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Curriculum



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L #37

LO #1- Implement quality standards

Instruction sheet

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 outcomes 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”. Try to understand what are being discussed. Ask your trainer for assistance if you have hard time understanding them.
4. Accomplish the “Self-checks” which are placed following all information sheets.
5. Ask from your trainer the key to correction (key answers) or you can request your trainer to correct your work. (You are to get the key answer only after you finished answering the Self-checks).
6. If your performance is satisfactory proceed to the next learning guide,
7. If your performance is unsatisfactory, see your trainer for further instructions or go back to “information sheets”.



Information Sheet 1.1 Acquiring and confirming agreed quality standard and procedures

1.0. Introduction

Quality is a subjective term for which each person or sector has its own definition. 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. Quality means “fitness for use”; or “conformance to requirements.”

Quality standard procedure is set of documents intended to ensure that a manufactured product or performed service adheres to a defined set of quality criteria or meets the requirements of the client or customer. Quality standard procedure is a key component of a well-run business. A quality standard helps to ensure your small business is delivering a consistent product, service and customer experience.

Quality standard documents 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.

Acquiring and confirming agreed quality standard and procedures

ISO 9001 – Working Procedures

One of the most important principles of the ISO 9001 Standard applies simply: “say what you do, do what you say”

That actually means that you must define first what you are required to perform and then perform it! One can also explain it differently; you will define in which cage (procedures and procedures hence requirements) you want to spend your time and work; the working processes and working instructions hence requirements. The purpose of the working instructions or procedures is to explain, very simply, what is required to



do be done by employees in their everyday tasks. The instructions are highly important! Why? Who asked that? You are not serious! The explanation is very simple; When you define a working procedure you define a frame. This frame defines what has to be done and leave much less possibilities for questions, nonconformities and faults. Your employees need guidance. Naturally people would try to break the frame they are living and working in, in order to maintain more comfort for themselves or to promote interests that are no conformed to the organization's objectives. This comes on behalf of efficiency and effectiveness. And when efficiency and effectiveness are declining, you can be pretty much sure that, in the not so long term, profitability and quality would decline as well.

Procedures give you the ability to examine where your employee tries short cuts. Straying from the procedures will create nonconformities. Nonconformities harm your profitability, even if you cannot realize it in the short term. In this case when you define a procedure, it is highly important to define the appropriate control over it as well. This issue is enforced by the ISO 9001:2015 Standard almost fanatically. In fact the requirement 4.4 Quality management system and its processes demands the establishment and maintenance of a method for planning, defining and documenting processes in the QMS. One of the means to eliminate nonconformities and defects is a clear procedure. A procedure must include:

- What is the purpose of the process? The objective or goal of the process.
- Who is responsible for maintaining and performing the process? In order for you to know exactly who is responsible for what had been done.
- What is the method? You must specify the steps, phases, or actions required to perform the process. We recommend being generous with details, specify within the most specific level and to explain with the simplest language what is to be done.
- What are the tools one needs to perform the process? Forms, software, working tools, etc. – This is actually the documentation and control over the procedure. By examining this tools we can decide whether the procedure was maintained and how well.



- What are the process outputs? The outputs expected at the end of the process (a price quote documented, a certificate of calibration, records of any kind, any form, etc).

**Self-Check1.1.****Written Test**

Directions: Answer all the questions listed below.

I. Direction: true or false. write “true” if the statement is correct or “False” if the statement is incorrect on the space provided.(each 2pts)

1. One of the most important principles of the ISO 9001 Standard applies simply: “say what you do, do what you say”.
2. Quality management procedure demand only the objective of the process
3. “the characteristics of a product or service that bear on its ability to satisfy stated or implied needs” is a technical definition.
4. One of the means to eliminate nonconformities and defects in quality is a clear procedure.
5. The purpose of the working instructions or procedures of quality is to explain and make an emphasis only the duties of the worker.

Note: Satisfactory rating – 5 out of 10points

Unsatisfactory - below 5 and 10points



Information Sheet 1

Introducing standard procedures.

