Ethiopian TVET-System

MEDICAL LABORATORY

Level -III

Based on Apr.2018G.C. Occupational Standard

MODULE TITLE: -	**APPLYING QUALITY CONTROL**
TTLM CODE:	**HLT MLT3 TTLM 0919V1**

This module includes the following Learning Guides

LG58: Implement quality standards

LG59: Assess quality of service delivered

LG60: Record information

LG61: Study causes of quality deviations

LG62: Complete documentation

Instruction Sheet	LG58: Implement quality standards

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

- Quality standards and procedures
- Quality standards documents

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

- Acquire and confirm agreed quality standard and procedures
- Introduce standard procedures to organizational staff/personnel.
- Provide quality standard,procedures and documents to employees in accordance with the organization policy.
- Revise standard procedures.

Learning Instructions

1.Read the information written in the “Information Sheets”.

2.If you earned a satisfactory evaluation proceed to next module. However, if your rating is unsatisfactory, see your teacher for further instructions.

3.Read the “Operation Sheet” and try to understand the procedures discussed.

4.Practice the steps or procedures as illustrated in the operation sheet. Go to your teacher if you need clarification or you want answers to your questions or you need assistance in understanding a particular step or procedure

5.Do the “LAP test” (if you are ready). Request your teacher to evaluate your performance and outputs.Your teacher will give you feedback and the evaluation will be either satisfactory or unsatisfactory. If unsatisfactory, yourteacher shall advice you on additional work.But if satisfactory you can proceed to the next Learning Guide

1.1. Acquiring and confirming agreed quality standard and procedures.

Quality standards are concise sets of evidence-based, measurable statements that provide guidance on important elements of high-quality health care in a specific topic area. Quality standards focus on areas where experts, patients, caregivers, and the public have identified a need for improvement in Ontario. They address standards of care for clinically defined populations (for example, adults with schizophrenia), service areas (for example, preoperative-operative testing), and health system issues (for example, care transitions).Each quality standard contains 5 to 15 quality statements. Each quality statement is a strong recommendation on high-quality practice for a specific aspect of care. Each quality statement is accompanied by one or more process, structural, or outcome indicators to help health care professionals and organizations measure their achievement of the practice outlined in the statement. Quality standards also include a small set of outcome indicators to measure the impact of the quality standard as a whole. Health Quality Ontario works with partner organizations to develop a multi stakeholder implementation plan for each quality standard to drive and support its adoption across the province.In another way the word quality, as you may already understand from the responses of different groups, is not understood uniformly. What constitutes health care quality is different for different people based on what is valued most. Due to this lack of standard understanding, quality particularly when applied to the health sector is not simple to define. With the greater emphasis given to quality of health care by patients, public health officials, funding agencies and governments during the last few decades, different authors and organizations have tried to define it. In this lesson, we will see some of the most frequently used definitions.

Definition 1. Quality is the totality of characteristics of an entity that bear on its ability to satisfy stated and implied needs. *(ISO 8402)*

Definition 2. Quality of health care is the application of medical science and technology in a way that maximizes its benefits to health without correspondingly increasing its risks. The degree of quality is, therefore, the extent to which care provided is expected to achieve the most favorable balance of risks and benefits. *(AvedisDonabedian)*

Definition 3. Quality health care is the proper performance (according to standards)

of interventions that are known to be safe, that are affordable to the society in question, and that have the ability to produce an impact on mortality, morbidity, disability, and malnutrition. (M.I. Roemer and C. Montoya Aguilar, WHO)

Definition 4. Medical quality is the degree to which health care systems, services and supplies for individuals and populations increase the likelihood for positive health outcomes *(AmericanCollege of Medical Quality)*

Definition 5. The degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge. *(IOM of the National Academies)*

1.1.2 Benefits of Standards

- Ensure that products and services are safe, reliable and of good quality and also care environment.
- They are strategic tools that reduce costs by minimizing waste and errors, and increasing productivity.
- Help companies to access new markets, level the playing field for developing countries and facilitate free and fair global trade.
- Frequently referenced by regulators and legislators for protecting user and business interests, and in support of government policies.

1.1.2Introduction to Quality Control

QC is the operational techniques and activities that are used to satisfy quality requirements or a procedure or set of procedures intended 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 an important part of the quality control is the Quality assessment. The system of activities to verify if the quality control activities are effective in other words: an evaluation of the products themselves. Quality control monitors activities related to the examination (analytic) phase of testing. The goal of quality control is to **detect, evaluate, and correct errors** due to test system failure, environmental conditions, or operator performance, before patient results are reported.

1.1.2.1 Types of QC

Internal quality control: a set of procedures for continuously assessing laboratory work and the emergent results. This can range from routine checking of equipment, having a co-worker go over another employee's data analysis, or running standards and controls on a regular basis.

External quality control: a process of checking a quality of test/product by external examiner. It is to verify results by sent to an outside lab (Proficiency Testing [PT]) or provided by an external source such as your regional reference laboratory (Spatial testing [ST])/rechecking and onsite evaluation.

1.1.2.2 Quality control procedures

QC consists of the procedures used to detect errors that occur due to

- test system failure,
- adverse environmental conditions
- variance in operator performance,
- variance in the monitoring of the accuracy and precision of the test performance over time.
- There's no *one* rule or one *set* of rules that's right for *all* tests and methods.

Some methods have better precision than others; therefore, different QC procedures should be used. The most cost-effective operation is possible when the QC procedures are selected for the individual tests on the basis of the quality required for the test and the performance observed for the method.

Self-Check 1	True/false

Name: _____Date: _____

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

I-True or False: Write TRUE if the statement is correct and write FALSE if the statement is wrong. (5pts. Each)

1. Quality standards are concise sets of evidence-based, measurable statements that provide guidance on important elements of high-quality health care in a specific topic area
2. Quality of health care is the application of medical science and technology in a way that minimizes its benefits to health without correspondingly increasing its risks.
3. Each quality standard contains 5-15 quality statement's

Answer Sheet

Score = _____

Rating: _____

Name: _____Date: _____

I- True/false:

1. _____
2. _____
3. _____

Information sheet 2	Introducing standard procedures.

1.2. Introducing standard procedures to organizational staff/personnel.

Policies and Procedures are two words frequently heard in the business world and there is often confusion between the two concepts.

What is an Organizational Policy?

A Policy defines an outcome; it is a premeditated rule set by a business to guide organizational direction, employees and business decisions, and to regulate, direct and control actions and conduct. Policies can range from a broad philosophy to a specific rule. They are the direct connection between a company's Vision and its daily operations and the underpinnings to a company's culture.

What is an Organizational Procedure?

A procedure is a means to an end. Procedures are step by step instructions, prescribing an exact sequence of action. A procedure explains how to and who (which position) will implement the policy. Procedures are specific, factual and succinct. They may include timelines, specific forms to be used and template forms. Procedures assist in eliminating common misunderstandings which can result in costly mistakes.

What is the difference?

Together Policies and Procedures empower a process by providing clear and concise direction necessary for consistent operation. The essential differences are outlined below:

Policies

- General in nature
- Identify company rules
- Explain why rules exist
- Explain when the rule applies
- Describe to whom (what position) it applies
- Explain how it is enforced
- Describe consequences
- Provide guidance for managerial thought and action
- Flexible - allows for discretion

Procedures

- Identify specific and alternative actions
- Explain when to take actions
- Describe emergency procedures
- Include warnings and cautions
- Give examples
- Show how to complete a specific form
- Prescribe how to carry out the action through step by step instruction
- Less flexible - concise and exact sequence of activities

Why does a company need Organizational Policies?

