Solar PV System Installation and Maintenance

Level-III

Learning Guide -17

Unit of Competence: -	**Apply Quality Control**
Module Title: -	**Applying Quality control**
LG Code:	**EIS PIM3 M05 LO1 LG-17**
TTLM Code:	**EIS PIM3 TTLM 0920v1**

LO1: Implement quality standard

ADRA ETHIOPIA

Instruction Sheet	Learning Guide:-17

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

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

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

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

Learning Instructions:

1. Read the specific objectives of this Learning Guide.
2. Follow the instructions described below.
3. Read the information written in the information Sheets
4. Accomplish the Self-checks
5. Perform Operation Sheets
6. Do the “LAP test”

Information Sheet-1	Acquire and confirm agreed quality standard and procedures.

1.1 Introduction/definition of terms/concepts

Checklist - help organize data by category

Durability - enduring; resisting wear

Flowchart - describes process in as much detail as possible by graphically displaying the steps in proper sequence

Histogram - plots data in a frequency distribution table

Hostile - being an enemy; unfriendly

ISO - International Standardization Organization

OHS - Occupational Health and Safety procedures

Pareto diagram- puts data in a hierarchical order which allows the significant problems to be connected first.

PPE - personal protective equipment

Quality - essential character nature; degree or grade of excellence

Scatter diagram- shows how two variables are related and is this used to test for cause and effect relationships

Standards - as one serving the emblem of a nation; something as accepted as a basis for comparison

- **Characteristic of materials used in specific areas**

The student must relate material properties to product and process quality. These are the factors that must be taken into consideration when choosing the right material for their components and assemblies:

- ✓ **Selection of material**

Material selection is one of the most common tasks for design engineering. The ability to assess the material's impact on the performance of a product is crucial for reliable performance. Sometimes, buyers are also considering the label or name of the company which are producing great quality of materials and are known in the market. Examples are the name HP for printer and Intel for some computer hardware.

- ✓ **Testing of material**

The testing of material properties is widely understood to be the key to obtaining data for a project, performing failure analysis, or understanding material interactions. Material testing also provides information on the quality of incoming and outgoing products. Inspection test equipment and techniques are demonstrated for a wide range of materials and assemblies during the class. This provides the participants with both knowledge of the common failure modes.

- ✓ **Cost of material**

The cost of material is also considered when buying or selecting materials for a specific project. The amount may vary but never taken for granted the quality and the reliability of the material. Will you buy material which is less expensive but worst quality? Will you buy material which you cannot afford? People look for places which can meet their standards and right cost for materials to buy.

Characteristic of common materials for increased security is also a great factor in the design and planning process. Evaluation of longevity criteria and assessment of site environmental factors are vital to project planning. Specific knowledge about the project and general common sense must dictate design and material selection. Although many materials can offer enhanced protection, often the most cost-efficient and readily available material that provides reasonable life expectancy for the project must be considered.

Before planning and designing takes place, you should evaluate the material options and system requirements. The characteristic of the materials to be used for specific project must be:

- **of good quality .** This is the most important factor when choosing materials to buy. Products with good quality are long-lasting and safe to use because you know that it follows certain standards before being commercialized.
- **reliable** - It means that you can be sure that it will perform its function well, will operate safely and will give the best it could give.

1.2 suitable for the application/purposes

Choose the materials which are very necessary to make the project possible. Making a list of products/materials to buy is a good trait of a wise consumer. Products which are not to be used must be crossed out.

- **low cost**

It doesn't mean that you will choose for the less expensive one and exclude the quality. Low cost means you can afford to buy the materials without hurting your pocket and assure of better quality.

Self-Check -1	Written Test

I. Choose the correct answer.

1. which of the following factors should be considered when choosing the right material?

A. material selection B. Testing of material C. Cost of material D. all of the above

2. The characteristic of the materials to be used for specific project should be:

A. reliable B. low cost C. of good quality D. All of the above

3. Good Quality of product refers to : A. long lasting B. safe to use C. A&B

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

Answer Sheet

Score = _____

Rating: _____

Information Sheet-2	Introduce standard procedures

4.1 Quality standards

Standards are sets of rules that outline specification of dimensions, design of operation, materials and performance, or describe quality of materials, products or systems. These standards should cover the performance expectations of the product for particular applications. The intent of standards is to provide at least minimum quality, safety or performance specifications so as to ensure relatively uniform products and performance, and to remove ambiguity as to the suitability of certain commercial products for particular applications. Following standards may reduce the risk of error in working.

4.2 Specific quality standards for:

- **products**

The durability of the work depends on the quality of its component parts and the assembly skills of those who install it. If the best-quality products are used but are installed incorrectly, the system will be a failure. The application of suitable hardware and products must be supported by adequate levels of training of person who use them so that they can identify and use only appropriate products. In judging a product ,the person must consider factors such as the following:

- ✓ Is the product under consideration suitable for the application or purpose?
- ✓ Will it be harmful to the health of the community in its normal use?
- ✓ Is there a risk of this product being released into the environment (e.g. the water) in the first instance or after the working life of the product has expired?

4.3 Production Process

In production process, checking of quality assurance must be highly considered. Quality assurance covers all activities from design, development, production, installation, servicing and documentation. This introduced the rules: "fit for purpose" and "do it right the first time". It includes the regulation of the quality of raw materials, assemblies, products and

components; services related to production; and management, production, and inspection processes.

A. FAILURE TESTING

A valuable process to perform on a whole consumer product is failure testing, the operation of a product until it fails, often under stresses such as increasing vibration, temperature and humidity. This exposes many unanticipated weaknesses in a product, and the data is used to drive engineering and manufacturing process improvements.

B. STATISTICAL CONTROL

Many organizations use statistical process control to bring the organization to Six Sigma levels of quality, in other words, so that the likelihood of an unexpected failure is confined to six standard deviations on the normal distribution. Traditional statistical process controls in manufacturing operations usually proceed by randomly sampling and testing a fraction of the output. Variances of critical tolerances are continuously tracked, and manufacturing processes are corrected before bad parts can be produced.

C. COMPANY QUALITY

The company-wide quality approach places an emphasis on three aspects:

- ✓ Elements such as controls, job management, adequate processes, performance and integrity criteria and identification of records.
- ✓ Competence such as knowledge, skills, experience and qualifications
- ✓ Soft elements, such as personnel integrity, confidence, organizational culture, motivation, team spirit and quality relationships. The quality of the outputs is at risk if any of these three aspects are deficient in any way.

D. TOTAL QUALITY CONTROL

Total Quality Control is the most necessary inspection control of all in cases where, despite statistical quality control techniques or quality improvements implemented, sales decrease.

As the most important factor had been ignored, a few refinements had to be introduced:

- ✓ Marketing had to carry out their work properly and define the customer's specifications.
- ✓ Specifications had to be defined to conform to these requirements.
- ✓ Conformance to specifications i.e. drawings, standards and other relevant documents, were introduced during manufacturing, planning and control.
- ✓ Management had to confirm all operators are equal to the work imposed on them and holidays, celebrations and disputes did not affect any of the quality levels.
- ✓ Inspections and tests were carried out, and all components and materials, bought in or otherwise, conformed to the specifications, and the measuring equipment was accurate, this is the responsibility of the quality assurance/quality control (QA/QC) department.
- ✓ Any complaints received from the customers were satisfactorily dealt with in a timely manner.
- ✓ Feedback from the user/customer is used to review designs.
- ✓ Consistent data recording and assessment and documentation integrity.
- ✓ Product and/or process change management and notification .

To conclude, the above forms are the basis from which the philosophy of Quality Assurance has evolved, and the achievement of quality or the "fitness-for-purpose" is "Quality Awareness" throughout the company.

Self-Check -2	Written Test

I. Write **True** if the statement is correct and **False** if the otherwise is wrong

_____1.Standards are set of rules that describe quality of materials, product or system.

_____2 .Quality assurance does not cover all the activities from design, development, up to documentation.

_____ 3.Customer service is a series of activities designed to enhance the level of customer satisfaction.

_____ 4.Customer service is not important in the company's customer value proposition.

_____ 5 The durability of the work do not depend on the skills of those who install it.

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

Answer Sheet

Score = _____

Rating: _____

Name: _____ Date: _____

Information Sheet-3	Provide quality standard and procedures documents.

3.1 Provide quality standard and procedures documents.

Different meaning could be attached to the word quality under different circumstances. The word quality does not mean the quality of manufactured product only. It may refer to the quality of the process (i.e., men, material, and machines) and even that of management. Where the quality manufactured product referred as or defined as “Quality of product as the degree in which it fulfills the requirement of the customer. It is not absolute but it judged or realized by comparing it with some standards”. Quality begins with the design of a product in accordance with the customer specification further it involved the established measurement standards, the use of proper material, selection of suitable manufacturing process etc., quality is a relative term and it is generally used with reference to the end use of the product.

Table 1.1 Quality System Elements.

