Ethiopian TVET-System

Electro Mechanical Equipment Operation and Maintenance

Level III

Based on March, 2017G.C. Occupational Standard

Module Title: Applying Quality Control

TTLM Code: EIS EME3 TTLM 0820v1

This module includes the following Learning Guides

LG53: Implement quality standards

LG Code: EIS EME3 M14LO1-LG-53

LG54: Assess quality of service delivered.

LG Code: EIS EME3 M14LO2-LG-54

LG55: Record information

LG Code: EIS EME3 M14LO3-LG-55

LG56: Study causes of quality deviations.

LG Code: EIS EME3 M14LO4-LG-56

LG57: Complete documentation.

LG Code: EIS EME3 M14LO5-LG-57

Instruction Sheet	Learning Guide 53: Implement quality standards

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

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

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

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

Learning Instructions:

1. Read the specific objectives of this Learning Guide.
2. Follow the instructions described below
3. Read the information written in the “Information Sheets 1- 4”. Try to understand what are being discussed.
4. Accomplish the “Self-checks1,2,3 and 4 ” in each information sheets on pages 7, 12,16 and 20.
5. Ask from your teacher the key to correction (key answers) or you can request your teacher to correct your work. (You are to get the key answer only after you finished answering the Self-checks).
6. After You accomplish self checks, ensure you have a formative assessment and get a satisfactory result; then proceed to the next LG.

Information Sheet-1	Acquiring and Confirming Agreed Quality Standard and Procedure

1.1 Introduction

The term quality might mean different things for different people and for different things (service, product, education etc…). For example

- Customer Based:- Fitness for use, meeting customer expectations
- Manufacturing Based:-Conforming to design, specifications, or requirements. Having no defects.
- Product Based:-The product has something that other similar products do not that adds value.
- Value Based:-The product is the best combination of price and features.

In its broadest sense, quality is a degree of excellence: the extent to which something is fit for its purpose. In the narrow sense, product or service quality is defined as conformance with requirement, freedom from defects or contamination, or simply a degree of customer satisfaction. In quality management, quality is defined as the totality of characteristics of a product or service that bears on its ability to satisfy stated and implied needs. Quality is also rapidly embracing the nature or degree of impact an organization has on its stakeholders, environment and society.

- Quality Assurance is a system of management activities involving planning, implementation, assessment, and reporting to make sure that the end product, the type and quality needed to meet the needs of the user.
- It is the sum of all activities and responsibilities intended to ensure the products or services meet all the applicable quality specifications at the end of every product or service. **"**A planned system of activities designed to ensure effective quality control."
- Efficient QA program is important to monitor and evaluate effectiveness of policies and procedures of quality control

1.2 Quality control (QC)

Quality Control is the overall system of operational techniques and activities that are used to fulfill requirements for quality. The QC activities are used to produce and document the quality of the end product. which is concerned with sampling, specification and testing and organization, documentation and release of procedure to ensure the quality of electro mechanical devices and components

1.3 Quality Standard

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

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.

Quality standards are concise sets of evidence-based, measurable statements that provide guidance on important elements of high-quality in a specific product or services. Quality standards focus on areas where experts, technicians, engineers, and the public have identified a need for improvement. Quality standards also include a small set of outcome indicators to measure the impact of the quality standard as a whole.

1.4 Quality system procedures

Develop and implement quality system procedures that are consistent with your quality policy.

- Develop your procedures for all areas of your quality system.

- Document your procedures, and keep them up to date.

  Each procedure should:

  - Specify its purpose and scope.
  - Describe how an activity should be carried out.
  - Describe who should carry out the activity.
  - Explain why the activity is important to quality.
  - Describe when and where it should be carried out.
  - Explain what tools and equipment should be used.
  - Explain what supplies and materials should be used.
  - Explain what documents and records should be kept.

- Procedures may also refer to detailed work instructions that explain exactly how the work should be done.

1.5 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	Written test

Name: _____Date: _____

Directions: Answer all the questions listed below

Part I: write True if the statement is correct and False 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 product or service in a specific topic area
2. Quality of electro mechanical maintenance service is repairing of machines and equipments with appropriate quality supplies on time.
3. The QC activities are used to produce and document the quality of the end product

Part II: write definition of words listed below

1. Quality
2. Standard
3. Quality assurance
4. Quality control
5. Quality standard

Answer Sheet

Score = _____

Rating: _____

Name: _____Date: _____

I- true false

1. _____
2. _____
3. _____

II easey

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Introduction

Standardization is defined as an activity that gives rise to solutions for repetitive application to problems in various disciplines. Generally, the activity constitutes the process of establishing (determining, formulating, and issuing) and implementing standards. Thus, standards are the perfect result of a standardization activity and inside the context of quality systems consist of quality documents or documents related to the quality system. High levels of quality are important to accomplish Company business objectives. Quality, a source of competitive benefit, should stay a symbol of Company products and services. High quality is not an additional value; it is an important elementary necessity. Ultimately, everyone in an institution is responsible for the quality of its products and services.

Standard Operating Procedures

Standard Operating Procedures (SOP) is a process document that describes in detail the way that an operator should perform a given operation. SOPs involve the purpose of the operation, the equipment and materials required, how to perform the set-up and operations required for the process, how to perform the maintenance and shutdown operations carried out by the worker, a description of safety issues, trouble-shooting, a list of spare parts and where to find them, illustrations, and checklists. The SOP is one of many process documents which is needed for consistent operation of a given process, with other documents involving process flow charts, material specifications, and so forth. SOPs are Level 2 quality documents and, along with other related quality documents, guarantee the efficacy and effectiveness of quality systems. Standard operating procedures (SOPs) are a vital component in any quality management system. Every good quality system is based on its Standard Operating Procedures (SOPs). The advancement and use of SOPs are a necessary part of a successful quality system as it supplies individuals with the information to carry out a job adequately, and aids precision in the quality and integrity of a product or

end-result. A quality system is defined as the organizational structure, responsibilities, processes, procedures and resources for implementing quality management

Standard Operating Procedures are sets of instructions having the force of a directive, covering those features of operations which lend themselves to a definite or standardized procedure without loss of effectiveness. Standard operating procedures or SOPs are written step-by-step procedures that quality control (QC), quality assurance (QA), and production units use in order to assure the accuracy and precision of the quantitative experimental results and materials that they generate and provide in support of other units.

Organizational policy and procedure

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

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.

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.

Difference of policy and procedure

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

Policies	Procedures
General in nature	Identify specific and alternative actions
Identify company rules	Explain when to take actions
Explain why rules exist	Describe emergency procedures
Explain when the rule applies	Include warnings and cautions
Describe to whom (what position) it applies	Explain each and every steps
Explain how it is enforced	Give examples
Describe consequences	Show how to complete a specific form
Provide guidance for managerial thought and action	Prescribe how to carry out the action through step by step instruction
Flexible - allows for discretion	Less flexible - concise and exact sequence of activities

Table 1.1 Difference between policy and procedure .

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.

Self check 2	Written test

Directions: Answer all the questions listed below. Use the answer sheet

Essay: Explain briefly:

1 . What is standardization?(5pts.)
2 . What is standard operating procedure? (5pts.)
3 . What is an organizational procedure? (5pts.)
4 . What is organizational policy? (5pts.)
5 . What are the difference of policy and procedure? Write at list four of their difference.(5pts.)