Introducing quality Standard Procedures

Quality Standard Procedures require that they be introduced and reviewed on a regular basis followed by approval and distribution to those who need them. It establishes a framework for how a business manages its key processes. They can help whether a business offers products or services and regardless of their size or industry. They can also help new businesses start off on the right foot by ensuring processes meet recognized standards, clarifying business objectives and avoiding expensive mistakes. To comply with the standards business organizations first need to implement quality standard procedures. Introducing and revising standard procedures can help business organization to:

- achieve greater consistency in the activities involved in providing products or services
- reduce expensive mistakes
- increase efficiency by improving use of time and resources
- improve customer satisfaction
- market your business more effectively
- exploit new market sectors and territories
- manage growth more effectively by making it easier to integrate new employees
- constantly improve your products, processes and systems

Introducing quality Standard Procedures helps for:

- Management responsibility - ensuring top level management shows commitment to the quality system and develops it according to customers' needs and the business' objectives
- Resource management- ensuring the people, infrastructure and work environment needed to implement and improve quality systems are in place
- Product realization- delivering what customers want, looking at areas such as sales processes, design and development, purchasing, production or service activities



- Measurement, review and improvement- checking whether you have satisfied customers by carrying out other measurements of your system's effectiveness.

The review and approval process is generally performed by quality management, and approval is indicated by signatures with appropriate dates. Policies for the approval, distribution, and revision of documents should be clearly established as a part of the documents and records policy.

Steps to Develop Quality standard procedures:

I. Set your quality standards

In some industries, you may have to meet quality standards set by an outside body, such as an industry association, the local health and safety inspector, or a government regulatory agency. In others, there aren't any official quality standards, so you'll need to set your own.

Each department of your business will have different quality control standards. However, they must all be objectively measurable. For example, if you're developing quality control standards for your customer service team, "sounding friendly on the phone" is not a measurable standard. Measurable standards might include:

- Answering all customer calls by the second ring
- Responding to all customer service emails within four hours
- Resolving customer service problems in five minutes or less

ii. Decide which quality standards to focus on

Of course, you want to ensure quality in all aspects of your operation. However, begin by focusing on the most important measures — those that have the biggest effect on your profits and your customer experience. This will enable you to get results quickly and also keeps you and your team from becoming overwhelmed.

For instance, if you own a restaurant, keeping the restrooms clean is definitely something to monitor in your quality control program—but not the most important thing. Getting orders out to customers quickly and accurately is a more important standard because it has a more direct effect on the quality of experience and customer satisfaction.

iii. Create operational processes to deliver quality



W. Edwards Deming, the founder of modern quality control, believed that well-designed processes lead to high-quality products and services. If you create good processes, continually measure the results of the processes, and work to consistently improve the process, your product or service will get better and better.

Starting with your critical operations, create step-by-step processes that include benchmarks. For instance, in a B2B company's accounting department, operational processes might require preparing and delivering invoices within 24 hours after a job is completed or a product is delivered. In a restaurant, operational processes might require servers to pick up food for delivery to the customer's table within two minutes of it being prepared.

iv. Review your result

Most business software, from financial and accounting apps to customer relationship management or customer service tools, lets you customize the information you collect and use dashboards to view it at a glance. Review your data regularly to see how well your company is meeting its quality standards.

v. Get feedback

Use measurable feedback from external sources, such as customer surveys, online ratings and reviews and net promoter scores (NPS), to get a fuller picture of product and service quality. Also, get regular feedback from employees. How well are the operational processes working to deliver quality? How could they be improved?

vi. Make improvements

Once you're meeting your quality control standards, don't stop there. For example, if you own a residential cleaning service business and you can cut the time it takes your maids to clean a home by 25 percent; you'll be able to handle 25 percent more business without hiring any additional employees. That will really boost your bottom line.

No matter how well your processes are running, quality control shows there's always room for improvement, and making small changes can pay off in big ways.



Self-Check 2	Written Test
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Name: _____

Date: _____

Instruction: Answer all the questions listed below, if you have some clarifications- feel free to ask your teacher.

I. Direction: true or false. write “True” if the statement is correct or “False” if the statement is incorrect on the space provided.(each 2pts)

- 1. Introducing standard procedures can help business organization to reduce mistakes.
- 2. Revision of documents cannot be a part of the documents and records policy.
- 3. Well-designed procedures lead to low-quality products and services.

