system (QMS) for organizations who want to prove their ability to consistently provide products and services that meet the needs of their customers and other relevant stakeholders*.

ISO 9004(2008).*Guidelines for performance improvement.*

Instruction Sheet	LG23: Complete documentation

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

- Recording Information on quality parameters
  - style/design/specifications
  - durability
  - service variations
  - materials, damage and imperfections
- Recording service processes and outcome

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 parameters
- Record service processes and outcome

Learning Instructions:

1. Read the specific objectives of this Learning Guide.
2. Follow the instructions described below
3. Read the information written in the “Information Sheets 1 & 2”. Try to understand what are being discussed. Ask you teacher for assistance if you have hard time understanding them.
4. Accomplish the “Self-checks" in each information sheets on pages 9 & 15.
5. Ask from your teacher the key to correction (key answers) or you can request your teacher to correct your work. (You are to get the key answer only after you finished answering the Self-checks).
6. If you earned a satisfactory evaluation proceed to “Operation sheets 1 on pages 17 and do the LAP Test on page 20”. However, if your rating is unsatisfactory, see your teacher for further instructions or go back to Learning Activity.
7. After You accomplish Operation sheets and LAP Tests, ensure you have a formative assessment and get a satisfactory result;
8. Then proceed to the next LG.

Information Sheet-1	Recording Information on quality parameters

1.1 Documents and records

It is important to have standards, policies, and procedures written in simple, clear language to help employees with their job. Written instructions are very useful and assists in learning and often leads to employees bringing up good questions to help continually improve a system! Good documentation lets employees quickly double check their own work, without necessarily having to rely on others.

Documentation will:

- Prove that programs are effective and being completed as written;
- Demonstrate due diligence;
- Meet requirements for third party customer assessments/audits;
- Meet regulatory requirements;

Documentation is the key to GMP(Good Manufacturing Practice) compliance and ensures traceability of all development, manufacturing, and testing activities. Documentation provides the route for auditors to assess the overall quality of operations within a company and the final product.

1.2 The 10 golden rules of good manufacturing practice (GMP)

The table below describes the 10 golden rules of GMP. Rule No.3 and 5 describe the importance of documentation and records. The basic issues to be to be noted include:

• The management of each operational site is required to define responsibility for origination, distribution, maintenance, change control, and archiving of all GMP documentation and records within that department or unit.

• Document owners are required to ensure that all aspects of documentation and records management specified in form of standard operating procedures (SOPs).

• All associates have the responsibility of ensuring that all GMP activities are performed according to the official SOPs; any deviations in procedure are reported to their supervisor and are adequately documented.

• The local quality assurance unit has the responsibility of ensuring via organizational measures and auditing that GMP documentation and records systems used within the operational unit are

complete and comply with the relevant GMP requirements, and also that the requirements of the SOPs are followed.

• Requirements for specific documents or record, including ownership, content, authorization, and change control procedures, has to be described or cross referenced in the quality modules which relate to the subject of the document.

Table 1: The 10 golden rules of GMP

Number	The golden rule
1	Get the facility design right from the start
2	Validate processes
3	Write good procedures and follow them
4	Identify who does what
5	Keep good records
6	Train and develop staff
7	Practice good hygiene
8	Maintain facilities and equipment
9	Build quality into the whole product lifecycle
10	Perform regular audits

1.3 General requirements of documentation

- Good documentation constitutes an essential part of the quality assurance system. Clearly written procedures prevent errors resulting from spoken communication, and clear documentation permits tracing of activities performed.
- Documents must be designed, prepared, reviewed, and distributed with care.
- Documents must be approved, signed, and dated by the appropriate competent and authorized persons.
- Documents must have unambiguous contents. The title, nature, and purpose should be clearly stated. They must be laid out in an orderly fashion and be easy to check.

Reproduced documents must be clear and legible.

- Documents must be regularly reviewed and kept up-todate. When a document has been revised, systems must be operated to prevent inadvertent use of superseded documents (e.g., only current documentation should be available for use).