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

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

Answer Sheet

Score = _____

Rating: _____

Essay:

1. _____

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2. _____

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3. _____

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4. _____

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5. _____

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Information sheet 3	Providing quality standard and procedures documents.

Introduction

Requirements for products or services quality can be specified by customers or by the organization in anticipation of customer requirements, or by regulation. The requirements for products and in some cases associated processes can be contained in, for example, technical specifications, product standards, process standards, contractual agreements and regulatory requirements."

Standard and specification

What is the difference between a standard and a specification? There is no single or simple answer to your question. The answer depends upon the context of the question.

ISO 9000:2005 defines specification as a document that states requirements. A specification can be related to activities (e.g. procedure document, process specification and test specification), or products (e.g. product specification, performance specification and drawing).

ISO 9000:2005 does not define "standard". The first part of the ISO 9000:2005 introduction reads:

"The ISO 9000 family of standards listed below has been developed to assist organizations, of all types and sizes, to implement and operate effective quality management systems.

- ISO 9000 describes fundamentals of quality management systems and specifies the terminology for quality management systems.
- ISO 9001 specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide products that fulfill customer and applicable regulatory requirements and aims to enhance customer satisfaction.

- ISO 9004 provides guidelines that consider both the effectiveness and efficiency of the quality management system. The aim of this standard is improvement of the performance of the organization and satisfaction of customers and other interested parties.

- ISO 19011 provides guidance on auditing quality and environmental management systems.

Together they form a coherent set of quality management system standards facilitating mutual understanding in national and international trade. In other words

ISO 9000 is a standard that describes fundamentals and specifies the terminology.

ISO 9001 is a standard that specifies requirements.

ISO 9004 is a standard that provides guidelines.

ISO 19011 is a standard that provides guidance.

ISO 9000:2005 also makes a distinction between quality management system requirements and requirements for products using the terms “specifications” and “standards.” It states:

“The ISO 9000 family distinguishes between requirements for quality management systems and requirements for products.

This implies that a standard is a formal document that establishes uniform criteria, methods, processes and practices — which may or may not be requirements.

Procedures

Six procedures are Control of Documents, Control of Records, Internal Audit, Corrective Action, Preventive Action, and Control of Non Conforming Products.

Six Mandatory Procedures as required by QMS ISO 9001

Every ISO standard has got its own specific requirement to proof conformity to the international standard. Mentioned below are the Six Mandatory Procedures as required by QMS ISO 9001

1) Control of Documents

2) Control of Records

3) Internal Audit

4) Corrective Action

5) Preventive Action

6) Control of Non Conforming Products

ISO 9001:2018 Documentation Requirements is a major part of the 2008 standard. ISO updated the standard in 2015 with ISO 9001:2015. If you are interested in learning about the current documentation requirements please read:
ISO 9001:2015 Documentation Requirements

Information sheet 4	Revise / update standard procedures
Self check 3	**Written test**

Direction:- write the correct answer for the following questions. Use the Answer sheet provided in the next page: Each question worth three points

1. What is the difference between a standard and a specification?
2. When quality standard documentation is revised?
3. What are the six procedure to control documents?
4. What is procedure?
5. What is quality standard document?

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

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

Answer Sheet

Score = _____

Rating: _____

Essay:

1. _____

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2. _____

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3. _____

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4. _____

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5. _____

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Introduction

Do you know what is worse than not having a policy and procedure manual? It is having an out-of-date policy and procedure manual. Yes, all the work you have out into this project could be at risk if you do not maintain the manual by making timely revisions.

Changes in employment laws and regulations, and in the size and scope of your company and staff, may make your current policies obsolete. As a rule of thumb, plan on reviewing your manual every year or two for any necessary changes. Important changes can be made sooner to your online document. You can let employees know about the change via email and/or company newsletter.

If you keep each policy section on a separate page, and organize your manual in a three-ring binder, these changes and updates do not have to be stressful, expensive, or time consuming.

After you have revised the online document, notify employees that they can read the updated policy online by providing them with a link to the updated section. Employees then can print out the revised page, or pages, and place them in their binder, if they have a print manual.

Be sure to note the date of the change and the reason for the change on your revised policy page.

4.1 Technical Updates

Technical updates are updates that occur between your scheduled review cycles for your manual. These updates provide clarification or communicate minor procedural changes (such as the changing of a department name).

Depending on how your organization is structured, you can usually make these technical changes without going through the formal review process.

However, when a manual requires multiple technical updates, a thorough formal review may be needed. Either way, be sure to flag these technical changes when it comes time for your formal manual review.

Do not waste time in making legal policy changes. Policies that are affected by changes to the law should be reviewed and made as soon as possible.

While some revisions come in the form of legal requirements, such new state or federal employee legislation, others may be spurred by problems that arise in your place of

business. For example, you may not have seen the need for a no-alcohol policy until a drinking incident occurred.

4.2 Some steps to help you make sure your policy and procedure manual is updated

1. Perform an annual review of the entire manual, noting any areas of concern.

2. Look for policies that may not apply to your organization any longer. Has your company grown to the point that certain rules can no longer be effectively managed?

3. Have your by-laws changed? If so, your policies and procedures may need to change, as well, so that the important documents are in alignment with each other.

4. Has the legal environment changed in a way that impacts your policies? For example, have you moved to a different community? Are you conducting international business now? Have your hired independent contractors? Take the time to review current and pending employment legislation.

5. Are your policies being effectively implemented and enforced?

6. Are they accomplishing their objectives?

7. Have you received any feedback from managers or employees on your policies? Are they requesting any changes?

Your answers to these questions and to others that are pertinent to your industry will help you make needed revisions. Keep a list of any issues that come up during the year, so that you can make a recommendation to your supervisory board about any needed changes.

4.3 Continuing to update the manual

Let's say you've just finished updating your policy and procedure manual. You wrote the updates, got them approved by management and by legal counsel.

You revised the PDF version and made printed copies of the changed pages available to all departments. You asked for, and got, written or electronic signatures to confirm employees read the new changes and understand that the new policy replaces previous versions.

You will have the revisions part of the hard copy given to all new employees. Whew! You can now breathe a sigh of relief, right?

Well, not exactly. Since this manual is a living document, you will be making these kinds of revisions on an ongoing basis.

4.4 steps for ongoing revisions:

1. Set a time for an annual or bi-annual review of your policy and procedure manual.

2. Keep abreast of any governmental changes that affect your current policies, or require you to make new ones.

3. Partner with your company management as to the need for any new policies. Talk with them about suggested wording, and them research similar policies at other companies.

4. Proofread any drafts for clarity, conciseness, and for grammatical and typing errors.

5. Ask your attorney to review any proposed revisions or additions.

6. Schedule a time to bring changes or revisions before your board of directors or your manual review committee.

7. Include the approval date on all changes and revisions.

8. Make approved changes online.

9. Notify employees via email, newsletter, memorandum, or posting of the new changes. Provide links to the revised PDF.

10. Require employees to sign a statement that they are aware of the changes.

11. Include the changes in any new hard copies of the manual.

Even in years when there are not any big changes in existing labor laws, you should still review your manual and make updates, as needed. When performing this review, here are a few areas to which you should pay close attention:

Self check 4	Written test

Directions: Answer all the questions listed below. Use the answer sheet

I-Essay: Explain briefly:

1. Write different methods that used in order to revise or update Standard Operation Procedures ?
2. How can revise policy or procedures?
3. What are the steps to update?
4. What are the steps that make you sure the procedure is updated?