II. Direction: choose the best answer and encircle the correct letter of your choice (each 2pts)

- 1. Delivering what customers want refers to:
 - A. Resource management
 - B. Management responsibility
 - C. Product realization
 - D. Measurement, review and improvement
- 2. Which one of the following is a measurable standard?
 - A. Responding to all customer service emails within four hours
 - B. Resolving customer service problems in five minutes
 - C. Answering all customer calls by the second ring
 - D. All of the above

Note: Satisfactory rating – 5 out of 10points

Unsatisfactory - below 5 and 10points

Score = _____
Rating: _____



Information Sheet 3 Providing quality standard and procedures documents

Providing quality standard and procedures documents

Documenting quality standard procedures refers to the quality manuals, quality plans, inspection and test plans and work instructions. It details the organization's structure, procedures, processes and resources and when followed result in a quality product or service being consistently delivered to the customer. Document control procedures specify who is responsible for the integration of such documents into the company system. They detail how to identify the external documents, whether a review is necessary and how to proceed with revisions if required.

Documents include all the quality manuals, written policies, processes, and procedures. In order to develop documents, it is important to understand each of these elements and how they relate.

- i. **Quality Manual**—this is the overall guiding document for the quality system and provides the framework for its design and implementation.

The Quality Manual document demonstrates the commitment to meeting customer expectations delivering quality products or services. The quality manual document is often the first form of documentation created during the process of establishing a quality management system of ISO standards. It is often used as a template for organizations to follow when implementing and improving their QMS. More specifically, a quality manual document “states the company’s intentions for operating the processes within the quality management system.” In other words, the manual includes information about the organization’s goals, expectations, policies, and more in relation to their QMS. The manual also includes requirements needed for the organization to be compliant with ISO 9001 standards.

- i. **Quality Policy**:- is a documented statement of overall intentions and direction defined by those in the organization and endorsed by management¹. Policies give broad and general direction to the quality system. They:

- tell “what to do”, in a broad and general way;
- include a statement of the organizational mission, goals, and purpose;



- serve as the framework for the quality system, and should always be specified in the quality manual.

Although there are national policies that affect quality operations, each business organizations will develop policies specific to its own operations.

ii. Quality Processes are the steps involved in carrying out quality policies. A process can be defined as a set of interrelated or interacting activities that transform inputs into outputs. Some examples of laboratory inputs include test requests, samples, and requests for information. Another way of thinking about a process is as “how it happens”. Processes can generally be represented in a flow chart, with a series of steps to indicate how events should occur over a period of time.

iii. Quality Procedures are the specific activities of a process. A procedure tells “how to do it”, and shows the step-by-step instructions that authority should meticulously follow for each activity. The term Standard Operating Procedure (SOP) is often used to indicate these detailed instructions on how to do it.

iv. Standard Operating Procedures (SOP)—SOP contain step-by-step written instructions for each procedure performed. These instructions are essential to ensure that all procedures are performed consistently by everyone.

Job aids, or work instructions, are shortened versions of SOPs that can be posted at the bench for easy reference on performing a procedure. They are meant to supplement, not replace, the SOPs.

vi. Reference **materials**—good reference materials are needed in order to follow methods, and procedures. Sometimes, there are difficult interpretive issues, for which references or textbooks will be needed.

Documents are the essential guidelines for all of the quality operations. Written documents are required by formal quality standards, including those leading to accreditation. Standards generally require that policies and procedures be written and available. Most inspection/ assessment activities include an examination of the quality documents. The documents are an important element on which the performance is assessed.

Documents are the communicators of the quality system. All policies, processes, and procedures must be written, so that everyone will know the proper procedures and can



carry them out. Verbal instructions alone may not be heard, may be misunderstood, are quickly forgotten, and are difficult to follow. Everyone must know exactly what is being done, and what should be done at each step.

Therefore, all of the guidelines must be written so that they are available and accessible to all who need them. A well-managed business organization will always have a strong set of documents to guide its work. A good rule to follow is: “Do what you wrote and write what you are doing.”

Quality standard procedures

Develop and implement quality standard 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.