Quality System Requirements		Contents
1	Management responsibility	Define and document commitment, policy and objectives, responsibility and authority, verification resources and personnel. Appoint a management representative and conduct regular reviews of the system
2	Quality system	Establish and maintain a documented quality system ensuring that products conform to specified requirements
3	Contract Review	Ensure that customer's contractual requirements are evaluated and met
4	Product development	Plan, control and verify product development to ensure that specified requirements are met
5	Document control	System for control and identification of all

		documents regarding quality, e.g. procedures, instructions, and specifications
6	Purchasing	Ensure that purchased products conform to specified requirements
7	Product identification and traceability	System to identify and control traceability of product at all stages from raw materials through production to the final product as delivered to the customer
8	Process control	Ensure and plan the control of production which directly effects quality by documented work instructions, monitoring and control of processes
9	Inspection and testing	Inspect and test incoming products, intermediate and final product; establish product conformance to specified requirements and identify non-conforming pro- ducts; maintain inspection and test records
10	Inspection, measuring and test equipment	Selection and control of equipment to ensure reliability and accuracy in measuring data
11	Inspection and test status	For the whole process the products shall be identified and clearly marked concerning test status, including indication of conformance or non-conformance
12	Control of non-conforming products	Identification, documentation, evaluation, isolation (if possible) and disposition of non-conforming products
13	Corrective actions	Prevention of reoccurrence of failures (non-conformance)
14	Handling, storage packaging	Protection of the quality of the product during

	and delivery	handling, storage, packaging and delivery .
15	Quality records	Records, including those which demonstrate that the specified requirements have been met, shall be controlled and maintained
16	Internal Quality Audits	Regular, planned internal audits shall be carried out, documented and recorded to verify the effectiveness of the quality system
17	Training	Training requirements at all levels shall be identified and the training planned, conducted and recorded
18	Cleaning and Disinfection	Although not required by the ISO 9000 standards, these two points should be given special attention in all food companies
19	Personal hygiene	

Self-Check -3	Written Test

I. Write **True** if the statement is correct and **False** if the otherwise is wrong

------1. Corrective actions prevent reoccurrence of failures (non- conformance)

------2. Quality is a relative term and is generally used with reference to the end use of the product.

-----3. Quality records include those which demonstrate that the specified requirements have been met, shall be controlled and maintained

Note: Satisfactory rating-2 & above points Unsatisfactory - below 2 points

Answer Sheet

Score = _____

Rating: _____

Information Sheet-4	Revise / update standard procedures.

4.1. Standard procedures are revised /updated when:

- designing a new job or task
- changing a job or task
- introducing new equipment
- reviewing a procedure when problems have been identified, example from an accident or incident investigation

4.2. The revision procedure should identify:

- the teacher for the task or job and the students who will undertake the task
- the tasks that are to be undertaken that pose risks
- the equipment to be used in these tasks
- the control measures that have been formulated for these tasks
- any training or qualification needed to undertake the task
- the personal protective equipment to be worn.
- action to be undertaken to address safety issues that may arise while undertaking the task . In order to identify/avoid accident the students will also be capable of participating and contributing to OHS management issues

Self-Check -4	Written Test

I. Write True if the statement is correct and False if the otherwise is wrong

-----1. Work instruction may be verbal or written.

-----2. Standard procedures are revised /updated when designing a new job or task

-----3. The revision procedure should identify action to be undertaken to address safety issues that may arise while undertaking the task.

Note: Satisfactory rating-2 & above points Unsatisfactory - below 2 points

Answer Sheet

Score = _____

Rating: _____

Operation Sheet-1	Quality control procedures

Techniques for-maintaining quality

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

Step 2- Determine the extent of QC

Step 3- Collect real data in a given PV component

Step 4- Report the results to management personnel

Step 5-Decide and take corrective action if the PV component has any failure

Step7 - The plan must be put into action.

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

List of reference materials

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Solar PV System Installation and Maintenance

Level-III

Learning Guide -18

Unit of Competence: -	**Apply Quality Control**
Module Title: -	**Applying Quality control**
LG Code:	**EIS PIM3 M05 LO2 LG-18**
TTLM Code:	**EIS PIM3 TTLM 0920v1**

LO2. Assess quality of service delivered.

Instruction Sheet	Learning Guide:-18

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

- Checking quality of services delivered against organization quality standards and specifications
- Evaluating service delivered using quality parameters.
- Identifying causes of faults & 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 of services delivered against organization quality standards and specifications
- Evaluate service delivered using quality parameters.
- Identify causes of faults & taking corrective actions.

Learning Instructions:

1. Read the specific objectives of this Learning Guide.
2. Follow the instructions described below.
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Information Sheet-1	Check quality of services delivered against organization quality standards and specifications

1.1 Check quality of services delivered against organization quality standards and specifications

An organizational structure consists of activities such as task allocation, coordination and supervision, which are directed towards the achievement of organizational aims. It can also be considered as the viewing glass or perspective through which individuals see their organization and its environment. Organizations are a variant of clustered entities. An organization can be structured in many different ways, depending on their objectives. The structure of an organization will determine the modes in which it operates and performs. Organizational structure allows the expressed allocation of responsibilities for different functions and processes to different entities such as the branch, department, workgroup and individual.

1.2 Quality

In technical usage, **quality** can have two meanings:

- the characteristics of a product or service that bear on its ability to satisfy stated or implied needs.
- a product or service free of deficiencies.

The quality of a product or service refers to the perception of the degree to which the product or service meets the customer's expectations. Quality has no specific meaning unless related to a specific function and/or object. Quality is a perceptual, conditional and somewhat subjective attribute. The dimensions of quality refer to the attributes that quality achieves in Operations Management:

Quality <-> Dependability <-> Speed <-> Flexibility <-> Cost

- ✓ Quality supports dependability
- ✓ Dependability supports Speed
- ✓ Speed supports Flexibility
- ✓ Flexibility supports Cost.

In the manufacturing industry it is commonly stated that “Quality drives productivity.” Improved productivity is a source of greater revenues, employment opportunities and technological advances. The best way to think about quality is in process control. If the process is under control, inspection is not necessary. However, there is one characteristic of modern quality that is universal. In the past, when we tried to improve quality, typically defined as producing fewer defective parts, we did so at the expense of increased cost, increased task time, longer cycle time, etc.

- **Quality Management Terms:**
  - ✓ Quality Improvement
  - ✓ Quality Control and
  - ✓ Quality Assurance

- **Quality and Task-Completion Checking**

The need to check quality and task completion applies at all stages of the development process but is underlined especially during the prototype validation stages. The importance of documenting checks applies whatever the size of the team and whatever the complexity of the product.

- **Quality Improvement Processes**

Manufacturers can choose from a variety of tools to improve their quality processes. The trick is to know which tools to use for each situation and increasing the sophistication of the tools in the repertoire. Easy to implement and follow up, the most commonly used and well-known quality process is the plan/do/check/act (PDCA) cycle . Other processes are a takeoff of this method, much in the way that computers today are takeoffs of the original IBM system. The PDCA cycle promotes continuous improvement and should thus be visualized as a spiral instead of a closed circle. Another popular quality improvement process is the six-step PROFIT model in which the acronym stands for:

P = Problem definition.

R = Root cause identification and analysis.

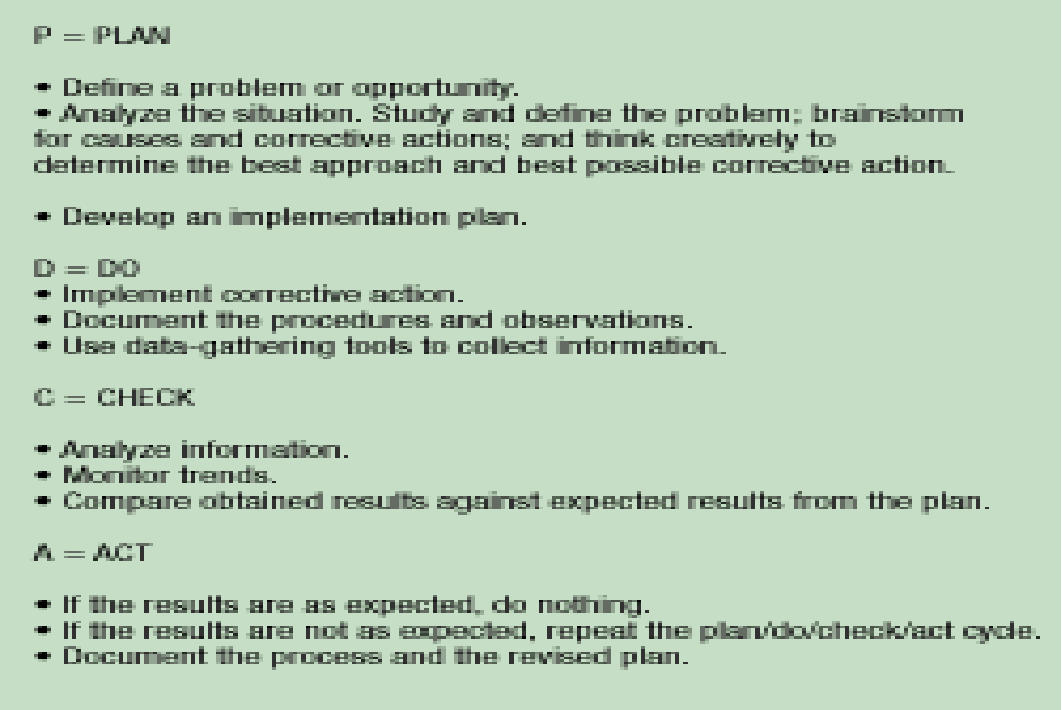
O = Optimal solution based on root cause(s).

F = Finalize how the corrective action will be implemented.

I = Implement the plan.

T = Track the effectiveness of the implementation and verify that the desired results are met

If the desired results are not met, the cycle is repeated. Both the PDCA and the PROFIT models can be used for problem solving as well as for continuous quality improvement. In companies that follow total quality principles, whichever model is chosen should be used consistently in every department or function in which quality improvement teams are working.