Note: Satisfactory rating above-3 P and unsatisfactory below-3 points

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

Answer Sheet

Score = _____

Rating: _____

I- Essay:

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2._____
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4._____
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Instruction Sheet 2	Learning Guide 54: Assess quality of service delivered.

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

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

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

- Check quality against organization quality standards and specifications.
- Evaluated service delivered using the appropriate evaluation quality parameters and in accordance with organization standards.
- Identify causes of any faults and use corrective actions in accordance with organization policies and procedures..

Learning Instructions:

1. Read the specific objectives of this Learning Guide.
2. Follow the instructions described below
3. Read the information written in the “Information Sheets 1- 4”. Try to understand what are being discussed. Accomplish the “Self-checks 1, 2, 3 &4” in each information sheets on pages 25, 28, 31and 36.
4. After You accomplish all self check, ensure you have a formative assessment and get a satisfactory result; then proceed to the next LG.

Information sheet 1	Checking quality of services delivered.

Introduction

Service quality tends to focus on meeting customers' needs and requirements and how well the service delivered meets their expectations. In order to deliver and maintain service quality, an organization must first identify what it is that constitutes quality to those whom it serves classified service quality into two categories: technical quality, primarily focused on what consumers actually received from the service; and functional quality, focused on the process of service delivery.

1.1 Service quality

Service quality (SQ), is a comparison of perceived expectations (E) of a service with perceived performance (P), giving rise to the equation SQ=P-E.

Service quality is an achievement in customer service.

Components of service quality
O Assessing own work
O Evaluating Service rendered
o Identifying Quality deviations
o Taking corrective actions
o Documentation

Service Quality Dimensions

Two service quality dimensions the technical aspect that is "what" service is provided and functional aspect and "how" the service is provided. The customers perceive what he/she receives as the outcome of the process in which the resources are used that is the technical quality. But he also and more often importantly, perceives how the process itself functions that is the functions quality.

How can quality be achieved?

Several methods have evolved to achieve, sustain and improve quality. They are known as quality control, quality improvement and quality assurance - collectively known as

quality management. Quality management is not the preserve of one manager but of all managers. Quality is achieved through a chain of processes, each of which has to be under control and subject to continual improvement.

The chain starts with top management expressing a firm commitment to quality, then:

- Establishing customer needs and expectations
- Developing and maintaining a management system that will enable achievement of customer needs and expectations - reliably, repeatedly and economically
- Designing products and services with features which reflect customer needs
- Building products and services so as to reproduce faithfully the design
- Verifying before delivery that products and services possess the features required
- Preventing the supply of products and services which possess features which dissatisfy customers
- Discovering and eliminating undesirable features in products and services
- Finding less expensive solutions to customer needs
- Making operations more efficient and effective
- Discovering what will delight customers and providing it
- Most importantly, honoring commitments

A variety of standards, philosophies, methodologies, tools, techniques and measures have been developed to help organizations meet these goals:

- Philosophies - total quality management
- Methodologies - business process management, continual improvement
- Tools and techniques - process charts, failure mode and effects analysis, statistical process control, quality function deployment

1.2 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. Continuous Quality Improvement (CQI) is an equivalent for Total Quality Management (TQM) in the industry.

1.3 Principles

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 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 1	Written test

Directions: Answer all the questions listed below. Use the answer sheet

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.

Note: **Satisfactory rating – 2 points** **Unsatisfactory - below 2 points**

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

Score = _____

Rating: _____

Answer Sheet

Name: _____ **Date:** _____

TRUE OR FALSE ITEMS

1_____

2_____

3_____

4._____

5._____

Information sheet 2	Quality standards and specification

2.1 Quality standards

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

2.2 Quality 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.

Quality specifications are detailed requirements that define quality of a product, service or process. Quality includes tangible elements such as measurements and intangible elements such as operate and taste.

The following are illustrative examples of quality specification.

Manufacturing

An electric cable manufacturer perform automated quality control testing on all units before supplying based on specifications such as detailed measurement designed to ensure that the cable thickness and conductor cover properly aligned.

Infrastructure

A solar panel manufacturer guarantees the conversion efficiency of its modules over time based on specification of rate power output and percentage of that output that can be expected as the panels approach end of life.

Self check	True/false

Name: _____Date: _____

Directions: Answer all the questions listed below. Use the answer

1. What is quality standard?
2. What are the types of specification?
3. What are the procedures that help the organization to achieve objectives?
4. What is quality specification?

Score = _____

Rating: _____

Answer Sheet

Name: _____ **Date:** _____

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4._____

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Information sheet 3	Evaluate service delivered using quality parameters.

Introduction

you have to 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.

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.

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.

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: _____

I- Essay:

1._____

_____

2,_____

_____

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

Introduction

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.

4.1Approach 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

4.2 Evaluating causes for poor work activities

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

There are three basic types of poor performance

1. Unsatisfactory 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

4.3 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

4.4 Corrective action

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

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

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?
4. What is corrective action?
5. How can you evaluate service quality?

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. _____

_____

4. _____

_____

5. _____

_____

Instruction Sheet 3	Learning Guide 55: Record information

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

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

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

- Record basic information on the quality performance in accordance with organization procedures.
- Records of work quality are maintained according to the requirements of the organization.

Learning Instructions:

1. Read the specific objectives of this Learning Guide.
2. Follow the instructions described below
3. Read the information written in the “Information Sheets 1and 2”. Try to understand what are being discussed.
4. Accomplish the “Self-checks1 and 2” in each information sheets on pages
5. Ask from your teacher the key to correction (key answers) or you can request your teacher to correct your work. (You are to get the key answer only after you finished answering the Self-checks). ensure you have a formative assessment and get a satisfactory result; then proceed to the next LG.

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

1.1 Introduction to quality information record

Quality record means Documents containing recorded information, regardless of the medium or characteristic, which demonstrate the effectiveness of the quality management system and that provide evidence that products meet regulatory requirements and comply with specified product requirements. In Quality Assurance Department ensures that records are established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system. Records remain legible, readily identifiable and retrievable. This procedure defines the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records. The Design QC Engineer shall prepare and submit monitoring reports to the Department of all design issues and review comments resulting from the scheduled and additional checks and reviews, including “over-the-shoulder” reviews. Quality Record Documents shall be maintained and controlled by the Core Systems engineers in accordance with their Quality Records and Document Control Implementing Procedures and are subject to Quality Audit by the organization.

1.2 Quality Performance

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

How do you achieve quality performance, using TQM and other principles?

Using the Deming Cycle while keeping some of the basic TQM principles in mind can help you design, deliver, refine, and maintain an effective program or initiative

Plan:- Conduct consumer research and use it for planning the product. The "product" here is the actual program you intend to conduct, and the "consumer research" is an

examination of actual needs of the target population, the community, and others who will be affected.