- Documents must not be handwritten; however, where documents require the entry of data, these entries may be made in clear legible handwriting using a suitable indelible medium (i.e., not a pencil). Sufficient space must be provided for such entries.
- Any correction made to a document or record must be signed or initialed and dated; the correction must permit the reading of the original information. Where appropriate, the reason for the correction must be recorded.
- Record must be kept at the time each action is taken and in such a way that all activities concerning the conduct of preclinical studies, clinical trials, and the manufacture

and control of products are traceable.

- Storage of critical records must at secure place, with access limited to authorized persons. The storage location must ensure adequate protection from loss, destruction, or falsification, and from damage due to fire, water, etc.
- Records which are critical to regulatory compliance or to support essential business activities must be duplicated on paper, microfilm, or electronically, and stored in a separate, secure location in a separate building from the originals.
- Date may be recorded by electromagnetic or photographic means, but detailed procedures relating to whatever system is adopted must be available.

Accuracy of the record should be checked as per the defined procedure. If documentation is handled byelectronic data processing methods, only authorized persons should be able to enter or modify data in the computer, access must be restricted by passwords or other means, and entry of critical data must be independently checked.

- It is particularly important that during the period of retention, the data can be rendered legible within an appropriate period of time.
- If data is modified, it must be traceable.

There are various types of procedures that a GMP facility can follow. Given below is a list of the most common types of documents, along with a brief description of each.

1. **Quality manual:** A global company document that describes, in paragraph form, the regulations and/or parts of the regulations that the company is required to follow.
2. **Policies:** Documents that describe in general terms, and not with step-by-step instructions, how specific GMP aspects (such as security, documentation, health, and

responsibilities) will be implemented.

3. **Standard operating procedures (SOPs):** Step-by-step instructions for performing operational tasks or activities.
4. **Batch records:** These documents are typically used and completed by the manufacturing department. Batch records provide step-by-step instructions for production-related tasks and activities, besides including areas on the batch record itself for documenting such tasks.
5. **Test methods:** These documents are typically used and completed by the quality control (QC) department. Test methods provide step-by-step instructions for testing supplies, materials, products, and other production-related tasks and activities, e.g., environmental monitoring of the GMP facility. Test methods typically contain forms that have to be filled in at the end of the procedure; this is for documenting the testing and the results of the testing.
6. **Specifications:** Documents that list the requirements that a supply, material, or product must meet before being released for use or sale. The QC department will compare their test results to specifications to determine if they pass the test.
7. **Logbooks:** Bound collection of forms used to document activities. Typically, logbooks are used for documenting the operation, maintenance, and calibration of a piece of equipment. Logbooks are also used to record critical activities, e.g., monitoring of clean rooms, solution preparation, recording of deviation, change controls and its corrective action assignment.

1.4 Terms and Definitions relating to Documents

The following terms and definitions are taken from ISO 9000:2005:

Term	ISO 9000:2005 Clause	Definition
Document	3.7.2	information and its supporting medium
Procedure	3.4.5	specified way to carry out an activity or a process (Note: Procedures can be documented or not)
Quality Manual	3.7.4	document specifying the quality management system of an organization
Quality Plan	3.7.5	document specifying which procedures and associated resources shall be applied by whom and when to a specific project, product, process or contract
Record	3.7.6	document stating results achieved or providing evidence of activities performed
Specification	3.7.3	document stating requirements