Once the basic problem-solving or quality improvement process is understood, the addition of quality tools can make the process proceed more quickly and systematically. Seven simple tools can be used by any professional to ease the quality improvement process: flowcharts, check sheets, Pareto diagrams, cause and effect diagrams, histograms, scatter diagrams, and control charts. (Some books describe a graph instead of a flowchart as one of the seven tools.)

The key to successful problem resolution is the ability to identify the problem, use the appropriate tools based on the nature of the problem, and communicate the solution quickly to others. Inexperienced personnel might do best by starting with the Pareto chart and the

cause and effect diagram before tackling the use of the other tools. Those two tools are used most widely by quality improvement teams.

FLOWCHARTS

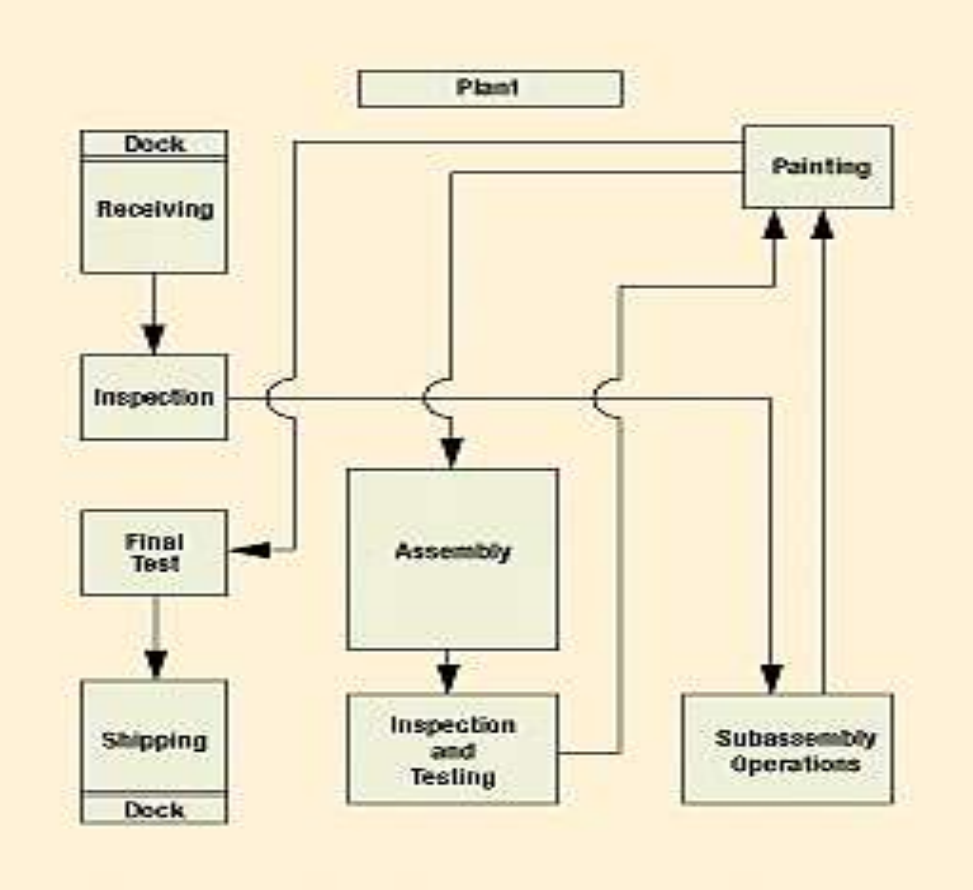


Figure1. A basic production process flowchart

Flowcharts describe a process in as much detail as possible by graphically displaying the steps in proper sequence. A good flowchart should show all process steps under analysis by the quality improvement team, identify critical process points for control, suggest areas for further improvement, and help explain and solve a problem.

Flowcharts can be simple or they can be made up of numerous boxes, symbols, and if/then directional steps. In more complex versions, flowcharts indicate the process steps in the appropriate sequence, the conditions in those steps, and the related constraints by using elements such as arrows, yes/no choices, or if/then statements.

a. CHECK SHEETS

Check sheets help organize data by category. They show how many times each particular value occurs, and their information is increasingly helpful as more data are collected. More than 50 observations should be available to be charted for this tool to be really useful. Check sheets minimize clerical work since the operator merely adds a mark to the tally on the prepared sheet rather than writing out . By showing the frequency of a particular defect (e.g., in a molded part) and how often it occurs in a specific location, check sheets help operators spot problems. The check sheet example shows a list of molded part defects on a production line covering a week's time. One can easily see where to set priorities based on results shown on this check sheet. Assuming the production flow is the same on each day, the part with the largest number of defects carries the highest priority for correction.

Product Number: XXXXXX

Line Name: ABC

Product Name: XYZ

Process Name: XYZ

Defective Item	2/5 (M)	2/6 (T)	2/7 (W)	2/8 (T)	2/9 (F)	TOTAL
Mold cracked	𝍸	///	𝍸 /	///	////	21
Fibers	//		𝍸	/		8
Grit	////	//	///	𝍸		14
Pinholes	/	𝍸		//	/	9
Cracks		/	/			2
Other	/	///			///	7
Total	13	14	15	11	8	61

Figure-2 a check sheet

- **PARETO DIAGRAMS**

The Pareto diagram is named after Vilfredo Pareto, a 19th-century Italian economist

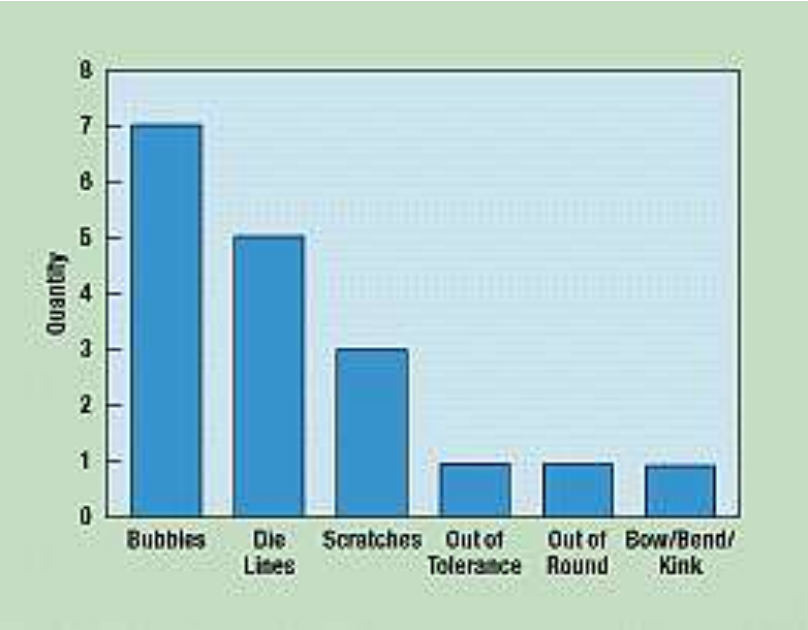


Figure 3.a Pareto diagram

A Pareto diagram puts data in a hierarchical order (Figure 3), which allows the most significant problems to be corrected first. The Pareto analysis technique is used primarily to identify and evaluate nonconformities, although it can summarize all types of data. It is perhaps the diagram most often used in management presentations.

To create a Pareto diagram, the operator collects random data, regroups the categories in order of frequency, and creates a bar graph based on the results.

b. CAUSE AND EFFECT DIAGRAMS

The cause and effect diagram is sometimes called an Ishikawa diagram after its inventor. It is also known as a fish bone diagram because of its shape. A cause and effect diagram describes a relationship between variables. The undesirable outcome is shown as effect, and related causes are shown leading to, the said effect. This popular tool has one severe limitation, however, in that users can overlook important, complex interactions between causes. Thus, if a problem is caused by a combination of factors, it is difficult to use this tool to depict and solve it.

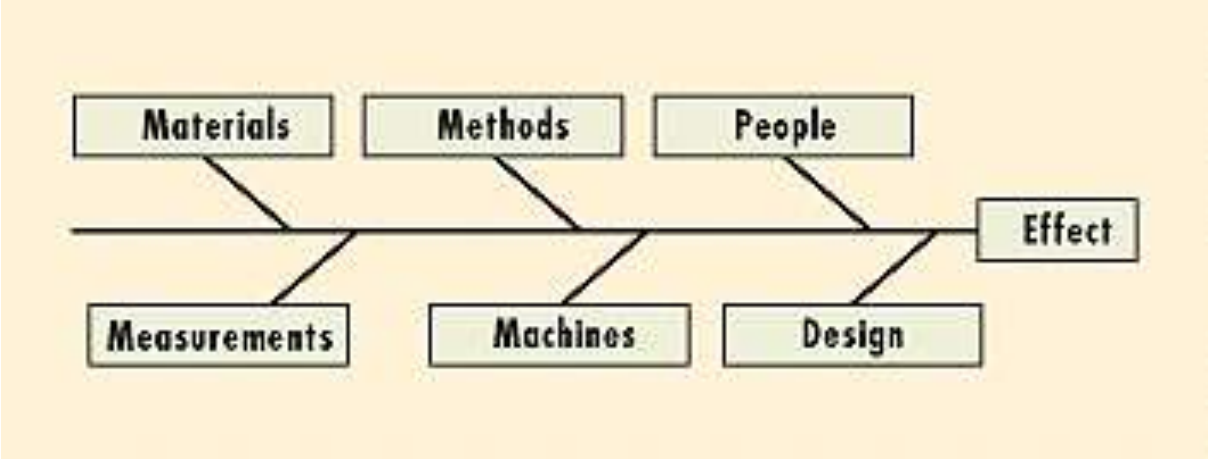


Figure 4. Fish bone diagrams

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

- **HISTOGRAMS**

The histogram plots data in a frequency distribution table. What distinguishes the histogram from a check sheet is that its data are grouped into rows so that the identity of individual values is lost. Commonly used to present quality improvement data, histograms work best with small amounts of data that vary considerably. When used in process capability studies, histograms can display specification limits to show what portion of the data does not meet the specifications. After the raw data are collected, they are grouped in value and frequency and plotted in a graphical form (Figure 6). A histogram's shape shows the nature of the distribution of the data, as well as central tendency (average) and variability. Specification limits can be used to display the capability of the process.