Thus, the "Plan" part of the cycle might include the following:

- Conducting a needs assessment, involving everyone concerned
- Deciding what the desirable outcomes are, from the perspectives of the target population, the organization, and the larger community
- Determining ways to reach those outcomes that are feasible, consistent with the guiding principles of the organization, inclusive (respectful of all and beneficial to as many people and groups as possible), and consistent with the needs and culture of the target population
- Developing indicators to show when you have reached either outcomes themselves or significant points on the way to reaching those outcomes
- Inviting all stakeholders to participate in the development of the plan

Do:- Produce the product. The "production" part of the process is the actual design of the program, outreach effort, treatment strategy, etc. that will meet the need determined in the "Plan" part of the cycle. Much of the actual work here depends not only on TQM principles (teamwork, employee involvement, scientific approach, obsession with quality, and customer focus), but also on common sense and organizing principles.

The following are important elements of designing an effective program:

- Finding out what has already been tried in the community, and how well it worked
- Discovering whether there's any residual bad feeling attached to certain methods or approaches -- or people -- which may resurface if they're proposed again
- Using as examples other communities that have successfully mounted similar programs, while remaining aware that not everything that works in one place will work in another
- Consulting the research to see what has worked in this situation
- Involving all stakeholders in the development of the program or initiative, especially the people who will do the actual work

- Taking care of the logistics: a place to operate, equipment and supplies, the proper staff and/or volunteers on board, etc.

Check:- Check the product to make sure it was produced in accordance with the plan. Compare the details and overall shape of the program or initiative to the plan. Does it align with the needs assessment? Does it look like it will address the desired outcomes in desired ways? Is it inclusive? Was everyone involved in its development? Is it feasible? Is it ready to go?

Act:- Market the product. "Marketing the product" here means actually running the program or initiative that you've planned.

If it's going to work well, there are some non-TQM standards that need to be applied:

- Everyone involved should understand the process that led up to this program, as well as the philosophy, concept, and workings of it
- Everyone involved should be committed to making every effort to bring about success. A program or initiative should never fail because people don't follow through or do their jobs. (This doesn't mean that you shouldn't expect mistakes; it means, rather, that mistakes shouldn't happen just because people weren't trying, or because they simply didn't bother to do something they knew they had to do.)
- All the planning in the world is useless if everyone involved doesn't go into the experience expecting to do their best, and if there aren't good people implementing the functions of the organization

1.3 Performance Management

Performance management is a way of systematically managing people for innovation, goal focus, productivity and satisfaction. It is a goal congruent win- win strategy. Its main objective is to ensure success to all manages i.e., all task teams who believe in its process, its approach and implementation with sincerity and commitment. The mange's success is reflected in organizations' bottom line in terms of achieving its planned goals. Performance Management is a means of getting better results from the organizations,

teams and individuals by understanding and managing performance within the agreed framework of planned goals and competency requirements.' It is a process for establishing shared understanding about what is to be achieved and an approach to managing and developing people

1.4 Quality performance indicators

Performance Indicators define factors the institution needs to benchmark and monitor. Assessment techniques provide the mechanism for measuring and evaluating the defined factors to evaluate progress or impact. KPIs specify what is measured and assessment techniques detail how and when it will be measured. KPI is a measure used to define and evaluate how successful an organization is. Typically is expressed in terms of making progress towards its long-term organizational goals. KPI incorporates information on the sources, calculations and definitions for each measure and sets out the timetable for submission of monthly data.

Self-Check -1	Written Test

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

1. What mean by quality record?
2. What is quality performance?
3. What are the principles of performance achievement in TQM and others?
4. What is performance management?

Answer Sheet-1

Name: _____ Date: _____

Part:-Short answer

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

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

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

Information Sheet-2	Maintaining records of work quality

2.1 Introduction to record documentation

All quality management system documentation as described in the list of quality records. Computer/cloud storage: All data produced on any databases and associated software that is quality related. It is the responsibility of the Quality Assurance Manager to ensure that all aspects of this procedure are adhered to and the responsibility of their senior manager to ensure that adequate facilities exist for the safe keeping of Quality Records.

The Document Control procedure includes a list of approved documents and describes the arrangements for approval, issues and changes/modifications to documents. These documents become quality records following completion of the quality related information for which each document has been designed. These records are then maintained for reference purposes to demonstrate achievement of the required quality and also the effective operation of the quality system.

2.2 Maintaining Records

Records are also maintained for relevant information not included in the quality system, e.g. pertinent subcontractor quality records, hazard warnings, NHS directives, manufacturers handbooks and records of management review meetings etc. Each type of record is maintained in a suitable electronic folder or hard-backed file and stored in a recognized location, such as a secure server, or in the case of paper based records, in a cupboard or filing cabinet.

Records retained as the result of work related issues must be securely retained for a minimum agreed period that meet the legal need in the event of documentation having to be produced in court.

Purchasing documents are held separately, while all audit related documents are held in a specific audit file held by the manager. The remainder of the quality literature, records and documents are held by the quality assurance manager in a quality records file or in

marked locations, while master documents are also held in a secure electronic location, or in a hard back folder. All locations must be logged and accessible to authorized staff. This ensures that retrieval of records can be performed when required and that deterioration and damage is reduced to a minimum.

Quality related data held on an individual computer must be automatically backed up daily. (Administrative and non-quality related data is backed up by the administration assistant at least monthly).

Each type of record is identified and located according to arrangements agreed by the Manager. Certain types of record may be held by other department personnel who carry responsibility for their effective maintenance. Where appropriate records will be filed, collected, protected and indexed. They will be legible, accessible and correctly stored.

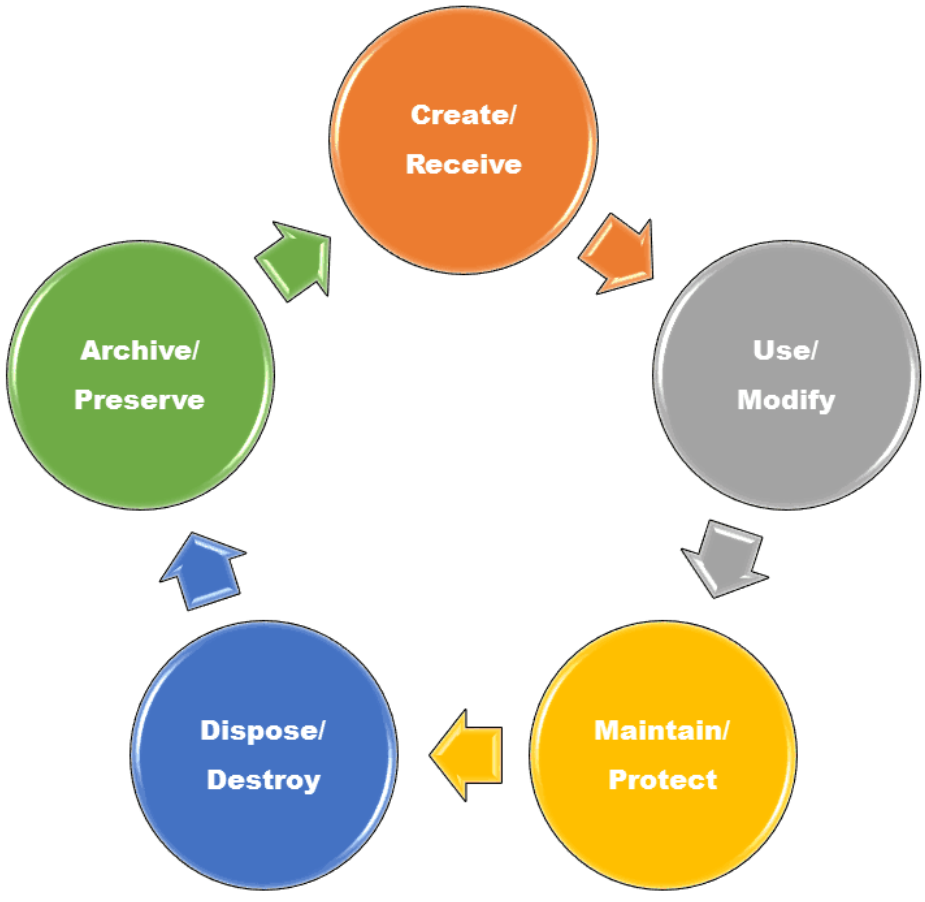


Figure 2.1 cycle of record

Reference to quality records may be made by department personnel. This facility will be

extended to customers or their representatives, when agreed in their contract, for a defined period. As a general rule, the quality records associated with this department are normally maintained for a minimum period of seven years. This period may be altered for individual records (e.g. Audits) by agreement with the manager.