Policies and Procedures (P&Ps) are essential when a company requires consistency in its daily operations. They provide clarity and direction re: accountability. P&Ps assist companies in meeting legal requirements set out by the Employment Standards Act,the Human Rights Code, the Occupational Health and Safety Act and numerous other compliance requirements. A properly written policy and/or procedure allows employees to understand their roles and level of responsibility and conduct their job by making decisions within predefined boundaries. By implementing P&Ps, management can provide guidance to employees without needing to micromanage, freeing managers to focus on strategic thought. P&Ps allow the workforce to not only understand the accountabilities and responsibilities of their own position, but also that of their co-workers, which can foster a cooperative work environment.

How big should a company be to consider implementing Policies and Procedures?

With as few as six employees there will be recurring issues. Productivity and efficiencies both from a legal and operational standpoint can be gained through the implementation of P&Ps.

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HR-Fusion's Hamilton, Ontario location is uniquely positioned to provide services to Brantford, Burlington, Oakville, and the surrounding Niagara region. HR requirements outside the immediate geographic area are handled through the HR-Fusion partner network and provides coast to coast coverage as required.

Self check 2	Written test

Name: _____Date: _____

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

I-Essay: Explain briefly:

1. What is an organizational procedure? (5pts.)
2. What is quality? (5pts.)

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

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

Answer Sheet

Score = _____

Rating: _____

Name: _____ Date: _____

I- Essay:

1._____

_____

2. _____
_____

Informtion sheet 3	Providing quality standard and procedures documents.

1.3.Providing quality standard and procedures documents

Quality standards are useful for several audiences:

- Patients, caregivers, and the public can use quality standards to understand what excellent care looks like and what to ask for when receiving treatment.
- Health care professionals can use quality standards to guide and measure evidence-based quality improvement, and to support continuing professional development.
- Local health integration networks and government agencies can use quality standards to inform regional improvement strategies and performance measurement.
- Government can use quality standards to identify provincial priority areas, inform new data collection and reporting initiatives, and design performance indicators and funding incentives

Self test 3	Written test

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

I-Essay: Explain briefly:

1. Write use of giving quality standards(3pt)

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

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

Answer Sheet

Score = _____

Rating: _____

Name: _____ Date: _____

Information sheet 4	Revising / updating standard procedures.

1.4.Revising / updating standard procedures.

Changes to Standard Operating Procedures (SOPs) follow a specific method that a company's Quality and Regulatory Affairs department establishes. Start documenting requested changes to an SOP as soon as relevant personnel consider the revision. Keep a list of conversations regarding these changes by date and participants. Then, include this record as part of your initial request to change an SOP.So now life is good: You have an SOP manual, a more knowledgeable staff, consistency of services, a great tool for performance measures, regular training, etc.

You didn't think you were done, did you?

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

Part I of this series explains why SOPs matter and presents strategies for creating them. These strategies are also useful for updating existing SOPS. Part II discusses ways to implement SOPs in your organization.

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

Do Your SOPs Still Do the Job?

Here are some questions to ask as you consider whether your existing SOPs are in use throughout your organization and are still working as you intended them to.

STAFF AWARENESS

Where are the SOPs kept? Is the "centralized" copy really still available?

Does everyone have a copy? Do new staff get a copy right away? Is there someone responsible for assuring this?Do all of the staff know more than vaguely what you are talking about when you ask about policies?

USEFULNESS OF CURRENT SOPS

Do you hear consistent grumbling from staff regarding any particular procedures?

Is the manual truly comprehensive? Have you noticed any gaps?

Are the SOPs still realistic? Efficient? Effective? Is there now a better way?

When did you last really read them?

INTEGRATION WITH YOUR OPERATIONS

Are staff still involved in conversations that arise about needed updates?

Are you open to changes and improvements, even though you worked so hard to get what you have now?

Is your training still linked to procedures, and successful at helping staff understand what it is they need to accomplish?

What Needs to Change?

The answers to the questions asked above should guide the kinds of changes that may be needed. For example:

If awareness is the issue, you may need to produce and distribute the procedures and ask supervisors to remind staff about them.

If the information is out of date, you can use the process outlined in Part I to identify and make necessary changes to the SOPs.

If there's a lack of acceptance of the SOPs, do some digging to find out why:

Is the use of the SOPs included in job descriptions, employment policies, performance objectives, and training?

Are the SOPs too cumbersome to use? Are they unnecessarily complicated or too far removed from day-to-day reality?

Do your supervisors believe in their value and insist on their use? If not, why?

Do line staff resist following the SOPs? If so, why?

Identifying where the gaps between the procedures and their acceptance occur means that you can focus on a response that addresses the real issues and involves the right people.

How to Make the Changes?

Designate only one person to actually enter changes in the master document. This person could be your director of operations, manager, executive director—based on what's best for your agency.Here is a suggested process for identifying and implementing changes to your SOPs:

Include SOPs on the agenda of regular department staff meetings if there are any suggestions for change, deletions, or additions that need to be discussed.After discussion with the entire department, the department supervisor advises the director of operations of his/her team's suggestions or needed clarification.The director of operations evaluates the requested change and if necessary discusses it with the executive director or leader.

If the Director of Operations and the ED agree to make the change, that section of the master SOP manual (both electronic and physical copy) is updated with the new wording and instruction.A memo then goes out to the entire staff with a summary of the update, and the page and section number that was updated. Each staff person also receives a printed copy of the new revised section for the staff member to update their own manual.

Keeping SOPs a Priority

Development of SOPs and keeping them up to date and used must be a priority of an agency. To go through this process to say "Yes, we have 'em" is a waste of time. Agencies who are most successful with following SOPs have made it someone's main task to:

keep the SOPs current,

Ensure training is taking place based on the SOPs, and prevent SOPs from falling to the bottom of the priority list.Many agencies are understaffed, and yours may be one of them. If you are thinking you can't devote staff time to SOPs, think again about all of the aspects of your operation that will run more smoothly, more safely, and more reliably when everyone follows a good set of SOPs. SOPs are the core of your entire operation, and therefore critical to the internal and external success of your program.

Finding an SOP Advocate

Who should take charge of SOPs in your organization? Look for a staff person who:is organized,does not "have an agenda,"likes people, and understands the importance of this project and document.

When you find this individual, see where you can make some changes so this person has the time and energy to take on your SOPs.

Self check 4	**Written test**

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

I-Essay: Explain briefly:

1. Write different methods that used in order to revise or update SOPs ?

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

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

Answer Sheet

Score = _____

Rating: _____

Name: _____Date: _____

I- Essay:

1._____

Operation Sheet-1	Quality control procedures

Techniques for-maintaining quality

Step 1- Decide which specific standards the product or service must meet.

Step 2- Determine the extent of QC actions (for example, the percentage of units to be tested from each lot).

Step 3- Collect real-world data (for example, the percentage of units that fail)

Step 4- Report the results to management personnel

Step 5-Decide and take corrective action (for example, defective units must be repaired or rejected and poor service repeated at no charge until the customer is satisfied).

Step 6- If too many unit failures or instances of poor service occur, a plan must be devised to improve the production or service process

Step7 - The plan must be put into action.

Step 8 - Finally, the QC process must be ongoing to ensure that remedial efforts, if required, have produced satisfactory results and to immediately detect recurrences or new instances of trouble.

Operation Sheet-2	Performing IQC for newly opened reagents

PURPOSE

The purpose of this activity is to enable you to practice those skills necessary to perform IQC for serological test reagents, and to achieve competency in these skills.