Self-Check 3	Written Test
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Name: _____

Date: _____

Instruction: Answer all the questions listed below, if you have some clarifications- feel free to ask your teacher.

I. Direction: True or False. write “True” if the statement is correct or “False” if the statement is incorrect on the space provided.(each 2pts)

1. “Do what you wrote and write what you are doing” is a rule to be followed.
2. Documents are the essential guidelines for all of the quality operations.
3. Work instructions are shortened versions of SOPs

II. Direction: choose the best answer and encircle the correct letter of your choice (each 2pts)

1. Quality standard documents provide the following except-----.
 - A. Specifications and manuals
 - B. Requirements and policies
 - C. Guidelines and procedures
 - D. None of the above
2. Which of the following tells “what to do”?
 - A. Quality Processes
 - B. Quality Manual
 - C. Quality Policy
 - D. Quality Procedures

Note: Satisfactory rating – 5 out of 10points

Unsatisfactory - below 5and 10points

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



Information Sheet 4 Revising / updating standard procedures

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.

The steps required for the conceptualization and implementation of a QMS include the following:

1. Define and map your Processes. ...
2. Define your **quality** Policy. ...
3. Define your **quality** Objectives. ...
4. Develop metrics to Track and monitor CSF data. ...
5. Define defects for Every Process. ...
6. Develop documents and Records. ...
7. Define **quality** Process.

Revising / updating standard procedures

5 Ways ISO 9001 guideline to update standard procedure

1. Leadership Involvement
2. Quality Policy, Objectives, and Planning
3. Risk Based Thinking
4. Corrective and Preventative Actions
5. Continual Improvement

I firmly believe that using the ISO 9001 framework improves the quality of what an organization produces.



Fig 1.1

1. Leadership Involvement

The most recent version of IOS 9001 puts a renewed emphasis on the role leadership takes when implementing a quality management system. It requires Top Management within an organization to take on the responsibilities of leading the front by taking accountability for how effective the system is.

Having the commitment of Top Management in a transition period is essential for putting ISO 9001 into action in your organization. If everyone is not on board it could sow seeds of doubt going down the line to other employees in the company. If your leaders do not believe in the change, how can everyone else?

Passionate and dedicated leadership is a cornerstone to improving overall quality. When they take an active roll in the process it motivates others to do the same. With ISO 9001 in place there are set procedures and everyone knows their place within



the system. This begins with the commitment of everyone at the very top levels of management.

2. Quality Policy, Objectives, and Planning

Implementing ISO 9001 in your organization comes along with requirements of documentation. Perhaps the most important of these documents are your Quality Policy and Quality Objectives.

The Quality Policy is a simple but effective tool that defines what quality means for your company. There is no set way to define quality for all businesses. Your Quality Policy should be unique to your organization and build upon the values you already hold.

Your Quality Objectives should align with your Quality Policy and be actively measurable for success. They can be anything from decreasing delivery time to reducing waste. They should stay in line with the definition you outlined in your Quality Policy and make sense for your company.

With these documents you have set a structure for your quality management system to work in. By communicating your policy and objectives throughout your organization you keep everyone at all levels on the same page when it comes to what is needed of them. Every single employee should know and understand the Quality Policy and how it applies to them.

On top of that, a regular review and update of both your Quality Policy and Quality Objectives leads to finding ways to constantly improve upon the current system. **The more you pay attention to what quality means to your business and your customers, the more effectively you can put it into action.**

While planning out your objectives, you are likely to learn a number of things about your system. You will be able to find out what is going to be done and what resources you'll need to get it done. You'll see who will be responsible for what parts of meeting your objectives. You will know when the objectives will be completed and how they will be evaluated when they are.



The requirement to maintain these documents by ISO 9001 undoubtedly leads to a very quality oriented mindset within your organization. When everyone understands and is focused on what needs to be done to sustain top quality you can be assured that quality will be the outcome.

3. Risk Based Thinking

ISO 9001 requires your organization to employ considerations for risks and opportunities in your quality management system. This approach can help to prevent things from going wrong and find ways to improve that might not have been obvious from the start.

When you use risk based thinking you are actively trying to prevent problems within your system before they arise. This way of thinking will assure that your system functions as it should, prevent or reduce negative effects, and continually improve your system.