The quality assurance manager is responsible for maintaining an index of all quality records, which provides information regarding each type of record, as follows:

- A unique reference number to facilitate identification
- The record title (or suitable description)
- The location of the record. (see above)
- The retention period which applies
- The person responsible for retaining the quality record

Self-Check -2	Written Test

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

1. How can maintain recorded documents?
2. What are the required documents in purchasing processes?
3. What are the information required for each type of records?
4. Draw the process cycle of maintaining recorded document?

Answer Sheet-1

Name: _____ Date: _____

Part:-Short answer

1. _____
_____
_____

2. _____
_____
_____

3. _____
_____
_____
_____
_____

4. _____
_____
_____

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

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

Instruction Sheet 4	Learning Guide 56 **Study causes of quality deviations.**

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

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

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

- Investigate and report Causes of deviations from final outputs or services in accordance with organization procedures.
- Suitable preventive action is recommended based on organization quality standards and identified causes of deviation from specified quality standards of final service or output.

Learning Instructions:

1. Read the specific objectives of this Learning Guide.
2. Follow the instructions described below
3. Read the information written in the “Information Sheets 1,2 and 3”. Try to understand what are being discussed.
4. Accomplish the “Self-checks1 and 2” in each information sheets on pages 4,11,14,19,23 and 26.
5. Ask from your teacher the key to correction (key answers) or you can request your teacher to correct your work. (You are to get the key answer only after you finished answering the Self-checks).
6. After You accomplish Operation sheets and LAP Tests, ensure you have a formative assessment and get a satisfactory result; then proceed to the next LG.

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

Introduction

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 Good Manufacturing Personnel and the sake of continuous improvement, these deviations are recorded in the form of Deviation Report (DR).

It is important to manage any deviations in expected standards in the development, manufacturing and distribution product and service. Deviations are measured differences between observed value and expected or normal value for a process or product condition, or a departure from a documented standard or procedure.

1.1 Deviations

A deviation may occur during sampling and testing, raw materials- and finished product acceptance and manufacturing. Deviations may also be triggered by customer complaints or comments when the customer company's standards do not meet critical attributes as delivered per plan or certificate. Any deviation from established procedures needs to be documented. Investigation of any deviation including documentation of conclusions and follow-up. The Quality Management System should ensure that deviations from established procedures are identified and recorded. Incidents that could affect the quality or the reliability of records or tests should be investigated and resolved.

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.

1.2 Deviation Management

Deviation Management is a part of Quality Management System providing efficient support for controlling deviation incidents, implementing corrective measures, helping avoid their recurrence, and for taking a proactive approach to continuous quality improvement. The system delivers deviation reports and remedial measures reports at any time, irrespective of where in the organization the deviation has occurred.

Deviation Management deals with different types of deviations such as standard deviations. The system provides pre-defined reports for initiating any possible deviation investigation. The entire deviation process is supported by the system, from initiation and investigation, to review, approval and closure in compliance.

1.3 Investigating of deviations

The deviation investigation should include the following: Event summary. Description of the deviation: Include who, where, what, when details in this section. Be specific, give exact and precise data.

A six-step, structured approach to incident investigation (Fig 1) helps to ensure that all the causes are uncovered and addressed by appropriate actions.

Step 1 – Immediate action. ...

Step 2 – Plan the investigation. ...

Step 3 – Data collection. ...

Step 4 – Data analysis. ...

Step 5 – Corrective actions. ...

Step 6 – Reporting

Ten Reasons the Deviation Investigation System Fails

R&D throws half-baked processes over the fence to operations, saying that they did their part to file a submission to the FDA ahead of the competition. Now it's time for Operations to take over in the spirit of continuous improvement.

2. The event occurs and is opened in the system, but there are delays in reporting time-sensitive information. It is not until the time gets close to release the product that open deviations surface and stand in the way. Unfortunately, no one has accurate information to assemble the facts for a meaningful investigation.

3. Products impacted by the deviation are not evaluated based on scientific data, and the perimeter is not drawn wide enough to include anything beyond the current batch—and certainly not to anything released into the market place.

4. The true root cause or most probable cause is not determined by a disciplined approach, and is not documented. The root cause reads more like a problem statement, or the symptoms of the problem. The bottom of the problem is not reached, and will surely stop short if the true cause touches on a politically sensitive subject.

5. Significant deviations cannot be distinguished from all the minor issues flooding into the system. When every single documentation error is entered into the system with its corresponding investigation and CAPA, it's no wonder that there is a backlog and meaningless activities working at cross-purposes.

6. Deviations are seen as singular events, rather than yet another example of a problem that is already identified as a deviation in the system. There is no “look back” to determine if the new event is already covered by a current effort, or the evidence of an ineffective CAPA.

7. Inappropriate ownership for deviations. The areas responsible for the deviation have no incentive to permanently resolve the problem, because they know that QA knows the “right way” to write it up to get the lot released.

8. Performance metrics are not presented to management for review in an action, decision-oriented forum where assignments are made, followed-up at subsequent reviews, and individuals by-name held accountable for results.

9. Because Track Wise (an excellent system) provides visibility to problems and serves as a tracking tool, junk gets into the system for those two reasons only (visibility/tracking) when in actuality they are neither a deviation, nor a CAPA. Events going into data management system must meet the definition of a deviation, and there cannot be a CAPA without first having a root cause.

10. There is a tolerance for repeated problems.

Knowing how and why a fault has occurred in mainly mechanical components in service as well as during their manufacturing phase is the first step in establishing the bases for an effective, Thanks to our experience and knowledge in lubrication, maintenance, mechanics or mechanical component design, among other things, *expertise* into specific solutions and with the maximum guarantee for detecting the causes of faults in industrial components in different sectors.