INSTRUCTIONS

This activity should be conducted in a skill laboratory/healthy facility. Learners should review Learning Guide for performing IQC for serological test newly opened reagents before beginning the activity. The teacher should demonstrate the steps/tasks in each learning guide one at a time. Under the guidance of the teacher, learners should then work in groups and practice the steps/tasks in the Learning Guide for IQC procedure and observe each other's performance; while one learner/group doing the activity, another learner/group should use the Learning Guide to observe performance. Learners should then rotate roles. Learners should be able to perform the steps/tasks before skills competency is assessed using the Checklist for IQC performance.

CONDITIONS OR SITUATION FOR THE OPERATIONS

This activity could be done in skill laboratory or in healthy facility

RESOURCES (Equipment and Materials)

- Laboratory coat
- Gloves
- Laboratory request form
- Water and soap
- Permanent Marker
- IQC Log book
- SOP
- Stationery

Precaution: When a IQC is being performed , adequate safety precautions must be taken to prevent contamination **.**

Standard Precautions

Always wash hands before and after obtaining and handling specimens

- Cover cuts and lesions with waterproof dressing
- Wear disposable aprons and appropriate gloves .
- Use PPE

Procedure-Learning guide/Checklist

LEARNING GUIDE 1:

Performing IQC/EQA for different test

(To be completed by **Participant/students**)

Rate the performance of each step or task observed using the following rating scale:

1. Needs Improvement: Step or task not performed correctly, out of sequence (if necessary), or is omitted

2. Competently Performed: Step or task performed correctly in proper sequence (if necessary) but participant/student does not progress from step to step efficiently

3. Proficiently Performed: Step or task performed efficiently and precisely in the proper sequence (if necessary)

Performing IQC/EQA for different laboratory tests (Some of the following steps/tasks should be performed simultaneously)				
STEP/TASK	1	2	3	Remark
Getting ready				
• Wearing the Laboratory coat				
• Washing your hand with soap				
• Wearing the gloves				
• Preparing the necessary equipment				
• Preparing newly opened working reagents				
• Prepare negative and positive control inserted				
7. Follow the instruction procedure inserted				
8. Mix reagents with negative and positive control				
HISTORY (ASK/CHECK RECORD)				

LAP Test 1	Practical Demonstration

Name: _____ Date: _____

Time started: _____ Time finished: _____

Instructions: Given necessary templates, tools and materials you are required to perform the following tasks within 3-4 hour.

Task 1. Perform quality control procedures

Task 2. Performing IQC for newly opened reagents

LG59: Assess the quality of service delivered

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

- Products/work outputs and work performance
- Work outputs and performance delivered
- Causes of any identified faults

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 against organization quality standards and specifications.
- evaluated service delivered using the appropriate evaluation quality parameters and in accordance with organization standards.
- identify faults and use corrective actions in accordance with organization policies and procedures.

Learning Instructions

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

2.1.Quality standards and specification

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.Standards provide organizations with the shared vision, understanding, procedures, and vocabulary needed to meet the expectations of their stakeholders. Because standards present precise descriptions and terminology, they offer an objective and authoritative basis for organizations and consumers around the world to communicate and conduct business.

Figure 1. Principles of 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.

2.1.2Quality specification

Specifications describe the requirements to which a product should conform.They are three specification types : item, supplier, and customer. Specification can be further defined using subtypes. By carefully defining your specification you can ensure that the correct specification is applied as you collect data.Each type of specification can be based on either an Item or Item Category. If your specification is based on an Item, you must assign an item and, depending on the item, an item revision. If your specification is based on an Item Category, and you have specified a default category set using the QA:Quality Category Set profile option, you must assign a category.You can also attach illustrative or explanatory file in the form of text, images, word processing documents, spreadsheets, video, and so on to specifications.Attachments can be used to document processing instructions as well as inspection and disposition procedures. They can be viewed by operations personnel during quality data collection.The quality specifications of a product or service derive from decisions and actions made relative to the quality of its design and the quality of its conformance to that design. Design quality refers to the inherent value of the product in the marketplace and is thus a strategic decision for the firm.These dimensions refer to the features of the product or service that relate directly to design issues. A firm designs a product or service to address the need of a particular market.A firm designs a product or service with certain performance characteristics and features based on what the intended market expects. Materials and manufacturing process attributes can greatly impact the reliability and durability of the product. Here the company attempts to design a product or service that can be produced or delivered at a reasonable cost. The serviceability of the product may have a great impact on the cost of the product or service to the customer after the initial purchase is made. It also may impact the warranty and repair cost to the firm. Aesthetics may greatly impact the desirability of the product or service, in particular consumer products. Especially when a brand name is involved, the design often represents the next generation of an ongoing stream of products and services. Consistency in the relative performance of the product compared to the state of art, for example, may have a great impact on how the quality of the product is perceived. This may be very important to the long-run success of the product or service.Conformance quality refers to the degree to which the product or service design specifications are met. The activities involved in achieving conformance are of a tactical, day-to-day nature. It should be evident that a product or service can have high design quality but low conformance quality and vice-versa.

Self check 1	True/false

Name: _____Date: _____

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

I-True or False: Write TRUE if the statement is correct and write FALSE if the statement is wrong. (5pts. Each)

1. Quality specifications describe the requirements to which a product should conform.
2. Organizations turn to standards for guidelinesin order to meet personal objectives

Answer Sheet

Score = _____

Rating: _____

Name: _____Date: _____

2.2. Checking quality of services delivered and Organizational structure for quality management

An organizational structure consists of activities such as task allocation, coordination and supervision, which are directed towards the achievement of organizational aims.It can also be considered as the viewing glass or perspective through which individuals see their organization and its environment.Organizations are a variant of clustered entities.An organization can be structured in many different ways, depending on their objectives. The structure of an organization will determine the modes in which it operates and performs.Organizational structure allows the expressed allocation of responsibilities for different functions and processes to different entities such as the branch, department, workgroup and individual. Organizational structure affects organizational action in two big ways. First,it provides the foundation on which standard operating procedures and routines rest. Second, it determines which individuals get to participate in which decision-making processes,and thus to what extent their views shape the organization's actions.The set organizational structure may not coincide with facts, evolving in operational action. Such divergence decreases performance, when growing. E.g., a wrong organizational structure may hamper cooperation and thus hinder the completion of orders in due time and within limits of resources and budgets. Organizational structures shall be adaptive to process requirements, aiming to optimize the ratio of effort and input to output.

Organizational structure types

Pre-bureaucratic structures

Pre-bureaucratic (entrepreneurial) structures lack standardization of tasks. This structure is most common in smaller organizations and is best used to solve simple tasks. The structure is totally centralized. The strategic leader makes all key decisions and most communication is done by one on one conversations. It is particularly useful for new (entrepreneurial) business as it enables the founder to control growth and development. They are usually based on traditional domination or charismatic domination in the sense of Max Weber's tripartite classification of authority

Bureaucratic structures

Weber (1948, p. 214) gives the analogy that "the fully developed bureaucratic mechanism compares with other organizations exactly as does the machine compare with the non-mechanical modes of production. Precision, speed, unambiguity, … strict subordination, reduction of friction and of material and personal costs- these are raised to the optimum point in the strictly bureaucratic administration."Bureaucratic structures have a certain degree of standardization.

They are better suited for more complex or larger scale organizations, usually adopting a tall structure. The tension between bureaucratic structures and non-bureaucratic is echoed in Burns and Stalker's distinction between mechanistic and organic structures.