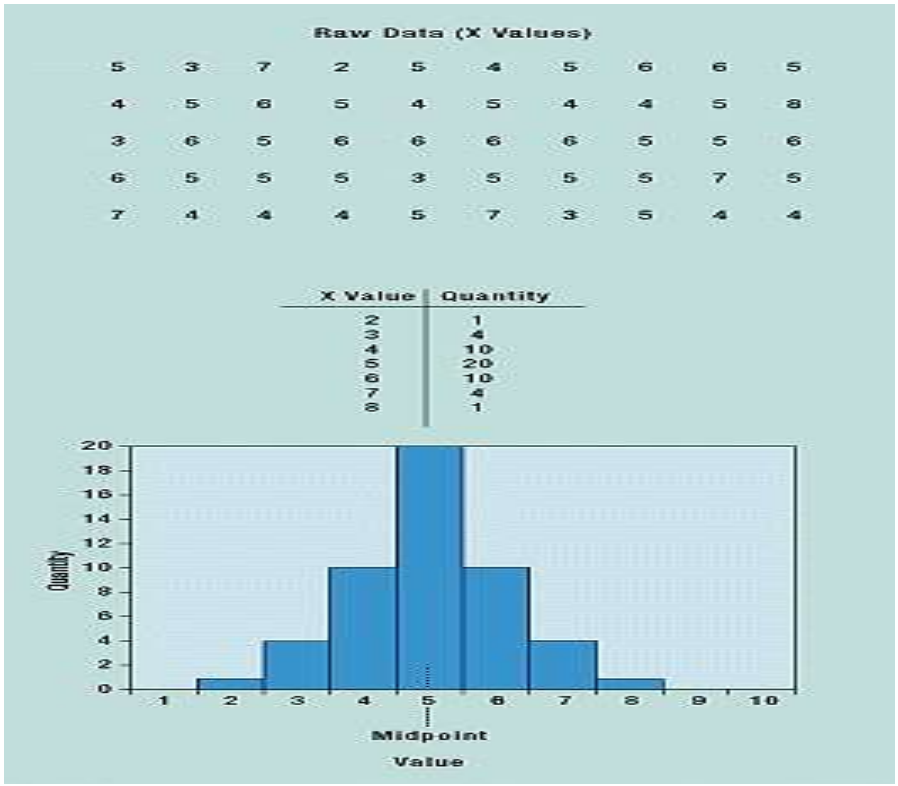
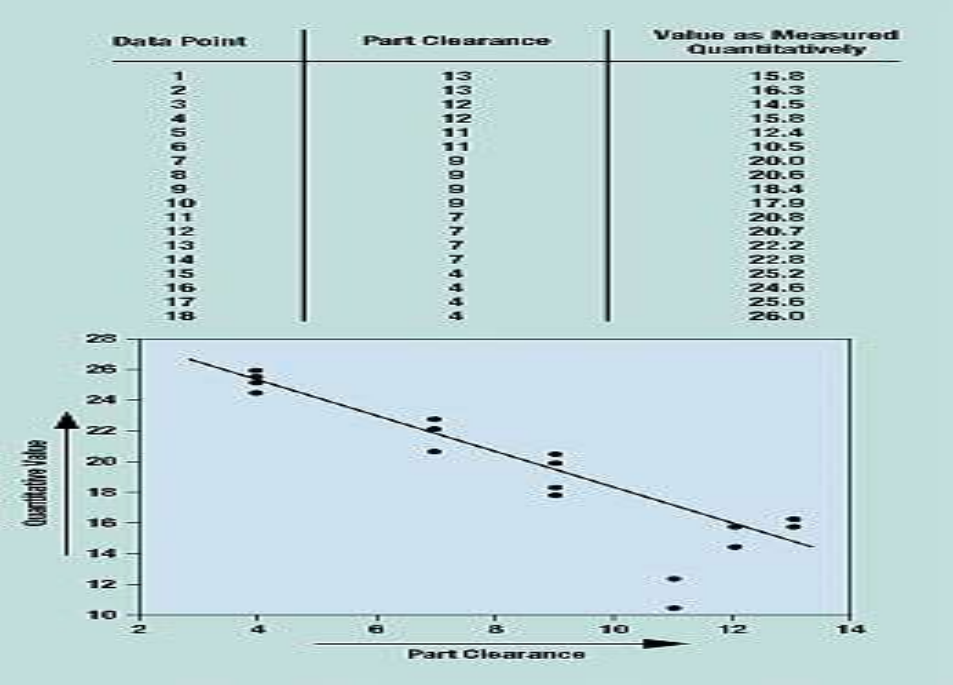


Figure 5. A histogram

- **SCATTER DIAGRAMS**

A scatter diagram shows how two variables are related and is thus used to test for cause and effect relationships. It cannot prove that one variable causes the change in the other, only that a relationship exists and how strong it is. In a scatter diagram, the horizontal (x) axis represents the measurement values of one variable, and the vertical (y) axis represents the measurements of the second variable. Figure 7 shows part clearance values on the x-axis and the corresponding quantitative measurement values on the y-axis.



Data Point	Part Clearance	Value as Measured Quantitatively
1	13	15.8
2	13	16.3
3	12	14.5
4	12	15.8
5	11	12.4
6	11	10.5
7	9	20.0
8	9	20.6
9	9	18.4
10	9	17.9
11	7	20.8
12	7	20.7
13	7	22.2
14	7	22.8
15	4	25.2
16	4	24.6
17	4	25.6
18	4	26.0

Figure 6. The plotted data points in a scatter diagram show the relationship between two variables.

- **CONTROL CHARTS**

A control chart displays statistically determined upper and lower limits drawn on either side of a process average. This chart shows if the collected data are within upper and lower limits previously determined through statistical calculations of raw data from earlier trials (Figure 8)

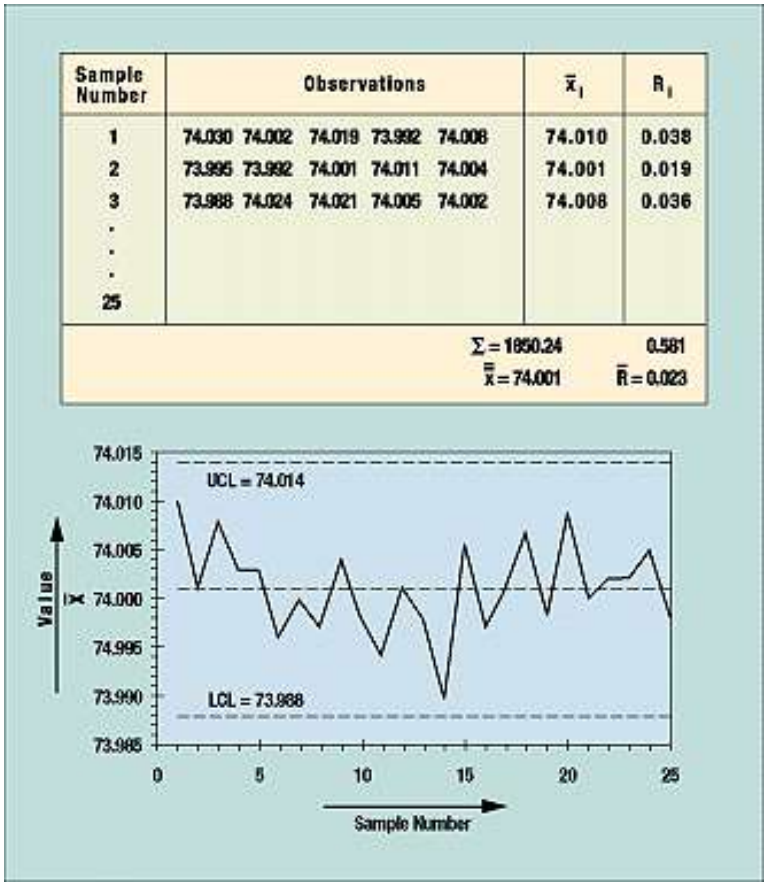


Figure 7. Control charts.

In preparing a control chart, the mean upper control limit (UCL) and lower control limit (LCL) of an approved process and its data are calculated. A blank control chart with mean UCL and LCL with no data points is created; data points are added as they are statistically calculated from the raw data.

Self-Check -1	Written Test

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I. Write **TRUE** if the statement is correct and **FALSE** if the otherwise is wrong.

----1. A scatter diagram shows how two variables are related and is thus used to test for cause and effect relationships

----2. The need to check quality and task completion applies at all stages of the development process

----3.Quality does not drive productivity

----4 A fish bone diagram displays all contributing factors and their relationships to the outcome to identify areas where data should be collected and analyzed.

----5. Quality Control is the ongoing effort to maintain the integrity of a process to maintain the reliability of achieving an outcome.

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

Answer Sheet

Score = _____

Rating: _____

Information Sheet-2	Evaluate service delivered using quality parameters.