Report Deviations

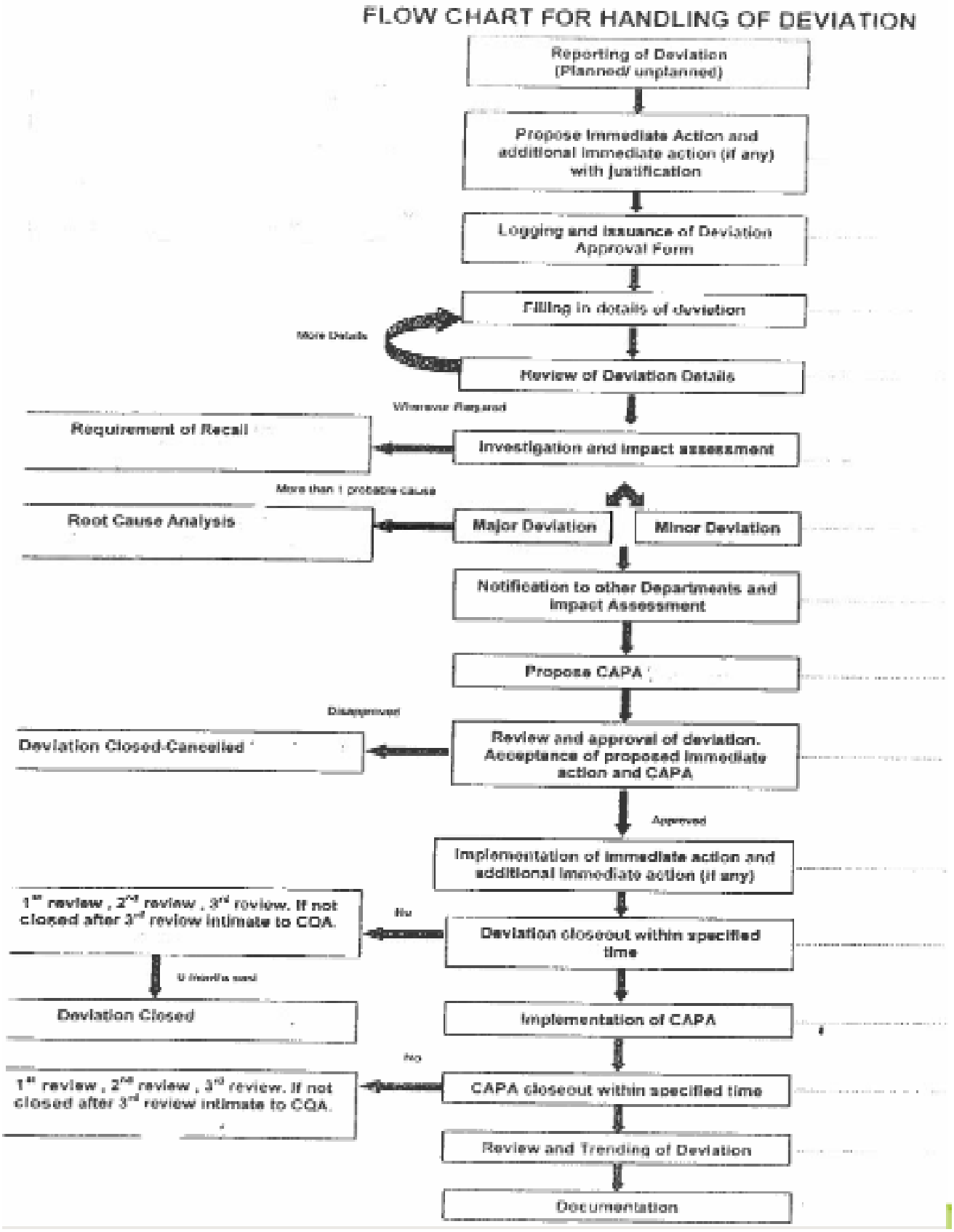
Deviation should be raised when there is a deviation from methods or controls specified in manufacturing documents, material control documents, standard operating procedure

for products and confirmed out of specification results and from the occurrence of an event and observation suggesting the existence of a real or potential quality related problems. A deviation should be reported if a trend is noticed that requires further investigation. All batch production deviations (planned or unintended) covering all manufacturing facilities, equipments, operations, distribution, procedures, systems and record keeping must be reported and investigated for corrective and preventative action. Reporting deviation is required regardless of final batch disposition. If a batch is rejected a deviation reporting is still required.

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 cannot 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.


FLOW CHART FOR HANDLING OF DEVIATION
Reporting of Deviation (Planned/ unplanned)
Propose Immediate Action and additional immediate action (if any) with justification
Logging and Issuance of Deviation Approval Form
Filling in details of deviation
More Details
Review of Deviation Details
Wherever Required
Requirement of Recall
Investigation and impact assessment
More than 1 probable cause
Root Cause Analysis
Major Deviation
Minor Deviation
Notification to other Departments and Impact Assessment
Propose CAPA
Disapproved
Deviation Closed-Cancelled
Review and approval of deviation. Acceptance of proposed immediate action and CAPA
Approved
Implementation of immediate action and additional immediate action (if any)
1st review , 2nd review , 3rd review. If not closed after 3rd review intimate to CQA.
No
Deviation closeout within specified time
Deviation Closed
Implementation of CAPA
No
1st review , 2nd review , 3rd review. If not closed after 3rd review intimate to CQA.
CAPA closeout within specified time
Review and Trending of Deviation
Documentation

Self check 1	Written test

Chose the best answer for the following questions

1. After receiving the Deviation information, the director should
   A. Identify the root cause of the deviation
   B. Identify the scope of the deviation
   C. Assess the impact of the deviation on the GLP study. D. All
2. Which one of the following is correct about the time in which deviation is reported?
   A. When there is a deviation from methods or controls specified in manufacturing documents
   B. when there is a deviation from standard operating procedure
   C. If a trend is noticed that requires further investigation D. All

Answer 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

Name: _____Date: _____

I- Enumeration:

1. _____
2. _____

II Easey

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

Information sheet 2	Recommending suitable preventive action

Introduction to Corrective Action Preventive Action (CAPA)

When illness strikes and we need medical attention, we put our trust in the medical products and care givers to provide relief. We expect the care we receive is without fault. Fortunately, failure is not experienced frequently in healthcare and medical devices. When failure does occur, we demand a rigorous process of investigation be initiated to identify why it occurred. Corrective Action Preventive Action (CAPA) is a process which investigates and solves problems, identifies causes, takes corrective action and prevents recurrence of the root causes. The ultimate purpose of CAPA is to assure the problem can never be experienced again. CAPA can be applied in many disciplines. A few of these disciplines are:

- Manufacturing
- Product Design
- Testing Verification and Validation
- Distribution, Shipping, Transport and Packaging
- Use-Applications

What is Corrective Action Preventive Action (CAPA)

The CAPA requirement applies to manufacturers of medical devices and compels them to include CAPA in their Quality Management System (QMS).

CAPA is split between two distinct but related functions.

1. Corrective Action (CA) is an extension of Root Cause Analysis (RCA). The first goal of CA is to find the root cause, base event or error that preceded the problem. The second goal is to take action directed at the root cause or error.
2. Preventive Action (PA) is similar to Lessons Learned / Read Across. PA resembles the replication activity of Design for Six Sigma (DFSS). Another example of PA in industry is Yokaten, a Japanese term used by Toyota, describing a sharing across the organization. The primary goal of PA is to inform

an organization and prevent the problem from returning in other facilities lines or products.

Why Implement Corrective Action Preventive Action (CAPA)

Identifying the root cause of failure is a key tenet of any effective QMS. When a problem occurs, it is often just a symptom of the real issue. Symptoms can be treated but finding out why the symptom is experienced is the true purpose for implementing CAPA. Failure to implement an effective Corrective Action Preventive Action process is a violation of FDA regulations defining Good Manufacturing Practice (GMP).