The Weberian characteristics of bureaucracy are:

- Clear defined roles and responsibilities
- A hierarchical structure
- Respect for merit.

Post-bureaucratic

The term of post bureaucratic is used in two senses in the organizational literature one generic and one much more specific.In the generic sense the term post bureaucratic is often used to describe a range of ideas developed since the 1980s that specifically contrast themselves with Weber's ideal type bureaucracy. This may include total quality management, culture management and matrix management, amongst others. None of these however has left behind the core tenets of Bureaucracy. Hierarchies still exist, authority is still Weber's rational, legal type, andthe organization is still rule bound. Heckscher, arguing along these lines, describes them as cleaned up bureaucracies rather than a fundamental shift away from bureaucracy. Gideon Kunda, in his classic study of culture management at 'Tech'argued that 'the essence of bureaucratic control the formalisation,codification and enforcement of rules and regulations -does not change in principle.....it shifts focus from organizational structure to the organization's culture'.Another smaller group of theorists have developed the theory of the Post-Bureaucratic Organization provide a detailed discussion which attempts to describe an organization that is fundamentally not bureaucratic. Charles Heckscher has developed an ideal type, the post-bureaucratic organization, in which decisions are based on dialogue and consensus rather than authority and command, the organization is a network rather than a hierarchy, open at the boundaries (in direct contrast to culture management); there is an emphasis on meta-decision making rules rather than decision making rules. This sort of horizontal decision making by consensus model is often used in housing cooperatives, other cooperatives and when running a non-profit or community organization. It is used in order to encourage participation and help to empower people who normally experience oppression in groups. Still other theorists are developing a resurgence of interest in complexity theory and organizations, and have focused on how simple structures can be used to engender

organizational adaptations. For instance, Miner *et al.* (2000) studied how simplestructures could be used to generate improvisational outcomes in product development. Their study makes links to simple structures and improviser learning.Other scholars such as Jan Rivkin and Sigglekow,and Nelson Repenningrevive an older interest in how structure and strategy relate in dynamic environments.

Functional structure

Employees within the functional divisions of an organization tend to perform a specialized set of tasks, for instance the engineering department would be staffed only with software engineers. This leads to operational efficiencies within that group.However it could also lead to a lack of communication between the functional groups within an organization, making the organization slow and inflexible. As a whole, a functional organization is best suited as a producer of standardized goods and services at large volume and low cost. Coordination and specialization of tasks are centralized in a functional structure, which makes producing a limited amount of products or services efficient and predictable. Moreover, efficiencies can further be realized as functional organizations integrate their activities vertically so that products are sold and distributed quickly and at low cost. For instance, a small business could make components used in production of its products instead of buying them.

Divisional structure

Also called a "product structure", the divisional structure groups each organizational function into a division. Each division within a divisional structure contains all the necessary resources and functions within it. Divisions can be categorized from different points of view. One might make distinctions on a geographical basis (a US division and an EU division, for example) or on product/service basis (different products for different customers: households or companies). In another example, an automobile company with a divisional structure might have one division for SUVs, another division for subcompact cars, and another division for sedans. Each division may have its own sales, engineering and marketing departments.

Matrix structure

The matrix structure groups employees by both function and product. This structure can combine the best of both separate structures. A matrix organization frequently uses teams of employees to accomplish work, in order to take advantage of the strengths, as well as make up for the weaknesses, of functional and decentralized forms. An example would be a company that produces two products, "product a" and "product b". Using the matrix structure, this company would organize functions within the company as follows: "product a" sales department, "product a" customer service department, "product a" accounting, "product b" sales department, "product b" customer service department, "product b" accounting department. Matrix structure is amongst the purest of organizational structures, a simple lattice emulating order and regularity

demonstrated in nature.

•**Weak/Functional Matrix:** A project manager with only limited authority is assigned to oversee the cross- functional aspects of the project. The functional Managers maintain control over their resources and project areas.

•**Balanced/Functional Matrix:** A project manager is assigned to oversee the project. Power is shared equally between the project manager and the functional managers. It brings the best aspects of functional and projectized organizations.However, this is the most difficult system to maintain as the sharing power is delicate proposition.

•**Strong/Project Matrix:** A project manager is primarily responsible for the project. Functional managers provide technical expertise and assign resources as needed.

Quality improvement

Quality Improvement (QI) refers to activities aimed at improving performance and is an approach to the continuous study and improvement of the processes of providing services to meet the needs of beneficiaries. This term generally refers to the overriding concepts of continuous quality improvement and total quality management. These phrases in general are used to describe the ongoing monitoring, evaluation, and improvement processes including the management of the improvement process itself. Contineous Quality Improvement (CQI) is an equivalent in health care for Total Quality Management (TQM) in the industry. CQI is an ongoing, organization wide framework in which HSOs and their employees and clinical staff are committed to and involved in monitoring and evaluating all aspects of the HSO's activities and outputs in order to continuously improve them. (American Hospital Association)

2.2.1Principles

Principles, we all use them (sometimes without knowing it) Whether in our personal lives or in our professional environment, our action take place as a result of a inherent set of principles. You could even define a principle of how we conform ourselves to the principles we previous have set. Some stick to them a great deal, others change whatever seems to be more convenient. In the book - 'the greatest salesman in the world' OgMandino elaborates a set of principles that made him a successful salesman. What happens within a group of people working together? Can you still define a common ground where they share the same principles?

Principles within companies and organizations

Companies and groups, teams departments or domains within companies have there own principles too. They are however less visible and the group might be less aware of the principles they share. Never the less, how implicit they are, the principles can be determined. By making the principles explicit, the driving power behind the

organization becomes more clear and with that, the power to improve management of the organization.

Self-Check 2	Written Test

Name: _____Date: _____

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

I-True or False: Write TRUE if the statement is correct and write FALSE if the statement is wrong. (2pts. Each)

1. Using multiple approaches of quality management is more likely to be effective as compared to using a single approach

2. If an organization gets accredited from a recognized accreditation body, there is no need to implement other quality management activities.

3. Setting and agreeing on standards alone will not lead to quality unless there is a mechanism to motivate or force organizations to comply with standards.

4. Standardization could be considered as the first step in the process of accreditation.

5. All standards of practice provide a guide to the knowledge, skills, judgment & attitudes that are needed to practice safely.

Answer Sheet

Score = _____

Rating: _____

Name: _____Date: _____

2.3.Evaluating service delivered using quality parameters.

In 2019, it's imperative that you provide excellent service to your customers. With a wealth of competition, companies that don't compete on customer experience will lose customers to those that are continually delighting and providing a high quality of service.However,even companies that understand the need to provide exemplary experiences have a hard time measuring their service quality. Since it's a qualitative measurement, rather than a quantitative measurement, it can be challenging to assess. Even some researchers have struggled with the issue of how to measure service quality and understand how you're impacting your customers.In this section we'll list ways to assess service quality and provide actionable insights on how to improve on your findings.

2.3.1 How to measure service quality

In a general sense, measuring service quality depends entirely on the context and brand promise, and service quality dimensions vary according to the industry. However, the industry standard and most widely-used metric is SERVQUAL.

SERVQUAL

SERVQUAL is based on a set of five dimensions which have been consistently ranked by customers to be most important for service quality, regardless of service industry. These dimensions defined by the SERVQUAL measurement instrument are as follows:

Tangibles: appearance of physical facilities, equipment, personnel, and communication materials.

Reliability: ability to perform the promised service dependably and accurately.