2.1 TYPES AND WORK-RELATED ERRORS

A. Quantity of work (untimely completion, limited production)

- Poor prioritizing, timing, scheduling
- Lost time
  - ✓ Tardiness, absenteeism, leaving without permission
  - ✓ Excessive visiting, phone use, break time, use of the Internet
  - ✓ Misuse of sick leave
- Slow response to work requests, untimely completion of assignments
- Preventable accidents

B. Quality of work (failure to meet quality standards)

- Inaccuracies, errors
- Failure to meet expectations for product quality, cost or service
- Customer/client dissatisfaction
- Spoilage and/or waste of materials
- Inappropriate or poor work methods

2.2 Work Behavior Which Result in Performance Problems

A. Inappropriate behavior (often referred to as "poor attitude")

- Negativism, lack of cooperation, hostility
- Failure or refusal to follow instructions
- Unwillingness to take responsibility ("passing the buck")
- Insubordination
- Power games

B. Resistance to change

- Unwillingness, refusal or inability to update skills
- Resistance to policy, procedure, work method changes
- Lack of flexibility in response to problems

C. Inappropriate interpersonal relations

- Inappropriate communication style: over-aggressive, passive
- Impatient, inconsiderate, argumentative
- Destructive humour, sarcasm, horseplay, fighting
- Inappropriate conflict with others, customers, co-workers, supervisors

D. Inappropriate physical behavior

- Smoking, eating, drinking in inappropriate places
- Sleeping on the job
- Alcohol or drug use
- Problems with personal hygiene
- Threatening, hostile, or intimidating behaviour

The process through which the standards are established and met with standards is called control. This process consists of observing our activity performance, comparing the performance with some standard and then taking action if the observed performance is significantly too different from the standards. The control process involves a universal sequence of steps as follows:

- Choose the control object
- Choose a unit of measure
- Set the standard value
- Choose a sensing device which can measure
- Measure actual performance
- Interpret the difference between actual and standard
- Taking action.

E. Need for Controlling Quality

In the absence of quality, the following will result:

- No yardstick for comparing the quality of goods/services.
- Difficulty in maintaining consistency in quality.
- Dissatisfied customers due to increased maintenance and operating costs of products/services.
- Increased rework cost while manufacturing products/providing services.
- Reduced life time of the products/services.
- Reduced flexibility with respect to usage of standard spare parts.

  Hence, controlling quality is an essential activity.

2.3 Steps in Quality Control

Following are the steps in quality control process:

- Formulate quality policy.
- Set the standards or specifications on the basis of customer's preference, cost and profit.
- Select inspection plan and set up procedure for checking.
- Detect deviations from set standards of specifications.
- Take corrective actions or necessary changes to achieve standards
- Decide on salvage method i.e., to decide how the defective parts are disposed of, entire scrap or rework.
- Coordination of quality problems.
- Developing quality consciousness both within and outside the organization.
- Developing procedures for good vendor-vendee relations

Benefits of Quality Control

- Improving the quality of products and services.
- Increasing the productivity of manufacturing processes, commercial business, corporations.
- Reducing manufacturing and corporate costs.

- Determining and improving the marketability of products and services.
- Reducing consumer prices of products and services.
- Improving and/or assuring on time deliveries and availability.
- Assisting in the management of an enterprise.

Self-Check -2	Written Test

I. Write **QN** if the statement affects the quantity of work and **QL** if the statement affects the quality of work. Write your answer on the space provided before each number.

_____ 1.Poor scheduling of work

_____ 2.Failure to meet expectations for product quality, cost or service

_____ 3.Customer/client dissatisfaction

_____ 4.Preventable accidents

_____ 5.Misuse of sick leave

_____ 6.Tardiness

_____ 7.Slow response to work requests

_____ 8.Break time

_____ 9.Excessive visiting

_____ 10.Spoilage and/or waste of materials

II. Write **TRUE** if the statement is correct and **FALSE** if the otherwise is wrong.

_____ 1.Poor attitude results in performance problem.

_____ 2.A safe working procedure should be written when retrieving old tasks.

_____ 3.Preventable accidents may affect the quantity of work.

_____ 4.Following certain procedure is very important in performing given operation or to a given event.

_____ 5.Safe working procedure should not identify the tasks that are to be undertaken that pose risks.

Note: **Satisfactory rating – 8 &above points**
Unsatisfactory - below 8 points
Answer Sheet

Score = _____

Rating: _____

Information Sheet-3	Identify causes of faults & take corrective actions.

3.1 Fault identification & reporting

These are the things to be considered when:

A. Receiving Materials:

- Match the packing slip to the items received and ensures that the materials are destined on tour department.
- That you are receiving the materials indicated on the purchase order with regard to quantity and discount.
- That the materials are in acceptable condition.
- That terms regarding installation and/or set-up of equipment are met.

B. Receiving Reports

Whenever goods are received:

- The person receiving the goods must document, using the administrative software, that all goods were received for each requisition before any payment can be made to the vendor.
- Any exceptions must be noted so that partial payments can be processed or defective goods can be returned.

C. Return of Merchandise

When merchandise is received which is incomplete or defective, the supervisor will return the materials to the supplier or to the store where it was bought and make arrangements with the vendor for replacement.

D. Make an Inventory Report of the Materials

All materials received must be listed and be reported to monitor how many materials are already on hand, purchased or damaged. Effective management checks are an important means of providing assurance of the integrity and security of the benefit processes. They are also useful in identifying training needs; indicating possible weaknesses in procedure and

ensuring the section meets its accuracy target set for Best Value Performance Indicators purposes.

Methodology

The teacher will be the assessor. Students will be randomly assigned that will:

- act as Quality Checker;
- responsible for monitoring and coordinating the checking arrangements and;
- must generate reports when receiving the equipments

The Quality checker will record the date of receipt, name of the materials purchased, quantity, official receipt number, signature of the person who bought the materials and signed his name afterwards. The Quality checker will identify if the materials are in good condition or damage and /or needing for replacements. This will also be recorded on his report.

3.2 Feedback

Once the Quality checker has completed all the reports, the assessor will check if the Quality Checker provides all the data needed in the report.

Example of Log Report (to be completed by the Quality checker)

Date Received	Official receipt number	Item Name	Quantity	Signature	Quality Checker

Example of Assessment of Materials Received (to be completed by the Quality checker)

Quality Checker:	**Date**

Item Name	**Total no. in Good Condition**	**Total no. of Errors**	**Comments**

Self-Check -3	Written Test

I. Write **TRUE** if the statement is correct and **FALSE** if the otherwise is wrong

---1. All materials received must be listed and be reported to monitor how many materials are already on hand, purchased or damaged.

---2. Receiving Materials should be in acceptable condition.

---3. When merchandise is received which is incomplete or defective, the supervisor will return the materials to the supplier.

----4. Effective management checks are an important means of providing assurance of the integrity and security of the benefit processes.

---5. The Quality checker will identify if the materials are in good condition or damage and /or needing for replacements

Note: Satisfactory rating – 3&above points

Unsatisfactory - below 3 points

Answer Sheet

Score = _____

Rating: _____

Operation Sheet-2	Solving quality problems

Techniques for Solving quality problems and improving processes

Step 1- Identify problems and select opportunities for improvement

Step 2- Define the problem operationally

Step 3- Identify who needs to work on the problem

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

Step 5- Develop solutions and actions for quality improvement

Step 6-. Implement and evaluate quality improvement efforts

List of reference materials

1. Management Sciences for Health (2012). MDS-3: Managing Access to Medicines and Health Technologies. Arlington, VA: Management Sciences for Health.
2. John Snow Inc./DELIVER (2004). The Logistics Handbook: A Practical Guide for Supply Chain Managers in Family Planning and Health Programs. Arlington, Va.: John Snow Inc./DELIVER, for the U.S. Agency for International Development (USAID).
3. USAID | DELIVER PROJECT, Task Order 1 (2011). The Logistics Handbook: A Practical Guide for the Supply Chain Management of Health Commodities. Arlington, Va.: USAID | DELIVER PROJECT, Task Order 1. Second edition.
4. John Snow, Inc./DELIVER in collaboration with the World Health Organization. Guidelines for the Storage of Essential Medicines and Other Health Commodities. 2003. Arlington, Va.: John Snow, Inc./DELIVER, for the U.S. Agency for International Development.
5. FMHACA (2011). Medicines Waste Management and Disposal Directive. Addis Ababa, Ethiopia.
6. PFSA (2015). Standard Operating Procedures (SOP) Manual for The Integrated Pharmaceuticals Logistics System in Health Facilities of Ethiopia, First Edition. Addis Ababa, Ethiopia.
7. Ans Timmermans and Anu Sharma (2006). UNHCR drug management manual. Geneva.
8. Drug store management &rational drug use (2010). State institute of Health & Family Welfare, Rajasthan, India.

Solar PV System Installation and Maintenance

Level-III

Learning Guide -19

Unit of Competence: -	**Apply Quality Control**
Module Title: -	**Applying Quality control**
LG Code:	**EIS PIM3 M05 LO3 LG-19**
TTLM Code:	**EIS PIM3 TTLM 0920v1**

LO3. Record information.