Once implemented, the CAPA system must exhibit ten objectives to meet the intent of the requirement. The 10 objectives of CAPA implementation are:

1. Verification of a CAPA system procedure(s) that addresses the requirements of the quality system regulation. It must be defined and documented.
2. Evidence that appropriate sources of product and quality problems have been identified.
3. Tracking of Trends (which are unfavorable) are identified.
4. Data sources for Corrective and Preventive Action are of appropriate quality and content.
5. Verify that appropriate Statistical Process Control (SPC) methods are used to detect recurring quality problems.
6. Verify the RCA work performed is aligned to the level of Risk the problem has been identified with.
7. Actions address the root cause and preventive opportunities.
8. CAPA process actions are effective and verified or validated prior to implementation.
9. Corrective and preventive actions for product and quality problems are implemented and documented.
10. Nonconforming product, quality problems and corrective / preventive actions have been properly shared and included in management review.

How to Implement Corrective Action Preventive Action (CAPA)

There are many ways to apply the two functions of CAPA. The Quality-One Corrective Action Preventive Action approach is as follows:

Corrective Action

When a symptom is observed or communicated, a systematic set of activities are initiated. The activities are intended to describe the problem in sufficient detail so that the team can identify a root cause path. Once a root cause path is selected, a permanent corrective action is identified, verified, implemented and validated. The Quality-One nine-steps for Corrective Action are detailed below:

1. Symptom is observed or communicated. The symptom must be quantified through the application of five questions, or 5Q, and confirmed as a true symptom, worthy of defining further.
2. Problem Statement is created by using the 5 Why approach, driving as deep into the problem as data will permit.
3. Affinity or Ishikawa (fishbone) diagram is used to identify possible causes of the Problem Statement.
4. Problem Description is written based on further investigation of the What, Where, When and How Big data collected.
5. Possible causes on the Affinity or Ishikawa (fishbone) diagram can then be reduced by using data from the Problem Description.
6. Theories are developed on remaining possible causes.
7. Root cause is verified by turning it on or off at will.
8. Permanent Corrective Actions are determined for root cause and inspection process (which also failed to stop the cause from escaping).
9. Implementation and Validation of the Corrective Action.

Preventive Action

Often the root cause of a root cause is the system or lack of policies, practices or procedures which supported the creation of the physical root cause. Preventive Action (PA) occurs after the physical root cause has been identified and permanent corrective action has been validated. PA recognizes the value of the information and actions taken during the CA function. This information is shared within the organization.

Quality-One suggests the following steps for Preventive Action:

1. Capture the Problem Statement as an Object-Defect for searchable databases.
2. Link root causes to the Problem Statement with the Permanent Corrective Action.
3. Identify other systems, facilities and processes which could benefit from the knowledge captured.
4. Assure Systems Documents are updated, including but not limited to:
    - Failure Mode and Effects Analysis (FMEA)
    - Control Plan Methodology
    - Work Instructions
5. Archive information for future retrieval including supporting information.
6. Publish and close-out team experience.

Self check 13	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

Introduction

Today the root causes of failures and quality deviations in manufacturing are usually identified using expert knowledge existing at each separate manufacturing site. The experience of the staff at the sites constitutes the basis for describing the causal correlations between different process steps and the output failures/quality deviations, and manual methods are then employed to identify the root causes for the failures.

Causes of poor quality

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

Simply **5 M and environment** in every manufacturing process

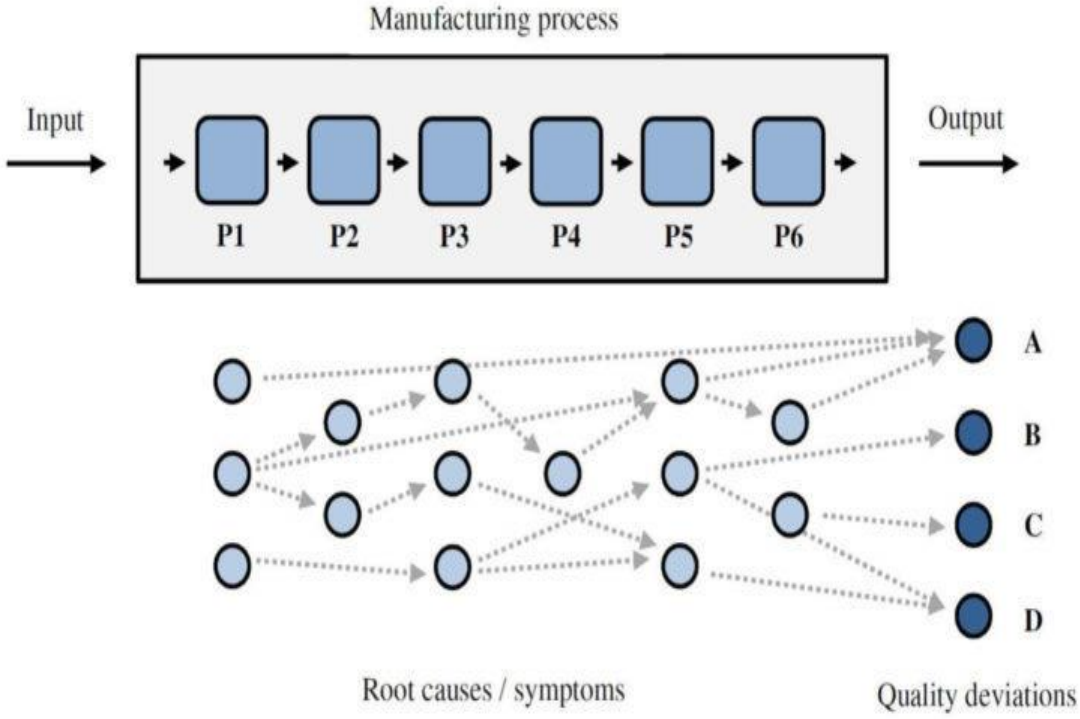


Figure 3.1 schematic illustration of a manufacturing line consisting of six process steps (P1-P6). Four quality deviations/failures (A-D) are illustrated with possible root causes and symptoms that have causal correlations with the quality deviations.

- 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	Written test

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. _____

Instruction Sheet	Learning Guide 57 Complete documentation.

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

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

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

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

Learning Instructions:

1. Read the specific objectives of this Learning Guide.
2. Follow the instructions described below
3. Read the information written in the “Information Sheets 1,2 and 3”. Try to understand what are being discussed.
4. Accomplish the “Self-checks1 and 2” in each information sheets on pages
5. Ask from your teacher the key to correction (key answers) or you can request your teacher to correct your work. (You are to get the key answer only after you finished answering the Self-checks) ensure you have a formative assessment and get a satisfactory result; then proceed to the next LG.

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

Introduction

Key Performance Indicators assist an organization to define and measure progress toward organizational goals and objectives. Once an organization has analyzed its mission and defined its goals, it needs to measure progress towards those goals. KPIs provide a measurement tool.

KPIs assist an organization to measure that it is 'on track' – most often, that it is working towards and attaining a beneficial outcome or improvement. In many cases, KPIs are used in projects and to measure service delivery.

There are as many KPIs as ways in which they can be constructed. For example, in an Electronic Document and Records Management (EDRM) project, KPIs could be used to measure client uptake as the system rolls out. Another example is to measure the timeliness and quality of service delivery – in this case, KPIs may be used to measure that records services meet agreed delivery times for correspondence in accordance with a Service Level Agreement (SLA).