Risk based thinking is not only the act of looking for risks that should be attended to, but also finding opportunities to improve upon things that could be doing better. By identifying opportunities you could establish new partnerships or create new products.

By being required to take a risk based approach you have a proactive culture in your organization for discovering risks and opportunities. This leads to more consistency in creating quality goods and services, which leads to greater customer confidence and satisfaction.

4. Corrective and Preventative Actions

While there will be issues that occur in your quality management system, ISO 9001 includes requirements that help to keep these issues to a minimum as well as fix them. With a risk based thinking approach to finding issues, it is possible to correct them as quickly as possible or even prevent them.

ISO 9001 outlines three specific types of problem solving:

1. **Corrections** are an action to eliminate a nonconformity



2. **Corrective Actions** are actions that eliminate the cause of a nonconformity so it does not recur or occur elsewhere
3. **Preventative Actions** are actions that eliminate the cause of a potential nonconformity

By implementing ISO 9001 you will have a greater focus on correcting issues and keeping them from happening again in the future. You will control and eliminate future damage within your system before it can get out of hand.

ISO 9001 requires that corrective and preventative actions are documented and kept as records. With this emphasis placed on problem solving it's easy to see how ISO 9001 can keep your quality management system running like a well-oiled machine. That way you can consistently provide quality products or services to your customers.

5. Continual Improvement

ISO 9001 puts a heavy focus on constantly improving your quality management system to meet requirements and even plan for the future. There are many useful ways you can improve upon your system in a way that provides evidence that things are always moving forward.

By keeping clear records on processes and their outputs you will have a good understanding of how your quality management system is functioning. ISO 9001 requires regular management reviews to go over these outputs and identify opportunities for improvement in the system.

A system can be improved by employing new technologies or launching new products. It's important to always be anticipating future needs and innovating ways to meet these needs to keep the your customers satisfied.

With such a strong emphasis placed upon improvement and a structure to constantly move forward it is impossible not to maintain the best quality for your products and services. ISO 9001 keeps your leadership on task to keep things fresh and maintain this quality no matter what.



Fig 1.2

Other benefits of ISO 9001

- Decision making based on clear evidence
- Improved efficiency and productivity
- Higher employee morale
- Proof of commitment to quality
- Cost reduction
- Greater customer satisfaction

With the addition of ISO 9001 certification you are held to a certain standard and must meet requirements that keep quality at the forefront of everyone's mind. But quality isn't the only benefit that comes out of this certification.

Evidence based decision making

Everyone wants to make the best decisions for their organization. Under ISO 9001 you are required to have evidence for the need of a change before implementing it. It is also easier to test changes in a smaller environment before placing them in the bigger system.



When you make decisions based on collected data rather than just suspicion, you are less likely to waste time, money, and resources on trial and error changes. Having evidence in hand gives you the confidence that change needs to be made so that you know without a shadow of a doubt whatever you are doing will be cost effective and only improve your system.

On top of decision making, by monitoring every part of the process so closely you will have concrete data of how your system is improving.

Increased efficiency and Production

A quality management system is meant to be an efficient system that keeps your production process running smoothly. While it's entirely possible to have an efficient system without being ISO 9001 certified, the addition of the standard can aid in keeping it that way.

Because ISO 9001 outlines specific requirements for certification, you are held to the standard that it sets out. If you don't keep up with all of the requirements you could risk losing your certification altogether. But having these guidelines in place certainly helps your organization keep focus on efficiency.

Once you have your quality management system set up under the ISO 9001 standard you will find that keeping it to that standard will be easy. The requirements help to keep all of your documentation in order as well as aid in identifying areas that need to be improved.

ISO 9001 creates a system that is easy for anyone to run. Everything is already set in place for them, so you don't have to worry about new management coming in. There is easy access to all documents and everyone knows their place in the process. Losing on piece of the puzzle won't result in the collapse of the entire system.

Employee morale

The importance of leadership commitment translates into a higher morale for all employees working within the system. When their management is passionate and communicates that passion to them, they will be more excited to be part of the change.