Instruction Sheet	**Learning Guide:-19**

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

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

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

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

Learning Instructions:

1. Read the specific objectives of this Learning Guide.
2. Follow the instructions described below.
3. Read the information written in the information Sheets
4. Accomplish the Self-checks
5. Perform Operation Sheets
6. Do the “LAP test”

Information Sheet-1	Record basic information on the quality performance

2.1 Record basic information on the quality performance

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. Once Quality Records have been completed in accordance with applicable operating procedures, and served their purpose, they are retained in approved Quality Assurance locations and as specified in this document. There are two types of media used to record Quality Records. The media types are:

- Computer Software File records (on diskette or hard drive)
- Hand written or computer printed paper records

The types of Quality Records (documentation or software), storage location and respective retention periods are defined (Quality Records Retention). When other Quality System procedures specify a retention period, this procedure shall take precedence. When a Customer's order defines special Quality Documentation and retention period(s), the Customer's requirement shall take precedence.

2.2 Identification :

Each record type is identified with the following information:

- Record Type Name/Description
- Record Type Part Number (When applicable)
- Originator Name (Person who issued and/or recorded the data)
- Date (The date the data was recorded)
- Status of the Item: Pass/Accept or Fail/Reject (When applicable)
- When applicable, the following shall also be recorded (when applicable):
  - ✓ Serial Number/Lot Number/Date Code, and/or Quantity
  - ✓ Product Part Number
  - ✓ Revision of Record

2.3 Documentation Retention

1. Quality Records are retained per the minimum requirements specified in (Quality Records Retention) unless otherwise specified by the Customer order.
2. Quality Assurance is responsible for ensuring that Quality Records are stored in a manner that prevents damage or degradation of the records. In addition, the records shall be controlled in a manner that allows the records to be easily located and not lost due to lack of organization.

2.4 Legibility

3. Quality Records shall be written or printed in a manner that ensures that the data is accurate, complete, legible, and can be read and understood by all users.
4. Quality Records that are computer printed shall be printed using a printer that has enough ink (light print not acceptable) and does not ink smear the information.

2.5 Changing Records

5. When changes are required in order to make the Quality Record accurate, the change shall be performed by the person who initially recorded the original data. Quality Assurance and the employee's supervisor/management are also authorized to make necessary corrections and initial/date each change.
6. All changes shall be performed in a manner that does not make the old data un-readable. A single line shall be drawn through the old data, the new data shall be recorded next to it, and initialed/dated by the approved person who made the change. Old data shall not be thrown away, and shall be kept with the new data. Whiting out old text using liquid white-out is not acceptable. Receiving Inspection, Test or In-process/Final/Shipping Inspection results shall not be altered or modified in a manner that allows nonconforming material to be accepted by Quality Assurance as acceptable product.

2.6 Disposition of Records

7. Quality Records that have been damaged/missing/illegally altered/not legible/incomplete are brought to the attention of Quality Assurance for disposition in accordance with QAP-1005, Nonconforming Material System.

2.7 Records Disposal

8. Quality Records shall not be disposed of unless approved by Quality Assurance unless the minimum retention period(s) specified (Quality Records Retention is satisfied).
9. Quality Records may be disposed of after the minimum retention period is satisfied or as directed by Customer order. Quality Records are stored in manner so that the records will not be damaged (i.e. rain, fire, direct sun light, high humidity, etc.) or lost.

2.8 Protection

10. Quality Records filed or stored in a manner suitable for the work environment and where access is available to the functional department who is responsible and Quality Assurance/ as defined in this document.

2.9 Retrieval

11. Quality Records are stored in manner that makes retrieval not difficult. Typically, Quality Records are retained in clearly labeled files/cabinets for the first year and then maybe placed into other types of controlled storage using clearly identified boxes or other means that allows the records to be retrieval in a timely manner when needed.

Self-Check -1	Written Test

I. Write **TRUE** if the statement is correct and **FALSE** if the otherwise is wrong.

----1. Records remain legible, readily identifiable and retrievable.

----2. Whiting out old text using liquid white-out is acceptable.

---3. Quality Records shall not be disposed of unless approved by Quality Assurance unless the minimum retention period(s) specified.

----4. Quality Records shall be written or printed in a manner that ensures that the data is accurate, complete, legible, and can be read and understood by all users.

----5. Quality Records are stored in manner that makes retrieval not difficult

Note: Satisfactory rating – 3&above points

Unsatisfactory - below 3 points

Answer Sheet

Score = _____

Rating: _____

Information Sheet-2	Maintain records of work quality.

2.1 Maintaining records of work quality

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

2.2 Setting Objectives

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

2.3 Observing and Measuring Performance

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

2.4 Comparing Results

The third step of comparing measured performance against an established standard is comparing the results with the standards to discover variations. Some variation can be expected in all activities and the range of variation has to be established (Plunkett, et al.). Management usually lets operations continue as long

as they are within the defined control limits. Deviations that exceed this range alerts the manager to a problem and leads to the last step.

2.5 Corrective Action

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

2.6 This section is applicable to All Site Locations

Appendix A – Quality Records Retention

Item No.	Quality Record Type	Minimum Retention Period	Responsible Function and Retention Location
1	ISO 9001 Management Report(s) and Quality Objective Data	3 Years minimum	Quality Assurance
2	Internal Audits; Schedule and Audit Results	3 Years minimum	Quality Assurance
3	Receiving Inspection Records; Vendor Supplied Packing Slips, C of C's, Vendor Data, etc.	3 Years minimum	Purchasing
4	Inspection and Test Documentation; Final Inspection Records	3 Years minimum	Business Operations/Human Resources
5	Purchasing Records; Supplier	3 Years minimum	Purchasing

	Purchase Orders		
6	Customer orders, correspondence change documentation	3 Years minimum	Business Operations
7	Corrective Action(s); Internal, Supplier and Customer	3 Years minimum	Quality Assurance
8	Calibration Records (When Applicable)	3 Years minimum	Quality Assurance
9	Training Records	3 Years minimum	Training
9	Document Control Documentation/ERs/ECNs; ISO 9001 QMS (Manual, Procedures, Instructions, Forms)	3 Years and as defined by Customer Order	Quality Assurance
10	Finance Records	3 Years and as defined by our Company Management	Finance
11	Proposals	3 Years for Customer orders and As Required for Non-Customer orders	Bid/Proposals or Corporate Secretary/General Admin.
12	Business Operations – Outsourcing and Business Solutions and Training Support Documentation & Software	3 Years minimum	Business Operations/Quality Assurance
13	Human Resource Documentation and Performance Reviews	3 Years minimum	Human Resources

Self-Check -2	Written Test

I. Write **TRUE** if the statement is correct and **FALSE** if the otherwise is wrong.

---1. Records shall be controlled in a manner that allows the records to be easily located and not lost due to lack of organization.

----2. For Finance Records; Quality Record Type ,Minimum Retention Period is 3 Years and as defined by Company Management **.**

----3. Human Resource Documentation and Performance Reviews has a 3 Years minimum Retention Period.

Note: Satisfactory rating – 3&above points

Unsatisfactory - below 3 points

Answer Sheet

Score = _____

Rating: _____

Operation Sheet-3	Maintain accurate work records

Techniques for maintaining accurate work record:

Step 1- Establish performance standards

Step 2- Measure actual performance

Step 3- Compare measured performance against established standards

Step 4- Take corrective action

LAP Test 3	Practical Demonstration

Name: _____ Date: _____

Time started: _____ Time finished: _____

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

Task 1. Maintain accurate work records

List of reference materials

1. Management Sciences for Health (2012). MDS-3: Managing Access to Medicines and Health Technologies. Arlington, VA: Management Sciences for Health.
2. John Snow Inc./DELIVER (2004). The Logistics Handbook: A Practical Guide for Supply Chain Managers in Family Planning and Health Programs. Arlington, Va.: John Snow Inc./DELIVER, for the U.S. Agency for International Development (USAID).
3. USAID | DELIVER PROJECT, Task Order 1 (2011). The Logistics Handbook: A Practical Guide for the Supply Chain Management of Health Commodities. Arlington, Va.: USAID | DELIVER PROJECT, Task Order 1. Second edition.
4. John Snow, Inc./DELIVER in collaboration with the World Health Organization. Guidelines for the Storage of Essential Medicines and Other Health Commodities. 2003. Arlington, Va.: John Snow, Inc./DELIVER, for the U.S. Agency for International Development.
5. FMHACA (2011). Medicines Waste Management and Disposal Directive. Addis Ababa,Ethiopia.
6. PFSA (2015). Standard Operating Procedures (SOP) Manual for The Integrated Pharmaceuticals Logistics System in Health Facilities of Ethiopia, First Edition. Addis Ababa,Ethiopia.
7. Ans Timmermans and Anu Sharma (2006). UNHCR drug management manual. Geneva.
8. Drug store management &rational drug use (2010). State institute of Health & Family Welfare, Rajasthan, India.

Solar PV System Installation and Maintenance

Level-III

Learning Guide -20

Unit of Competence: -	**Apply Quality Control**
Module Title: -	**Applying Quality control**
LG Code:	**EIS PIM3 M05 LO4 LG-20**
TTLM Code:	**EIS PIM3 TTLM 0920v1**

LO4.Study causes of quality deviations.

Instruction Sheet	Learning Guide:-20

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

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

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

- Investigate and report causes of deviations from final outputs or services.
- Recommend suitable preventive action.
- Identify causes of deviation from specific quality standards

Learning Instructions:

1. Read the specific objectives of this Learning Guide.
2. Follow the instructions described below.
3. Read the information written in the information Sheets
4. Accomplish the Self-checks
5. Perform Operation Sheets
6. Do the “LAP test”

Information Sheet-1	Investigate and report causes of deviations from final outputs or services.