Responsiveness: willingness to help customers and provide prompt service.

Assurance: knowledge and courtesy of employees and their ability to convey trust and confidence.

Empathy: the caring, individualized attention the firm provides its customers.These five SERVQUAL dimensions are used to measure the gap between customers' expectations for excellence and their perception of the actual service delivered. The SERVQUAL instrument, when applied over time, can help you understand both customer expectations, perceptions of specific services, and areas of needed quality improvements.SERVQUAL has been used in many ways, such as identifying specific service elements that need improvement, and targeting training opportunities for service staff.Proper development of items used in the SERVQUAL instrument provides rich item-level information that leads to practical implications for a service manager.The service quality dimensions evaluated by SERVQUAL should be adjusted for optimal performance in different industries, including public and private sector applications. SERVQUAL scores are highly reliable, but when used in different industries may fail to produce a clear delineation of the five basic dimensions. Other measures, such as the Six Sigma model should be considered for applicability in

quantifying the gap between service expectations and perceptions.

2.3.2SERVICE QUALITY QUESTIONNAIRES

In order to improve service, you must understand customer satisfaction and customer expectations. This can be done by asking for feedback from your customers using service quality questionnaires. These are typically completed after the service with a follow-up email or paper survey. Following up immediately is the best way to fix any mistakes or clear up misunderstandings before your customers become detractors.

SERVICE QUALITY QUESTIONS

There are many types of questions that can be asked in a Service Quality Questionnaire. They should focus on the customer's interaction with the customer service rep (positive and negative), the service and experience overall, and if the customer would use your service again. It's also good to have a couple open text questions so your customers can write in their own feedback.

Sample questions include

The service rep was helpful (strongly agree to strongly disagree)
Which of the qualities about the service did you like (include a list patient, friendly, attentive, willing to help, empathetic, etc)
Was there anything about our service that stood out to you? (open-text response)
Over the next 12 months, how likely are you to use our product or service again (strongly agree to strongly disagree)

Self check 3	**Written test**

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

I-Essay: Explain briefly:

1. Write different methods of measuring service quality
2. What are the parameters for measuring service quality?

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

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

Answer Sheet

Score = _____
Rating: _____

Name: _____Date: _____

Information sheet 4	Identifying causes of any faults and taking corrective actions.

2.4. Identifying causes of any faults and taking corrective actions.

Corrective and preventive action (**CAPA**, also called **Corrective Action / Preventive Action**, or simply **Corrective Action**) are improvements to an organization's processes taken to eliminate causes of non-conformities or other undesirable situations. It is usually a set of actions that laws or regulations require an organization to take in manufacturing, documentation, procedures, or systems to rectify and eliminate recurring nonperformance.The corrective and preventive action is designed by a team that includes quality assurance personnel and personnel involved in the actual observation point of non-conformance. It must be systematically implemented and observed for its ability to eliminate further recurrence of such non-conformation.

Examples of corrective actions

Error proofing

Process redesign

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

Process steps of corrective action

Cause analysis, root cause

Analyzing non-conformities effects and needs for action

Selection and implementation of corrective actions

Monitoring of corrective actions

Additional audits

2.4.1 Safe or current work practices and procedures

Safe work practice are generally written methods out lining how to perform a task with minimum risk to people, equipment, materials averment and process. Safe job procedures are a series of specific steps that guide a worker through a task from start to finish in a chronological order Making safe work practice and procedure part of standard operating procedure may seem a matter of common sense. But in fact an effective health and safety program for worker is required by occupational health and safety regulation. Measurements of these items in the audit will include written safe work procedures, practice and/ or instructions include all routine and non-routine expected operations of the company a work place hazardous materials information system Instructions that direct the first aid service, supplies and equipment to be provided and

how employees receive that service procedures addressing possible emergencies, training of workers in those procedures, testing their effectiveness, and evaluating and revising the procedures based on drills and actual emergencies in order to meet the above objectives, the audit checks whether

- The employee has safe work procedures based on the hazard/ risk assessment done at the work site
- Employees participate in the hazard/risk assessment
- There is a first aid assessment done for each site that the company operates
- There are procedures for workers to follow when they are injured
- Employ know their roles in the first aid and emergency response plan training is documented

2.4.2 Identifying problems during quality control procedure

Opportunities for improvement can be found at every level of the health system, problem solving and process improvement work best when conducted as part of a quality assurance program in which standards are developed and quality indicators are monitored. Nevertheless, the problem-solving steps presented here in can be applied whenever and however an opportunity for improving quality arises.

Approach to quality assurance

Four main principles define the approach presented in this monograph for ensuring and improving quality and for resolving quality problems as they arises. These are summarized below:

A focus on client needs: Client needs and desires should derive the planning and performance of any activity. Ensuring quality begins with knowing who the clients are and understanding their needs and expectations. Within this idea of 'client' every worker plays the complementary roles of serving clients and of being a client health of the individuals and communities they serve.

A focus on system and process: The quality of health services is usually judged by outcomes, specifically, the immediate and long term effects on the service provided.

A focus on data based decisions: Improving processes requires information about how they function. Decision about problem area and improvements should be based on accurate and timely data, not on assumption

A focus on participation and team work in quality improvement: For quality improvement to succeed, workers must participate in making changes in the organization's system and processes

2.4.3 Evaluating causes for poor work activities

A simple definition of unsatisfactory job performance is a gap between the employee's actual performance required by the organization

There are three basic types of poor performance

1. Un satisfactory work content- in terms of quantity, quality etc
2. Breaches of work practice, procedures and rules- such as breaching occupational health and satisfy requirements
3. Employees' personal problems usually off the job issues that affect their performance at work

The performance management process should be able to identify these problems. The performance management interview and feedback processes can discuss the problems to diagnose the cause and explore possible remedies, such as job redesign, training or counseling

The following list indicates the scope of casual factors and their symptoms, and suggests appropriate remedial actions

-The work environment: inadequate resource and equipment

-Work organization: Work flow issue

-Employee condition: Excessive work load,

-Recruitment/selection issues: mismatch of job and employee

-Promotion: employee promoted beyond

-Stress

2.4.4 Quality improvement techniques

Quality improvement sometimes referred to as continues quality improvement or TQM. Its application to health care, and to laboratory practice in particular

The ability to apply principles of quality improvement to evaluate systems performance is one of the five competencies

Quality improvement tools and techniques may include:

Run charts, control charts, histograms and scatter grams to present routine quality control data

Plan, do, check, act (PDCA) logic tree ,similarity/difference analysis,Pareto charts and analysis and force field/strength weakness opportunities threats (SWOT) analysis

Self check 4	Written test

Answer the following questions

1. Describe and discuss the six steps to solve quality problems and improving processes

2. What is safe working practice?

3. Describe quality improvement tools and techniques

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

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

Answer Sheet

Name: _____Date: _____

I- Essay:

1._____

_____

2. _____

_____

3. _____

_____

_____

_____

Operation Sheet-1	Solving quality problems

Techniques for Solving quality problems and improving processes

Step 1- Identify problems and select opportunities for improvement

Step 2- Define the problem operationally

Step 3- Identify who needs to work on the problem

Step 4- Analyze and study the problem to identify major causes

Step 5- Develop solutions and actions for quality improvement

Step 6-. Implement and evaluate quality improvement efforts

Operation Sheet-2	Preventave action

Techniques for preventave actions

Step 1-Data collection for potential non-conformities

Step 2- Cause analysis for root cause for potential non-conformities

Step 3- Selection and implementation of preventive actions

Step 4- Monitoring of preventive action

Step 5- Records of corrective and preventive actions

LAP Test 1	Practical Demonstration

Name: _____ Date: _____

Time started: _____ Time finished: _____

Instructions: Given necessary templates, tools and materials you are required to perform the following tasks within 3-4hour.