1.1 Maintenance service performance indicator

The key area of technical supply management work at a company is the **maintenance service**. Maintenance service for business has an important meaning, mainly for preparing and maintaining the technical condition of the machine parks as well as for efficient supply management.

Keeping the technical infrastructure at adequate productivity and efficiency levels, requires the use of appropriate methods and management tools as well as an adequate organization of the **maintenance services**.

Choosing the right maintenance strategy will generate multi- level gains for the company: safe and effective development, modernized production processes,

elimination of waste and losses. The basic element of effectiveness assessment in the case of production processes and maintenance, are various indicators allowing to estimate the factual effectiveness, reliability and availability of the machine park. It is rather difficult to imagine the lean management philosophy without **key performance indicators**.
Find out what **KPIs** actually are, how to measure them, and why they are actually worth your time.

1.2 Key Performance Indicators Characteristics

Other KPI characteristics identified in the literature are listed below. A KPI does not need to satisfy all of these characteristics to be useful to the organization and characteristics may overlap. A KPI should be:

- relevant to and consistent with the specific organization's vision, strategy and objectives
- focused on organization wide strategic value rather than non-critical local business outcomes – selection of the wrong KPI can result in counterproductive behavior and sub optimized outcomes;
- representative – appropriate to the organization together with its operational performance;
- realistic – fits into the organization's constraints and cost effective;
- specific – clear and focused to avoid misinterpretation or ambiguity;
- attainable – requires targets to be set that are observable, achievable, reasonable and credible under expected conditions as well as independently validated;
- measurable – can be quantified/measured and may be either quantitative or qualitative;
- used to identify trends – changes are infrequent, may be compared to other data over a reasonably long time and trends can be identified;
- timely – achievable within the given timeframe;

- understood – individuals and groups know how their behaviors and activities contribute to overall organizational goals;
- agreed – all contributors agree and share responsibility within the organization;
- reported – regular reports are made available to all stakeholders and contributors;
- governed – accountability and responsibility is defined and understood; and
- resourced – the program is cost effective and adequately resourced throughout its lifetime.

1.3 effectiveness and key performance indicators

In order to be able to discuss **key performance indicators**, you first need to define what effectiveness actually is. Effectiveness is one of many defining indicators in the collection of objects and systems. It is usually defined as property of the object used or of the system of objects, which defines the level of goals reached in a certain time period.

Exploitation effectiveness is a ratio of the effects achieved in a time period, throughout the course of the object's exploitation, to the reserve that caused such effect.

The effectiveness of an operating element or a collection of operating elements is impacted by the pre operating indicators (required actions and initial disbursals, related to the system's features and environment), as well as the operating indicators identified in the operating process (external factors) and operating features (dependability, durability, repairability, etc.)

To assess the system effectiveness, there is a number of assessment criteria available. Nevertheless, the most common and most favorable one is the assessment system based on **key performance indicators**. These indicators can be used on many levels of maintenance and production processes, to measure quality of a production area, effectiveness of a production line, or of a single machine, or a device. Key performance indicators are defined based on the economic,

organizational and technical criteria. Moreover, the above mentioned norm enables choosing the right KPI. **Key performance indicators** are the basis for the company's success.

Choosing the right **KPI**, its implementation and analysis will in turn impact maintenance and the final success of administered improvements within production processes.

1.4 Fundamental parameters of quality service

Quality service is used to describe achievements in service levels. It reflects both objective and subjective aspects of services.

For quality services some fundamental parameters need to be focused on:-

- Understand and Improve operation processes
- Identify problems systematically
- Service Performance measures
- Measure the customer satisfaction
- Other performance criteria which affects quality

The accurate measurement of an objective aspect of customer service requires the use of carefully predefined criteria. The measurement of subjective aspects of customer service depends on the conformity of the expected benefit with the perceived result. This in turns depends upon the customer's imagination of the service they might receive and the service provider's talent to present the imagined service. Pre-defined objective criteria may be unattainable in practice, in which case, the best possible achievable result becomes the ideal. The objective ideal may still be poor, in subjective terms.

Service quality can be related to service potential (for example, worker's qualifications); service process (for example, the quickness of service) and service result (customer satisfaction).

The listed below are some of the important attributes for delivering quality service to the customer:

Competence: It is the possession of the required skills and knowledge to perform the service.

Courtesy refers to factors such as politeness, respect, consideration and friendliness of the contact personnel; consideration for the customer's property and a clean and neat appearance of contact personnel.

Credibility refers to factors such as trustworthiness, believability and honesty. It involves having the customer's best interest at heart. It may be influenced by company name, company reputation and the personal characteristics of the contact personnel.

Security represents the customer's freedom from danger, risk or doubt including physical safety, financial security and confidentiality.

Access refers to approachability and ease of contact. For example, the waiting time is not excessive and there are convenient hours of operation and a convenient location.

Communication means both informing customers in a language they are able to understand and also listening to customers. A company may need to adjust its language for the varying needs of its customers. Information might include for example, explanation of the service and

its cost, the relationship between services and Costs and assurances as to the way any problems are effectively managed.

Knowing the customer means making an effort to understand the customer's individual needs, providing individualized attention, recognizing the customer when they arrive and so on.

Tangibles are the physical evidence of the service, for instance, the appearance of the physical facilities, tools and equipment used to provide the service; the appearance of personnel and communication materials and the presence of other customers in the service facility.

Reliability is the ability to perform the promised service in a dependable and accurate manner. The service is performed correctly on the first occasion, the accounting is correct, records are up to date and schedules are kept.

Responsiveness refers to the willingness of employees to help customers and to provide a prompt timely service, for example, mailing a transaction slip immediately or setting up appointments quickly.

The above points give a valuable insight to the quality perspectives one can strive to achieve and provide a quality service to the customer.

Self check

Answer the following questions

1. what is performance indicater?
2. What are the parameters of service quality?
3. What is effectiveness of performance indicator?
4. How can measure the performance of quality service?

Answer sheet

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

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.

2.1.1. Human resources:

- The availability of physicians, nurses, pharmacists, laboratory

  technicians, supportive staff
- The provision of appropriate trainings for the health workforce

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

a. *Process* service

It is service related to the activities that are expected to be accomplished in order to achieve desired outcomes 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

2.3. Outcome service

It is services related to the desired effect of services on populations. It includes:

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

Outcomes are dependent on different factors of which is only one of them. Other factors determining outcome measures include behaviors of customer, socioeconomic status of customers and the performance of other actors.

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	Written test

1. Setting minimum requirements for different levels 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: _____

I- Enumeration:

1. _____
2. _____
   _____
   _____
   _____
3. _____
   _____
4. _____
   _____
5. _____
6. _____
   _____
7. _____

8. _____

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Outcome Measures, Balance Measures, and Process Measures

What exactly are evidence-based process measures? First it helps to understand the three types of measures we use in every service:

1. **Outcome measures:** These are the high-level tangeble or financial outcomes that concern in any organizations. They are the quality and cost targets you are targeting for improvement. These measures are often reported to government and commercial payers. Some examples of metrics for outcome measures include mortality rates and readmissions rates.
2. **Balance measures:** These are the metrics a maintenance system must track to ensure an improvement in one area isn't negatively impacting another area. For example, let's say length of stay (LOS) in labor and delivering goods is the outcome metric.
3. **Process measures:** These measures are the specific steps in a process that lead — either positively or negatively — to a particular outcome metric.