ISO 9001 places defined roles and responsibilities for all employees in the production process, which makes them feel more comfortable and confident in their work. It also provides a structure for training and ensures companywide involvement so that all employees feel included in the system.

When your employees are happy they do better work which leads to greater production. All of this amounts to higher customer satisfaction with your product.

Objective proof of Quality

Having a certification in ISO 9001 is a sort of badge of honor that shows your organization is committed to quality. It also proves that your company is regularly evaluated by an independent party to ensure you are meeting the requirements of the standard.

Because your customers know you are held to this standard they are likely to be more confident in the quality of your products. Most people are happier to put their trust in a company that holds themselves to a high standard and can show proof that they meet that standard.

ISO 10014 - Quality Management Guidelines

One supporting document that can help you to realize the benefits of ISO 9001 is ISO 10014. **This document outlines quality management guidelines for realizing financial and economic benefits under the requirements of the ISO 9001 standard.**

ISO 10014 requires heavy involvement by Top Management and works along with IOS 9004 to improve the performance of your quality management system. It shows examples of achievable benefits and gives you the tools to realize them.

These benefits are achieved from application of the ISO 9000 quality management Principles

1. Customer Focus
2. Leadership
3. Engagement of People
4. Process Approach



5. Improvement
6. Evidence-Based Decision Making
7. Relationship Making

The document provides a plan-do-check-act style approach to each of the seven quality management principles and lists activities for each stage. It also includes a gap checklist evaluation tool which gives recommendations for self-assessment within your organization.

The **economic benefit** of implementing ISO 9001 comes from the improved processes that it employs. These processes generally result in better resource management, better customer relationships, and improved worth of an organization.

The **financial benefit** is the direct result of organizational improvement and cost-effective management practices.

Cost reduction is perhaps one of the best ways ISO 9001 can benefit your company and aid in financial success. By implementing ISO 9001 in your quality management system, you can see savings in a variety of areas.

Reduced cost with ISO 9001 can result from

1. Improved product reliability
2. Improved process control and flow
3. Improved documentation of processes
4. Greater employee quality awareness
5. Reduction in waste, reworks, and rejections of products

At the outset, implementing the transition to ISO 9001 is a big deal, but with such benefits in mind it's hard to disagree with its effectiveness.



Fig 1.3

ISO 9004 Guidance to Achieve Sustained Success

ISO 9004 works alongside the standard requirements of ISO 9001 and gives guidelines for sustaining success in your quality management system. While ISO 9001 provides the framework for managing your processes in your system there is always room to improve them down the line.

Using the seven quality management principles, ISO 9004 gives you guidance to achieve sustained success by considering the quality of your organization. It defines quality by the degree to which the characteristics of your organization fulfill the needs and expectations of its customers.

Improvement of your company's overall performance is the focus of the guidance provided by ISO 9004. It includes planning, implementation, analysis, evaluation, and improvement practices. Like other documents in the ISO 9000 series it places emphasis on Top Management involvement in order to achieve sustained success.



How to Achieve Sustained Success

1. Meet the needs and expectations of customers
2. Effectively manage your organization
3. Be aware of your organization's environment
4. Always strive to learn and improve

Regardless of the size or scope of your organization, ISO 9004 can be used to achieve long term success by taking a quality management approach. This document pushes self-assessment as a key component to reviewing the level of your organization and provides a framework for identifying strengths and weaknesses.

ISO 9004 expands on ISO 9001 by addressing the needs and expectations of all interested parties within your quality management system. It also provides guidance for continual improvement of your organization's overall improvement.

If you are looking to get the greatest benefits possible from ISO 9001 then ISO 9004 is an invaluable resource. It will help you to maintain the success of your established quality management system and sustain it far into the future.

ISO 9001 is a commitment to quality

It can be hard to see at first how exactly all of the requirements of the ISO 9001 standard can possibly translate into better quality products. It is a lot to take in and requires a lot of work on your part to establish a quality management system that meets the standard.

By putting focus on certain areas of your business and requiring you to monitor things in a certain way, ISO 9001 leads to improved quality within your organization. Emphasis on leadership involvement, prevention, correction, and improvement ensures that your quality management system is producing only the best of what your customers require.

Improved quality isn't the only benefit you can expect to see from ISO 9001.