Task 1. Solve quality problems

Task 2. Perform preventave action

Instruction Sheet	LO3: Record information

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

- Records of work quality
- Recording on quality performance

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 quality in accordance with organization procedures.
- Record of work quality according to the requirements of the organization.

Learning Instructions

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

Information sheet 1	Record information

3.1.Recording basic information on the quality performance.

An important part of any operating system is documentation, the technical manuals that describe the operation and use of programs. As part of its efforts to create a high-quality free operating system, the Debian Project is making every effort to provide all of its users with proper documentation in an easily accessible form. Do have these at hand when you make your first Debian installation, it will probably answer many questions and help you work with your new Debian system.

3.1.2 Types of documentation

Most of the documentation included in Debian was written for GNU/Linux in general.There is also some documentation written specifically for Debian. These documents come in these basic categories:

- manuals
- HOWTOs
- FAQs

other shorter documents

Manuals

The manuals resemble books, because they comprehensively describe major topics.

HOWTOs

The HOWTO documents, like their name says, describe *how to* do something, and they usually cover a more specific subject.
Some of the most important Linux HOWTOs are:

- Hardware Compatibility HOWTO,
- Unix and Internet Fundamentals HOWTO,
- Filesystems HOWTO,
- Configuration HOWTO,
- Networking HOWTO, and many others

FAQs

FAQ stands for *frequently asked questions*. A FAQ is a document which answersthose questions.

Other, shorter documents

The following documents include quicker, shorter instructions:

manual pages

Traditionally, all Unix programs are documented with *manual pages*, reference manuals made available through the man command. They usually aren't meant for beginners. .

info files

Many GNU software is documented through *info files* instead of manual pages. These files include detailed information of the program itself, options and example usage and are available through the info command.

Self check 1	**True/false**

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

I-True or False: Write TRUE if the statement is correct and write FALSE if the statement is wrong. (5pts. Each)

1. The HOWTO documents, like their name says, describe *how to* do something, and they usually cover a general subject

Answer Sheet

Score = _____

Rating: _____

Name: _____Date: _____

I- True /false:

1. _____

3.2. Maintaining records of work quality

The maintaining process is a continuous flow between measuring, comparing, and action

Setting Objectives

Establishing performance standards are when objectives are set during the planning process. Its standard is a guideline established as the basis for measurement. It is a precise, explicit statement of expected results from a product, service, machine, individual, or organizational unit. It is usually expressed numerically and is set for quality, quantity, and time (Plunkett, et al.). There are several sub-controls in this step: time controls, material controls, equipment controls, cost controls, and budget controls, financial controls, and operations controls (like total quality management).

Observing and Measuring Performance

During step two, measuring actual performance, supervisors collect data to measure actual performance to determine variation from the standard. Personal observation, statistical reports, or oral reports can be used to measure performance. Observation of employees working provides hands on information, extensive coverage, and the ability to read between the lines. While providing insight, this method of management by walking around might be misinterpreted by employees as mistrust (Plunkett, et al.).

Comparing Results

The third step of comparing measured performance against an established standard is comparing the results with the standards to discover variations. Some variation can be expected in all activities and the range of variation has to be established (Plunkett, et al.). Management usually lets operations continue as long as they are within the defined control limits. Deviations that exceed this range alerts the manager to a problem and leads to the last step.

Corrective Action

The last step, taking corrective action, is when a supervisor finds the cause of the deviation. Then he or she takes action to remove or minimize the cause. If the source of the variation in performance is from a deficit activity, then the supervisor can take immediate corrective action and get performance back on track. Also, the manager can opt to take basic corrective action, which determines how and why performance has deviated, and correct the source of the deviation. Immediate corrective action is more efficient, while basic corrective action is more effective

3.2.1Regulations and legislation

Legislation The process of making or enacting laws.

Act	Primary legislation that has been passed by both houses of Parliament.
Regulations	The practical details and rules made under Acts.
Codes	A collection of rules on a given subject.

Legislation is a directive placed by a government or governing body on either an industry, a section of community or placed on people of a country which must be complied with in order to remain within the legal boundaries of that particular country, community or industry. In industry, legislation acts as an external driver which must be met by all players in order to be compliant. Legislation is passed as laws by a parliament of a country or some other legislative arm of a government. After legislation is passed, there will be regulators, usually government bodies, who will examine the laws passed and work out the details that need to be enforced so that they are followed. For instance a parliament may pass a legislation that enforces a uniform interconnection fee for telecommunication service providers in a country, and then a government department (regulator) of communications will detail the nitty-gritty of the legislation and enforce it. At times before a part of legislation becomes a law, it may be referred to as a bill. Some countries require legislation to be validated by the executive (usually President) before it could be enforced as law. Commonly a member of the governing body or legislature will propose legislation or by the executive, which then becomes open for debate by legislators. Amendments are usually made before it is finally passed. Government legislative priorities often determine whether a given bill is proposed and enforced as law.

A regulation refers to a specific requirement that can take on various forms, such as industry specific regulation or regulations that are much broader in scope. They are basically the way the legislation is enforced by regulators and they support the requirements of the legislation. In industry, they specify the particular formal (legal) requirements that need to be followed by organizations, workers and employers alike so as to create a level playing field within the competitive environment of the organizations as well as within a particular organization. This is so because regulations address product safety, consumer protection and other factors in public interest. The thing with regulations is that they could either be internally or externally developed so as a means of compliance, they may be developed through technical specifications or may be through some standards in the private sector.

3.2.2 Control points

A **control point** (**CP**, also **control** and **checkpoint** and **passport control**) is a marked waypoint used in orienteering and related sports such as rogaining and adventure racing. It is located in the competition area; marked both on an orienteering map and in the terrain; and described on a control description sheet.

The control point must be identifiable on the map and on the ground. A control point has three components: a high visibility item, known as a flag or kite; an identifier, known as a control code; and a recording mechanism for contestants to record proof that they visited the control point. The control point is usually temporary, except on a permanent orienteering course. For events held under IOF Rules the kite has a triangular form with each face being about 30 cm x 30 cm and coloured white and orange. Most national governing bodies, and related sports, use the same design. The earlier specification used white and red.

The location of control points is kept secret from the competitors until the start of the competition, when they receive the map. The map may be pre-printed with the control points, or the competitor may be required to copy control points onto the map from a master map. Control points are selected and prepared anew for each competition. Permanent courses, with their permanent control points, are used primarily for training and recreation, but rarely for competition.

In the early days, control points were staffed. Often the competitors were given at the outset only the location of the first control point, and were given the next location by the control point staff, who also stamped the control cards.

The first public orienteering competition, in Norway in 1897, had three controls, at the farms Finnerud, Bjørnholt and Slakteren, while start and finish were on the farm Grøttum (see map in ref). The first Swedish public orienteering competition, near Stockholm in 1901, used two churches (Bromma and Spånga Church) and two large farms as control points. Control description sheet

Control description sheet for an orienteering course in Poland

In orienteering competitions the locations of the control points are described on a **control description sheet** (or **clue sheet**). It is sometimes incorrectly referred to as a "Course Description Sheet". For beginners, and the younger competitors, the description is written in a simple text format, but for advanced orienteers the descriptions use symbols (pictorial), in accordance with the *IOF Control descriptions*. These symbols eliminate any language-based confusion, vital for international competition. The control descriptions are fixed to or printed on the map, and separate control description sheets may be available at the prestart. Some competitors wear the extra control description sheet in a holder strapped onto their forearm, so that they can read it while running.