Records required by ISO 9001:2008

Clause	Record required
5.6.1	Management reviews
6.2.2 e)	Education, training, skills and experience
7.1 d)	Evidence that the realization processes and resulting product fulfil requirements
7.2.2	Results of the review of requirements related to the product and actions arising from the review
7.3.2	Design and development inputs relating to product requirements
7.3.4	Results of design and development reviews and any necessary actions
7.3.5	Results of design and development verification and any necessary actions
7.3.6	Results of design and development validation and any necessary actions
7.3.7	Results of the review of design and development changes and any necessary actions
7.4.1	Results of supplier evaluations and any necessary actions arising from the evaluations
7.5.2 d)	As required by the organization to demonstrate the validation of processes where the resulting output cannot be verified by subsequent monitoring or measurement
7.5.3	The unique identification of the product, where traceability is a requirement
7.5.4	Customer property that is lost, damaged or otherwise found to be unsuitable for use
7.6 a)	Basis used for calibration or verification of measuring equipment where no international or national measurement standards exist
7.6	Validity of the previous measuring results when the measuring equipment is found not to conform to requirements
7.6	Results of calibration and verification of measuring equipment
8.2.2	Internal audit results and follow-up actions
8.2.4	Indication of the person(s) authorizing release of product.
8.3	Nature of the product nonconformities and any subsequent actions taken, including concessions obtained
8.5.2 e)	Results of corrective action
8.5.3 d)	Results of preventive action

To make any assessment, basic information needs to be captured on the what, when, why, where and who. It is gathered on the standard template or checklist that encourages this initial data gathering phase. This should be available so anyone can raise a deviation when they detect one. Information should be recorded in a clear and concise manner and stick to the basic facts. Unless it is obvious , a root cause does not need to be stated**.** The information should be gathered by requesting basic issues as indicated below:

- When was it discovered?
- When did it happen?
- Where did it happen?
  - Building / Room / Functional location
- Who was involved?
  - Who discovered it?
  - Where there any witnesses?
- What is the extent of problem/time period (quantities/areas)
  - A description of the deviation i.e. what is immediately obvious
  - The identity of any process, equipment or system implicated by the deviation.
- Why it is a deviation?
  - What should have occurred?
  - What are the expected results or outcome?
  - Which part of your QMS is it not compliant with
- Is there an obvious root cause?
- Details of other batches affected if known
- What Immediate action taken was taken?
  - Any initial actions taken to stop the deviation

1.5 **Importance** of good documentation

Good documentation enhances the reliable data accessing and ease of utilizing information as a resources for further decision making. The following are among the importance of of good documentation.

- An essential part of the quality assurance system and should exist for all aspects of good manufacturing process.
- Good documentation practice is an expected practice!
- Correct, complete, current, and consistent information effectively meet customer and stakeholder' requirements.
- Helps to reduce observations raised on inadequate documentation practices

1.6 Some tips on Good Documentation Practices

The following characteristics of good documentation:

- Records should be completed at time of activity or when any action is taken
- Superseded documents should be retained for a specific period of time
- Records should be retained for at least one year after the expiry date of the finished product
- Concise, legible, accurate and traceable
- Picture is worth a thousand words
- Clear examples
- Don’t assume knowledge.

What constitutes Good Documentation?

- Approve, review and update documents
- Changes & current revision status of documents identified
- Relevant versions of applicable documents available at points of use
- Documents remain legible and readily identifiable
- Documents of external origin identified and their distribution controlled
- Prevent unintended use of obsolete documents, and archiving.

Self-Check -1	Written Test

Direction I: Short answer item

Instruction I: Give short answer to the following questions.

1. Write the 10 golden rules of good manufacturing practice (GMP)
2. What constitutes good documentation?
3. List the 7 common documents of a good manufacturing practice.
4. What is the importance of Logbook of a business organization?
5. List at least 5 characteristics of good documentation.

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

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

Answer Sheet-1

Score = _____

Rating: _____

Name: _____ Date: _____

Information Sheet- 2	Recording service processes and outcome

2.1 Guidelines for Developing Quality Documentation

A. Structure and format of quality manuals

The Q-documentation consists of at least the following three levels or parts also referred to as Document Hierarchy:

I. Quality Manual (Q-Manual) + annexes or appendices

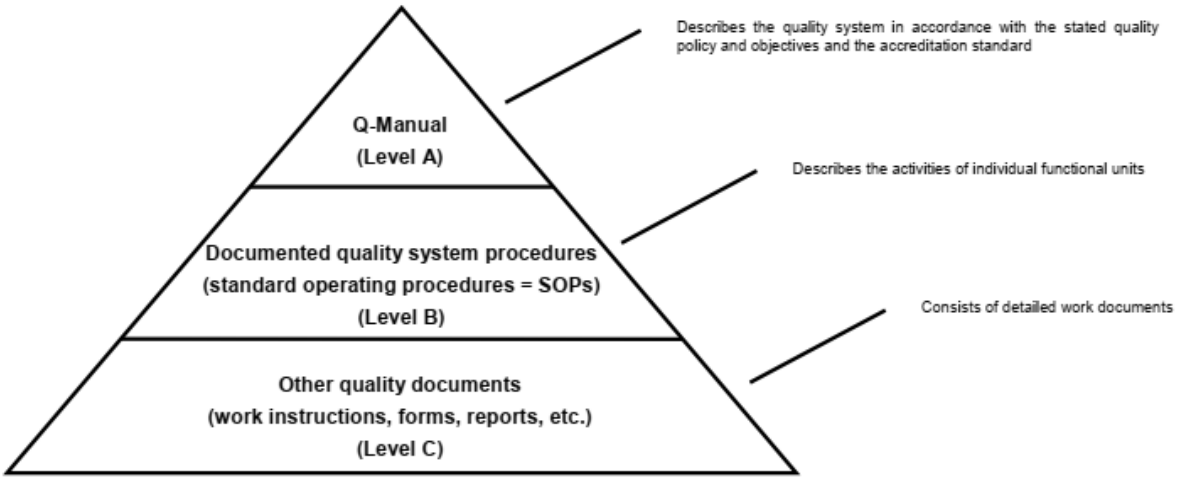
The purpose of a Q-Manual is to outline the general policies and procedures for staff, customers, accreditation bodies and/or legal bodies to provide an overview of the laboratory"s quality system.

II. Documented quality system procedures such as Standard Operating Procedures (SOPs)

Standard Operating Procedures describe standard procedures in a concise manner to provide sufficient information to carry out the work concerned. The volume depends on the size of the laboratory, number of tests, number and qualification of staff and kind of equipment in use.

III. Other quality documents such as working instructions, forms, reports

Working instructions give details on the standard procedure concerned. This may be e.g. species related information on a specific test method. Forms, checklists, reports related to a standard procedure should be provided where appropriate. Working instructions or specimen forms may be directly attached to the respective SOP if applicable.



2.1 Figure 2.1 levels of quality documentation

B. How to start with the preparation of a Q-manual?

The process of establishing quality assurance system documentation should begin with appointment of the coordination task to a management-delegated competent body, which may be an individual or a group of individuals. The appointee or the group of appointees is responsible for the following tasks:

- to obtain data on the actual state of the quality assurance system
- to plan the documentation system
- to collect and compile existing documentation and require additional documentation where necessary
- to review the documentation to ensure clarity, suitability and proper structure
- to develop a distribution policy
- to incorporate pertinent changes
- to act as contact person/s in all matters of the quality assurance system

C. The Q-manual(Quality manual)

Q-manuals may be developed and used by an organisation for purposes including, but not limited to the following:

- communicating the manufacturing quality policy, procedures and requirements
- describing the quality system
- providing documented bases for auditing quality systems
- providing continuity of the quality system and its requirements during changing circumstances
- training personnel in the quality system requirements and methods of compliance
- presenting the quality system for external purposes, such as demonstrating compliance with respective accreditation standard

2.2 Recording service processes and outcomes

Recording of data is not only restricted to documentation of the causes of quality deviations but extends to capturing of all the processes and respective outcomes of the business system.