2.1 Investigate and report causes of deviations from final outputs or services

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

- **Definition: Deviation**
  - ✓ The action of departing from an established course or accepted standard.
  - ✓ An unplanned event that has been assessed as having a potential to impact material or product in terms of quality, customer safety& regulatory compliance.
  - ✓ Any occurrence that is not in conformance with established SOPs, master Batch records regulatory filings, test methods, specifications or other standards, that may affect the purity , efficacy or safety of products or components.

- **Deviation classification standard**

  The deviations are organized according to the following levels.
  - ✓ C-deviation –Critical deviation
  - ✓ L-deviation-Legal requirement deviations (treated as c-deviations)
  - ✓ M-deviation –major deviation
  - ✓ S-deviation-standard deviation
  - ✓ **Critical Deviation**

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

- ✓ **Standard Deviation**

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

2.2 When to Report Deviation:

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

Factor	Critical	Critical / Major	Major	Minor	Information
Consequence	Impact or potential impact for patient safety, including product efficacy. Non-compliance with label claim or regulations			Product safety or efficacy not directly affected.	
				Impact on product release. Potential regulatory compliance implications, adverse comments from inspectors, or major business cost	Impacts appearance of the product or be related to minor document irregularities
Detection	Detected by chance. Systematic failure - no system in place		Detected by routine check at a later stage	Detected at or close to point of error	
Implications	Implicated batches are already released	Implicated batches are still within your control & quarantined.			
	Investigation required to determine if further batches are affected		Resolution may be required before forward manufacture. No immediate implications for other batches		
Priority	High. Immediate action is required. Incident management procedures invoked to initiate assessment processes to determine the need for recall or notification.	High. Immediate action is required. Potential for further batches being implicated. A serious failure of process/ controls has occurred and requires immediate investigation.	Medium. Prompt action is advised. Deviation has been contained, an incident of this severity should be resolved as soon as possible.	Low. Potential for reoccurrence and subsequent cost implications	
Timeline to Address	Investigation and identification of root cause should be completed within 1 week.		The target to complete within 1 to 2 weeks	Target to complete within 1 month so lessons can be learned and implemented	

Error	Critical	Critical / Major	Major	Minor	Information
Packaging error. Misprinted labels on finished product	Rogue cartons with distributor. Not detected on line (no bar code reading system present). Noted by chance by distribution centre	Rogue cartons within final batch . Detected by chance by line operator (no bar code reading system present).	Rogue cartons detected by online bar code checking machine. Erroneous labels not detected at issuance	Incorrect batch number placed on labels. Error noted as part of QA document review process	Cosmetic marks noted on final carton during In Process Control checks.
Actions	Recall impacted batch. Launch investigation to determine other impacted batches Establish root cause and implement CAPA	Quarantine impacted batches. Launch investigation to determine other impacted batches Establish root cause and implement CAPA	Quarantine impacted batches. Establish root cause and implement CAPA	Establish root cause and implement CAPA	Establish root cause and implement CAPA

Self-Check -1	Written Test

I. Write **TRUE** if the statement is correct and **FALSE** if the otherwise is wrong.

-----1. Deviation is the action of departing from an established course or accepted standard.

----2. Deviation classification standard includes: C-deviation ,L-deviation, M-deviation & S-deviation.

---3. Deviation is any occurrence that is in conformance with established SOPs

Note: Satisfactory rating – 2&above points

Unsatisfactory - below 2 points

Answer Sheet

Score = _____

Rating: _____

Information Sheet-2	Recommending suitable preventive action

2.1 Recommending suitable preventive action.

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

2.2 Common Misconceptions

There are three common misconceptions about corrective and preventive action:

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

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

2.3 Corrective Action Process

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

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

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

Self-Check -2	Written Test

I. Write **TRUE** if the statement is correct and **FALSE** if the otherwise is wrong.

1. A corrective action deals with a nonconformity
2. .Locate and document the root cause of the nonconformity.
3. there are three common misconceptions about corrective and preventive action

Note: Satisfactory rating – 2&above points

Unsatisfactory - below 2 points

Answer Sheet

Score = _____

Rating: _____

Information Sheet-3	Identify causes of deviation &recommend suitable preventive action from specific quality standards

3.1 Identifying causes of deviation from specific quality standards

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

Simply **5 M and environment**

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

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

- **Machine**

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

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

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

- Low grade material
- Unspecified material
- Variation
- **Management**

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

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

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

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

- **Environment**

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

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

.

3.2 Deviation step-by –step guide:

The general steps that are to be followed once the deviation occurred has been discovered are the following.

3.2.1 Deviation feedback adjustment & report.

- Identify the deviation.
- Call the assembly area responsible for the mounting
- Write the information about the deviation
- Record the deviation in process
- The area responsible for the assembly controls the deviations & gathers information to be able to find a solution
- The areas responsible for the assembly corrects the deviation
- Reports back to the responsible assembler and the area of assembly.
- The area of assembly that is responsible for the assembly returns to their workplace to further work on solution before this the assembling area checks on line (with a C-or L-deviation)
- Inspection/short term solution is introduced without any delay

3.2.2 Problem solving

Information about deviation

Once a deviation has been discovered there is a range of information that needs to be registered & available for future use. The information that must be available is the following:

- Must have information
- The solution responsible
- Time when the deviation occurred
- Date for the follow-up of the deviation
- Status of the deviation
  - ✓ Open –present deviations that is being worked on

- ✓ Pending – deviations that are in a waiting status which could be for example waiting for implementation
- ✓ Closed-deviations that have been approved
- ✓ Null- deviations without a status

3.2.3 Recommended to have information

- The group handling the deviation
  - ✓ Improvement group
  - ✓ Local directorate
  - ✓ Q-team

3.2.4 How to manage deviations?

- Regulatory requirement to capture all sorts of deviations evolves in order to maintain the continuous improvement of processes and systems.
- All batch production deviations (planned or unintended) covering all manufacturing facilities, equipments, operations, distribution, procedures, systems and record keeping should be reported and investigated for corrective and preventative action (CAPA).
- Deviation should be documented when there is a deviation from methods or controls in manufacturing documents, material control documents, and/or standard operating procedures.

3.2.5 **Diamond-model->** preventive action

The diamond model is a visual tool used to analyze the deviations that are classed as C- or L-deviation

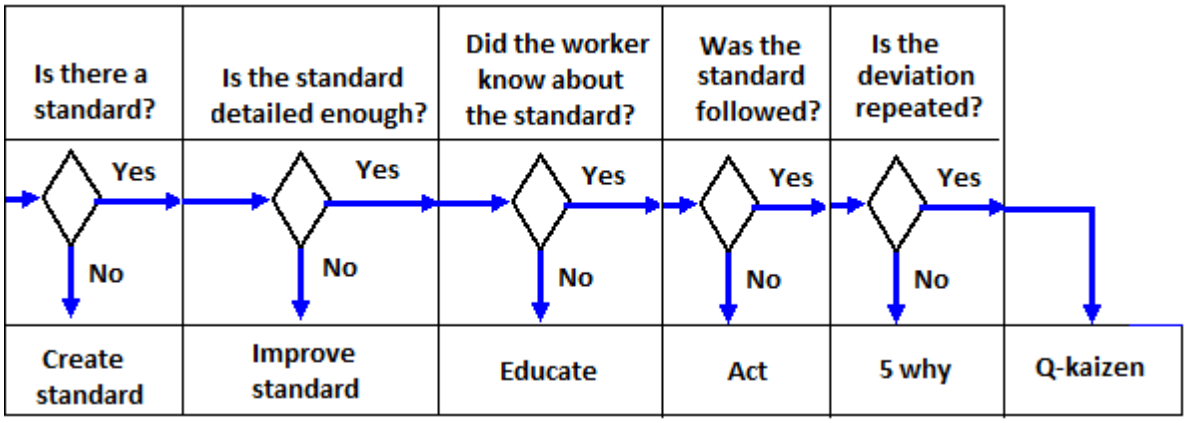

Figure 8. Diamond-model

The top row contains questions to be answered which are based on how well the assembly standard has been followed. The bottom row shows the different actions that ought to be taken when the top row questions are negative.

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

List of reference materials

1. Management Sciences for Health (2012). MDS-3: Managing Access to Medicines and Health Technologies. Arlington, VA: Management Sciences for Health.
2. John Snow Inc./DELIVER (2004). The Logistics Handbook: A Practical Guide for Supply Chain Managers in Family Planning and Health Programs. Arlington, Va.: John Snow Inc./DELIVER, for the U.S. Agency for International Development (USAID).
3. USAID | DELIVER PROJECT, Task Order 1 (2011). The Logistics Handbook: A Practical Guide for the Supply Chain Management of Health Commodities. Arlington, Va.: USAID | DELIVER PROJECT, Task Order 1. Second edition.
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Solar PV System Installation and Maintenance

Level-III

Learning Guide -21

Unit of Competence: -	**Apply Quality Control**
Module Title: -	**Applying Quality control**
LG Code:	**EIS PIM3 M05 LO5 LG-21**
TTLM Code:	**EIS PIM3 TTLM 0920v1**

LO5. Complete documentation.

Instruction Sheet	Learning Guide:-21

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
4. Accomplish the Self-checks
5. Perform Operation Sheets
6. Do the “LAP test”

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

2.1 Introduction

An indicator, in the context of quality management, is an aspect of patient care measured to determine an organization's performance with regard to a particular element of care. An indicator may measure a particular structure, process or outcome. Performance measurement systems are management systems that track selected performance measures at regular time intervals with aim to assess performance and enhance organizational decision-making, performance and accountability. Including the general management function, performance measurement system consists of three components:

- data collection and processing,
- analysis
- and action.