A popular software program for producing control description sheets is Clue, available free from the Delaware Valley Orienteering Association Control card and punching each competitor is required to carry a **control card**, and to present it at the Start and hand it in at the Finish. The control card is marked by some means at each control point to show that the competitor has completed the course correctly.

In both trail orienteering and North American style mounted orienteering, it may not be feasible, safe, or permitted for the competitor to go to the control point itself. Instead, the competitor views the control point from a short distance and marks the

control card with a pen. Several marking schemes are in use, including a pre-printed multiple choice form, and a "secret word" posted at the control point that the competitor must copy down.

In foot orienteering, the oldest form of orienteering, the first control cards were card stock with a perforated stub, the stub to be handed in at the Start as a safety check. At each control, originally, the control staff or the competitor rubber stamped the control card using a rubber stamp and inkpad kept at that control. Rubber stamps soon were replaced with ticket punches, usually with a different punch shape (circular, square, diamond, star, etc.) at each control. Card stock control cards are in limited use today, having been mostly replaced by weatherproof stock such as Tyvek. Ticket punches have been replaced by needle punches that punch a pattern of small holes in the control card (similar to a perfin)

Self check 2	**Written test**

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

I-Essay: Explain briefly:

1. Write how to maintain and record quality work

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

Answer Sheet

Score = _____

Rating: _____

Name: _____ Date: _____

I- Essay:

1._____

Operation Sheet-1	Maintain accurate work records

Techniques for maintaining accurate work record:

Step 1- Establish performance standards

Step 2- Measure actual performance

Step 3- Compare measured performance against established standards

Step 4- Take corrective1 action

.

LAP Test 1	Practical Demonstration

Name: _____ Date: _____

Time started: _____ Time finished: _____

Instructions: Given necessary templates, tools and materials you are required to perform the following tasks within 5-6 hour.

Task 1. Maintain accurate work records

Instruction Sheet	LG61: Study causes of quality deviations

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

- Cause of deviation and report accordance with organizational procedures
- Preventive action based on organizational quality

This guide will also assist you to attain the learning outcome stated in the cover page.

Specifically, upon completion of this Learning Guide, you will be able to –

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

Learning Instructions

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

Information sheet 1	Study causes of quality deviations

4.1. Investigating and reporting causes of deviations from final outputs or services.

Deviation is a departure from standard procedures or specifications resulting in non-conforming material and/or processes or where there have been unusual or unexplained events which have the potential to impact on product quality, system integrity or personal safety. For compliance to GMP and the sake of continuous improvement, these deviations are recorded in the form of Deviation Report (DR).

Types of Deviations:

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

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

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

3. Quality Improvement Deviation - may be raised if a potential weakness has been identified and the implementation will require project approval.

4. Audit Deviation - raised to flag non-conformance identified during internal, external, supplier or corporate audits.

5. Customer Service Deviation - raised to track implementation measures related to customer complaints.

6. Technical Deviation - can be raised for validation discrepancies. For example: changes in Manufacturing Instruction.

7. Material Complaint - raised to document any issues with regards to non-conforming, superseded or obsolete raw materials/components, packaging or imported finished goods.

8. System Routing Deviation - raised to track changes made to Bill of materials as a result of an Artwork change.

When to Report Deviation:

Deviation should be raised when there is a deviation from methods or controls specified in manufacturing documents, material control documents, standard operating procedure for products and confirmed out of specification results and from the occurrence of an event and observation suggesting the existence of a real or potential quality related problems. A deviation should be reported if a trend is noticed that requires further investigation. All batch production deviations (planned or unintended) covering all manufacturing facilities, equipments, operations, distribution,

procedures, systems and record keeping mustbe reported and investigated for corrective and preventative action. Reporting deviation is required regardless of final batch disposition. If a batch is rejected a deviation reporting is still required.

Different Levels of Deviation Risks:

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

Level 1: Critical Deviation

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

Level 2: Serious Deviation

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

Level 3: Standard Deviation

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

How to Manage Reported Deviation:

The department Manager or delegate should initiate the deviation report by using a standard deviation form as soon as a deviation is found. Write a short description of the fact with a title in the table on the form and notify the Quality Assurance department within one business day to identify the investigation. QA has to evaluate the deviation and assess the potential impact to the product quality, validation and regulatory requirement. All completed deviation investigations are to be approved by QA Manager or delegate. QA Manger has to justify wither the deviation is a Critical, Serious or Standard in nature. For a deviation of either critical or serious nature QA delegate has to arrange a Cross Functional Investigation.

For a standard type deviation a Cross functional Investigation (CFI) is not necessary. Immediate corrective actions have to be completed before the final disposition of a batch. Final batch disposition is the responsibility of Quality Assurance Department. If a critical or serious deviation leads to a CFI, corrective and preventive actions should be determined and follow up tasks should be assigned to area representatives. Follow up tasks should be completed within 30 business days of the observation of

deviation. If a deviation with CFI can not be completed within 30 business days, an interim report should be generated detailing the reason for the delay and the progress so far. After successful completion of the Follow up tasks Deviation should be completed and attached with the Batch Report /Audit report/ Product complaint report /Safety investigation report as appropriate.

4.1.1 investigation and report

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

Self check 1	**Mcq**

Chose the best answer for the following questions

1. After receiving the Deviation information, the director should

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

2. Which one of the following is correct about the time in which deviation is reported?
   A. When there is a deviation from methods or controls specified in manufacturing documents
   B. when there is a deviation from standard operating procedure
   C. If a trend is noticed that requires further investigation
   D. All

Information sheet 2	Recommending suitable preventive action.

4.2 Recommending suitable preventive action.

Quality professionals frequently express confusion as to the difference between corrective and preventive action. A corrective action deals with a nonconformity that has occurred, and a preventive action addresses the potential for a nonconformity to occur. Many ISO 9000 registrar auditors tell their clients to use separate procedures and forms to document each type of action. Nothing in the standard says this must be done, but p. 13 includes the word “prevent” in the clauses on corrective and preventive action.

Common Misconceptions

There are three common misconceptions about corrective and preventive action:

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

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

TABLE 1 Four Types of Action

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

Table 1: preventive Action

Corrective Action Process

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

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

Initiate an improvement project, with project plans, justification for planned expenditures, resource controls and evaluation.Contain a related series of actions, often separated by long periods so you can wait and see progress and results.

Use a variety of appropriate disciplines at different times during the project.

Establish a means for communicating what has been done and what has to be done to facilitate communication about changes to project team members.
Include a clear trail of actions taken and decisions made to substantiate the decision to proceed, document lessons learned and avoid needless reinvention on future similar projects.Documenting and controlling corrective and preventive actions ensure appropriate action is taken within a reasonable timeframe and the resulting changes work.

Self check 2	**Written test**

Answer the following question

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

Answer Sheet

Score = _____

Rating: _____

Name: _____Date: _____

I- short answer

_____

_____

_____

_____

_____

_____

_____

_____

_____

Information sheet 3	Identifying causes of deviation from specific quality standards

4.3. Identifying causes of deviation from specific quality standards

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

Simply **5 M and environment**

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

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

Machine

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

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

Material

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

- Low grade material
- Unspecified material
- Variation

Management

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

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

- Lack of fact-based decision making

Method

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

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

Environment

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

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

Self-Check 3	**Mcq**

Chose the best answer for the following questions

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

4. Which one of the following machine factor cause poor quality standard?

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

Answer Sheet

Score = _____

Rating: _____

Name: _____Date: _____

I- Enumeration:

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

LG62: Complete documentation

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

- Information on quality and Indicators of service
- Recorded service process and out come

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 –

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

Learning Instructions

1.Read the information written in the “Information Sheets”.