There are international formats and procedures to record data of different aspects of quality that are agreed in common. For example, ISO9001:2008 one of the commonly used standards. This is composed of different components indicated by different clause numbers as indicated as the following :

The following comments are intended to assist users of ISO 9001:2008 in understanding the intent of the general documentation requirements of the International Standard.

a) Documented statements of a quality policy and objectives:

− Requirements for the quality policy are defined in clause 5.3 of ISO 9001:2008. The documented quality policy has to be controlled according to the requirements of clause 4.2.3. Note Organizations that are revising their quality policy for the first time, or in order to meet the amended requirements in ISO 9001:2008, should pay particular attention to clause 4.2.3 (c), (d) and (g).

− Requirements for quality objectives are defined in clause 5.4.1 of ISO 9001:2008. These documented quality objectives are also subject to the document control requirements of clause 4.2.3.

b) Quality Manual:

− Clause 4.2.2 of ISO 9001:2008 specifies the minimum content for a quality manual. The format and structure of the manual is a decision for each organization, and will depend onthe organization’s size, culture and complexity. Some organizations may choose to use the quality manual for other purposes besides that of simply documenting the QMS

− A small organization may find it appropriate to include the description of its entire QMS within a single manual, including all the documented procedures required by the standard.

− Large, multi-national organizations may need several manuals at the global, national or regional level, and a more complex hierarchy of documentation.

− The quality manual is a document that has to be controlled in accordance with the requirements of clause 4.2.3.

c) Documented procedures:

− ISO 9001:2008 specifically requires the organization to have “documented procedures” for the following six activities:

- 4.2.3 Control of documents

- 4.2.4 Control of records
- 8.2.2 Internal audit
- 8.3 Control of nonconforming product
- 8.5.2 Corrective action
- 8.5.3 Preventive action

− These documented procedures have to be controlled in accordance with the requirements of clause 4.2.3

− Some organizations may find it convenient to combine the procedure for several activities into a single documented procedure (for example, corrective action and preventive action). Others may choose to document a given activity by using more than one documented procedure (for example, internal audits). Both are acceptable.

− Some organizations (particularly larger organizations, or those with more complex processes) may require additional documented procedures (particularly those relating to product realization processes) to implement an effective QMS.

− Other organizations may require additional procedures, but the size and/or culture of the organization could enable these to be effectively implemented without necessarily being documented. However, in order to demonstrate compliance with ISO 9001:2008, the organization has to be able to provide objective evidence (not necessarily documented) that its QMS has been effectively implemented.

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

− In order for an organization to demonstrate the effective implementation of its QMS, it may be necessary to develop documents other than documented procedures. However, the only documents specifically mentioned in ISO 9001:2008 are:

- Quality policy (clause 4.2.1.a)
- Quality objectives (clause 4.2.1.a)
- Quality manual (clause 4.2.1.b)

− There are several requirements of ISO 9001:2008 where an organization could add value to its QMS and demonstrate conformity by the preparation of other documents, even though the standard does not specifically require them. Examples may include:

- Process maps, process flow charts and/or process descriptions
- Organization charts

- Specifications
- Work and/or test instructions
- Documents containing internal communications
- Production schedules
- Approved supplier lists
- Test and inspection plans
- Quality plans

− All such documents have to be controlled in accordance with the requirements of clause 4.2.3 and/or 4.2.4, as applicable

e) Records:

− Examples of records specifically required by ISO 9001:2008 are presented in Annex B.

Organizations are free to develop other records that may be needed to demonstrate conformity of their processes, products and quality management system.

− Requirements for the control of records are different from those for other documents, and all records have to be controlled according to those of clause 4.2.4 of ISO 9001:2008.

Guidance_on_the_documentation_requirements_of_iso_9001_2008.

httpswww.iso.orgfileslivesitesisoorgfilesarchivepdf

Self-Check -2	Written Test

Direction I: Short answer items

Instruction: Give short answer for the following questions

1. List the three levels of quality documentation
2. What is the purpose of developing quality manual(Q-manual) documentation? Mention at least 5.
3. Mention at least 5 tasks that an appointee for documentation should do.
4. What does ISO 9001:2008 represent?

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

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

Answer Sheet-2

Name: _____ Date: _____

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