Responsibility of management function is to clarify and communicate the strategic framework and to orient performance measures toward that framework. Data collecting and processing are often the most time consuming and expensive part since data are usually input by decentralized organizational units in different locations which later must be gathered and stored in common databases. In analysis component indicators are converted into useful information in a way that they are compared with something (over time, against goals and targets, across units, with external entities etc). Finally, the results must be used to inform decision-making regarding strategy, program, service delivery, ongoing operations, resource acquisition and allocation and other purposes. Also, the performance data can be used to refine performance indicators and decide if and when comprehensive program evaluations should be undertaken.

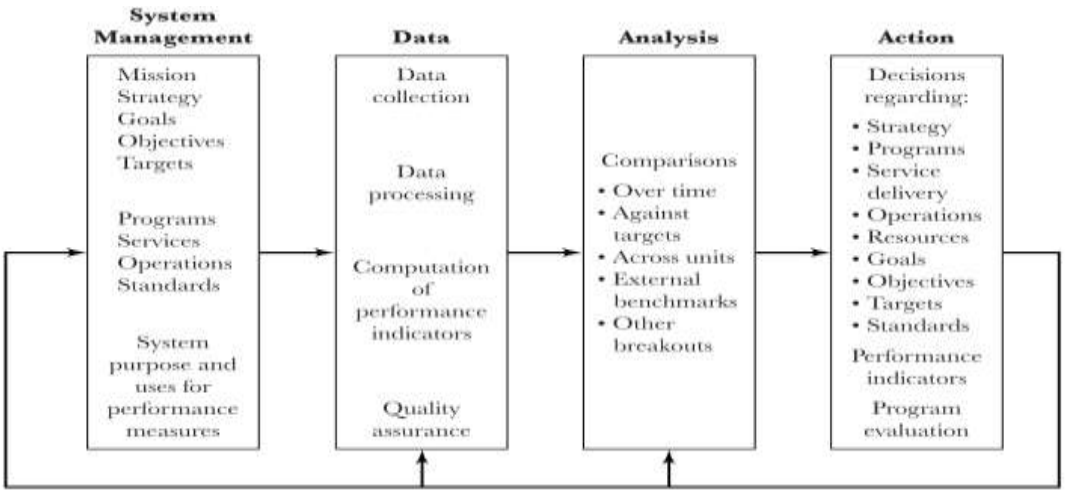

Figure 9 .Performance management system

2.2 Performance indicators

Group of authors define performance indicators (PIs) as measures which give information and statistics context, allow comparisons between fields, over time and with commonly accepted standards and provide information about the degree to which objectives are being met. PIs should be measurable and clearly defined in the same way over a number of years in order to perform comparisons .They are described by their function (what they measure), the means of obtaining it (formula and needed data), their quality (the extent to which they can be used over time) and the limits on their use (what they do not measure or measure poorly). It is relevant to ensure that PIs do not provide a partial and thus potentially misleading picture of quality or effectiveness .Prerequisite for PIs' usefulness is clear definition of purpose and objectives of service which is evaluated. Good indicators share two characteristics:

- first, they are well-founded in theory, having explanation for the assumption that they correctly represent a given feature of reality and
- second, they are robust against limitations in the underlying data .

After adding a few more important characteristics, quality indicators should be: cost-effective, timely, reliable, valid and specific. Also, the most illuminating or key performance indicators are those that carry the central motifs of the institutional story and reflect the critical success factors of an organization . The test of usefulness of performance indicators is that over time

they facilitate actual improvement in organization or program performance .In general, PIs can be categorized as quantitative and qualitative:

A. Quantitative indicators:

- input indicators – reflect the human, financial and physical resources involved in supporting institutional programs, activities and services;
- output indicators – reflect the quantity of products or services generated;
- impact indicators – reflect final and long-term impact of a project or program.

B. Qualitative indicators:

- outcome indicators – refer to the direct, short-term effects on beneficiaries; reflect the quality of program, activity or service;
- process indicators – include the means used to deliver programs, activities or services;
- impact indicators – describe less tangible progress toward the achievement of the strategic objective.

2.3 Advantages

- PIs reflect the strengths, weaknesses and effectiveness of institutions
- PIs help in institution's self-understanding, the establishment of its objectives and priorities and the evaluation of its work
- PIs help in managing programs and operations more effectively
- PIs can be used to communicate the results produced by the organization (helping in marketing activities) ; here PIs may reflect current favorable performance ;
- PIs support budget requests to funding organizations (to attract investment) and help in performance-based allocation of resources
- PIs provide information for (comparative) judgments and decision-making
- PIs help to shape critical questions for exploration of an issue
- PIs offer experts additional information and counterbalance peer review's shortcomings
- PIs reveal changes in an institution's identity over time (trend lines) ; here are important changes in the structure of income and expense (fund-raising performance);

2.4 Disadvantages and limitations

- the ability of PIs to reflect objective reality may be limited :
  - ✓ PIs are not useful when they are devoid of context
  - ✓ often information is produced merely because the data happen to be available
  - ✓ technical (establishing link between inputs and outputs) and political (stakeholders have different priorities and give different weights to each measure) problems of PIs usage ,
  - ✓ there is room for manipulation by selection, weighting and aggregating PIs
  - ✓ unnecessary burden for stakeholders during introduction of public service reforms ; data collection and processing may require too much time, money and effort; there are significant direct costs
  - ✓ PIs do not provide a clear indication of cause and effect or of the extent to which a program or agency might be responsible for producing the results observed
  - ✓ Inappropriate PIs can lead to goal displacement and behavior that detracts from rather than enhances performance.

2.5 Selection of performance indicators

In practice, it seems that the main criterion used for the selection of PIs is availability of the required data (the data can be collected with an acceptable level of effort). Using only available/feasible PIs allows targets to be set but will not always precisely describe the related objective. So there is a number of other criteria that can help in the selection of PIs

- relevance – the relative importance of PI according to stakeholders' perspectives;
- validity – the PI measures what it claims to measure;
- reliability – the PI is measured on the same way regardless of who collects the data or when;
- comparability – the PI allows comparison from one situation to another.

  Selecting indicators is a process that consists of three stages :
- the first stage is analytical and results in the identification of the challenges which ask for special attention and should be monitored;
  - the second stage is more pragmatical where PIs are identified and linked to the challenges from first stage;

- the third stage standardizes the presentation of selected PIs in a form of documentation (information) sheet.

2.6 Documentation sheet

Documentation sheets contain definitions, calculations, interpretations, availability info, quality and other metadata for PIs . Metadata are used to facilitate exchange, reporting and dissemination of data about PIs. For example, metadata are: PI name, PI definition, source of the data, data type, frequency of collecting and processing the data, users of the data (level of aggregation), levels of thresholds and target, possible actions if a threshold is reached, person responsible, time zone (past/current/future), method of measurement, unit of measure, unit multiplier etc.

Self-Check -1	Written Test

I. Write **TRUE** if the statement is correct and **FALSE** if the otherwise is wrong.

---1. PIs reveal changes in an institution's identity over time.

---2. PIs reflect the strengths, weaknesses and effectiveness of institutions.

---3. The PI allows comparison from one situation to another.

---4. Output indicators reflect the quantity of products or services generated

--5**.** PIs provide information for (comparative) judgments and decision-making

Note: Satisfactory rating – 2&above points

Unsatisfactory - below 2 points

Answer Sheet

Score = _____

Rating: _____

Information Sheet-2	Record all service processes and outcomes.

2.1 Record all service processes and outcomes

Reports should be published and should be written in a style which is clear and readily accessible to its intended readership. Any decisions, commendations or recommendations contained in reports should be easy for a reader to find.

2.2 What is a Record?

In order to define records management, the concept “record” needs to be fully explored. A record is defined either in terms of the physical tangible format in which it appears, or in terms of the information it contains. It must be noted that records differ in format or size and have different contents, any definition of records is a pragmatic one. The definition change with the passage of time and as the profession gets involved in more complex issues.

Cornwell Management Consultants (2001) define a record as a document produced or received by a person or organization in the course of business and retained by that person or organization. Langemo (1995) further defines a record as the memory of the organization, the raw material for decision- making and the basis for legal defensibility.

A record is viewed by Penn, Pennix & Couson (1994) as any information captured in reproducible form that is required for conducting business. Roberts (1998) states that records are information created, collected or received in the initiation, conduct or completion of an institution or personal activity. Based on the above definitions, the concept record can be defined as the end product of the business activity through which the performance of employees can be measured and thus enforce accountability. It is created or received by employees as evidence in the course of their normal operation in an organization. The purpose of this element is to define the records that are critical to the project, the information to be included in reports, the data reporting format, and the document control procedures to be used.

A good file plan is one of the essential components of a recordkeeping system, and it is key to a successful records management program. It can help you complete the following:

- Document your activities effectively
- Identify records consistently
- Retrieve records quickly
- Determine disposition of records no longer needed
- Meet statutory and regulatory requirements

Self-Check -2	Written Test

I. Write **TRUE** if the statement is correct and **FALSE** if the otherwise is wrong.

---1. Reports should be published and should be written in a style which is clear and readily accessible to its intended readership.

---2. A record is a document produced or received by a person or organization in the course of business and retained by that person or organization.

--3. A record is an end product of the business activity through which the performance of employees can be measured and thus enforce accountability.

Note: Satisfactory rating – 2&above points

Unsatisfactory - below 2 points

Answer Sheet

Score = _____

Rating: _____

List of reference materials

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