2.If you earned a satisfactory evaluation proceed to next module. However, if your rating is unsatisfactory, see your teacher for further instructions.

3.Read the “Operation Sheet” and try to understand the procedures discussed.

4.Practice the steps or procedures as illustrated in the operation sheet. Go to your teacher if you need clarification or you want answers to your questions or you need assistance in understanding a particular step or procedure

5.Do the “LAP test” (if you are ready). Request your teacher to evaluate your performance and outputs.Your teacher will give you feedback and the evaluation will be either satisfactory or unsatisfactory.If unsatisfactory, your teacher shall advice you on additional work.But if satisfactory you can proceed to the next Learning Guide.

5.1.informotion on quality and Indicators of service

1. Definition of Indicator

An indicator, in the context of quality management, is an aspect of patient caremeasured to determine an organization's performance with regard to a particular element of care. An indicator may measure a particular structure, process or outcome.Quality of care indicators are usually derived from clinical guidelines, standard operating procedures and other manuals stating what types of services need to be provided to a patient/client/population with specific needs. Such guides provide the standard against which performance will be measured.These manuals could be developed by government bodies, professional associations, orany other authorized body.

Examples of clinical guidelines and manuals:

- Guideline for the management of severe and complicated malaria
- Guideline for the management of opportunistic infections and antiretroviral therapy for adults and adolescents in Ethiopia
- National Tuberculosis and Leprosy Control Program Manual
- Guideline for the Prevention of Mother to Child Transmission of HIV
- Procedure Manuals for Health Management Information System

What are the characteristics of a good indicator?

- ☐ Evidence of importance
- ☐ Degree of control at the specific level of care
- ☐ Measurability
- ☐ Sensitivity
- ☐ Specificity
- ☐ Validity
- ☐ Reliability
- ☐ Understandability
- ☐ Comparability

2. Selecting health care quality indicators

Quality improvement is not expected to happen as a result of a single institution. It

requires the participation of all relevant stakeholders so as to ensure, from the beginning, that measurement results will be accepted by different actors. Therefore, whenever possible it is advisable to use indicators which are widely used by different groups. But, if there is a need to develop new indicators, all relevant stakeholders need to be involved. This will guarantee acceptability of measures and help address the information needs of stakeholders with no additional cost to collect and report data.During selection of health care quality indicators, quality improvement teams need to consider characteristics of a good indicator. These characteristics are:

2.1. *Evidence of importance/Relevance/:* indicators to be used as measures of health care quality need to have established scientific evidences showing its relationship with the outcome of interest.

2.2. *Degree of control at the specific level of care:* indicators of health care quality need to measure aspects of care which is under the control of the primary actor in the improvement process. Selection of indicators on aspects of care which are out of control of the primary actor will lead to wastage of resources for data collection rather than initiation of an improvement process.

2.3. *Measurability:* refers to the practical feasibility of measuring the indicator with already available resources and expertise. It should be noted that resources (including health workers' time) to be used for measurement should be balanced with resources to implement improvement efforts.

Measurability of indicators is related to:

- availability and integrity of data to be used
- resources required to collect and analyze the data
- ethical issues related to data collection

2.4. *Sensitivity:* is the ability of an indicator to change with minimal change in the actual situation under measurement. It is a measure of an indicator to show

audiences the minimum amount of change desired to be recognized.

2.5. *Specificity:* is the ability of an indicator not to change whenever there is no change in the situation under measurement. Measurement results of a specific indicator of health care quality increase or decrease only when there is change in performance of the health facility with regard to the specific aspect of care.

2.6. *Understandability:* is the potential for measurement results to be clear for targeted audiences. Understandability of an indicator should always be examined by considering intended audiences.

2.7. *Comparability:* A good indicator needs to be comparable through time and across different health facilities. The use of standard indicators and avoiding frequent changes in indicator definitions help quality management teams compare their performance with other health facilities and through time to see the results of their improvement efforts.

Self check 1	**Written test**

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

I-Essay: Explain briefly:

1. What are the characteristics of a good indicator?
2. Define the term indicator used to measure sevice performance?

Answer Sheet

Score = _____

Rating: _____

Name: _____ Date:

5.2. Recorded service process and out come

5.2.1. *Structural* service:refer to the availability of required resources and the setup in which they are used to produce desired outcomes.Moreover, structural measures may also include the presence of networks between health facilities for referral system. Resources include human resources, material resources and technology.

5.2.1.1. Human resources:

- The availability of physicians, nurses, pharmacists, laboratory technicians, supportive staff
- The provision of appropriate trainings for the health workforce

5.2.1.2. Material resources

- Uninterrupted supply of drugs, laboratory reagents
- Presence of equipments
- Rooms, space, transportation and other resources required for care provision

5.2.1.3. Technology

- Type of diagnostic and therapeutic procedures being used as compared to current advances in the field

5.2.2. *Process* serviceare services related to the activities that are expected to be accomplished in order to achieve desired outcomes of health care and how such activities are delivered to beneficiaries. These include:

- Appropriate investigation of patients
- Provision of appropriate treatment for patients
- Treatment of patients in a way meeting their expectations

5.2.3. *Outcome*serviceare services related to the desired effect of health care services on clients/patients/populations. It includes:

- Improvement in health conditions or reduced morbidity
- Decreased mortality
- Satisfaction of clients as a result of health care

Outcomes are dependent on different factors of which health care is only one of them. Other factors determining outcome measures include behaviors of patients, socioeconomic status of patients and the performance of other actors. For example, treatment of a patient infected with HIV using highly active antiretroviral therapy is expected to improve the quality of life of the patient. However, quality of life is affected by a number of factors of which the treatment is only one. The use of outcome indicators as a measure of quality thus faces a problem of attribution.

self check-2	**MCQ,T. or F & MATCHING**

1. Setting minimum requirements for different levels of clinics is one of the activities expected from the regulatory body of the Ethiopian Ministry of Health. The purpose of this activity is to ensure that the population will receive health care of good quality. Under which approach of quality management can this activity be categorized?
    a. Standardization
    b. Accreditation
    c. Quality improvement
    d. Quality Assurance
    e. None

Answer the following questions by saying "True" if the sentence is correct and "False" if the sentence is wrong.

1) Using multiple approaches of quality management is more likely to be effective as compared to using a single approach
2) If an organization gets accredited from a recognized accreditation body, there is no need to implement other quality management activities.
3) Setting and agreeing on standards alone will not lead to quality unless there is a mechanism to motivate or force organizations to comply with standards.
4) Standardization could be considered as the first step in the process of accreditation.

Match the list under column "A" with column "B"

Column A

____ 6. Standardization

____ 7. Accreditation

____ 8. Quality management

____ 9. Quality improvement

Column B

A. *The process of setting and agreeing standards*
B. *Requires the presence of a recognized body to assess if organizations are meeting preset standards and certify qualitying ones*
C. *An internal process of contineously studying and improving processes of care provision*
D. A set of different activities that organizations use to direct, control, and coordinate quality

Answer Sheet

Score = _____

Rating: _____

Name: _____ Date: _____

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