**Self-Check1.4.****Written Test**

Directions: Answer all the questions listed below.

I. Direction: explain the following (each 4pts)

1. List the source of cost reduction in ISO 9001
2. What are the application of the ISO 9000 Quality Management Principles
3. List 5 Ways ISO 9001 guideline to update standard procedure

Note: Satisfactory rating – 6 out of 12 points

Unsatisfactory - below 6 and 12 points

Score = _____
Rating: _____



L #38

LO #2- Assess quality of service delivered

Instruction sheet

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

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

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

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

Learning Instructions:

Read the specific objectives of this Learning Guide.

1. Read the specific objectives of this Learning Guide.
2. Follow the instructions described below.
3. Read the information written in the “Information Sheets”. Try to understand what are being discussed. Ask your trainer for assistance if you have hard time understanding them.
4. Accomplish the “Self-checks” which are placed following all information sheets.
5. Ask from your trainer the key to correction (key answers) or you can request your trainer to correct your work. (You are to get the key answer only after you finished answering the Self-checks).
6. If your performance is satisfactory proceed to the next learning guide,
7. If your performance is unsatisfactory, see your trainer for further instructions or go back to “information sheets”.



Information Sheet 1 Quality standards and specifications

Quality standard and specification

Quality standard and specification is a document jointly developed by management and quality experts to express the quality objectives of the organization, the acceptable level of quality and the duties of specific departments to ensure quality.

Your quality policy should:

- ✚ State a clear commitment to quality.
- ✚ Recognize customer needs and expectations.
- ✚ Be actively supported by senior management.
- ✚ List the quality objectives you want to achieve.
- ✚ Be understood by everyone in the organization.
- ✚ Be consistent with your organization's goals.
- ✚ Be maintained throughout your organization
- ✚ Be applied throughout your organization.

Quality system

Develop a quality system and a manual that describes it. Your quality system should ensure that your products conform to all specified requirements.

Your quality manual should:

- State your quality policy.
- List your quality objectives.
- Provide an overview of your quality system.
- Describe the structure of your organization.
- Discuss your quality system procedures.
- Introduce your quality documents and records.
- Teach people about your quality system.
- Control quality system work practices.
- Guide the implementation of your quality system.
- Explain how your quality system will be audited.



Quality Assurance

Quality Assurance is a system of management activities involving planning, implementation, assessment, and reporting to make sure that the end product (i.e., environmental data) is of the type and quality needed to meet the needs of the user.

Quality Control

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.

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.

Manage quality

Quality is represented by how close the project and deliverables come to meeting the client's requirements and expectations. In other words, quality is ultimately measured by the client.

Quality management system

Quality management system (QMS) standards establish a framework for how a business manages its key processes. They can help whether your business offers



products or services and regardless of your size or industry. They can also help new businesses start off on the right foot by ensuring processes meet recognized standards, clarifying business objectives and avoiding expensive mistakes.

To comply with the standard you'll first need to implement a QMS. Implementing a QMS can help your business to:achieve greater consistency in the activities involved in providing products or services

- reduce expensive mistakes
- increase efficiency by improving use of time and resources
- improve customer satisfaction
- market your business more effectively
- exploit new market sectors and territories
- manage growth more effectively by making it easier to integrate new employees
- constantly improve your products, processes and systems

✚ **Management responsibility** - ensuring top level management shows commitment to the quality system and develops it according to customers' needs and the business' objectives

✚ **resource management** - ensuring the people, infrastructure and work environment needed to implement and improve quality systems are in place

✚ **product realization** - delivering what customers want, looking at areas such as sales processes, design and development, purchasing, production or service activities

measurement, analysis and improvement - checking whether you have satisfied customers by carrying out other measurements of your system's effectiveness



Self-Check 1	Written Test
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Directions: Answer all the questions listed below.

I. Direction: True or False. write “True” if the statement is correct or “False” if the statement is incorrect on the space provided.(each 2pts)

1. Quality Assurance is a system of management activities involving planning, implementation, assessment, and reporting to make sure that the end product.
2. Quality Control is the overall system of operational techniques and activities that are used to fulfill requirements for quality
3. It is not necessary to state quality policy in your quality manual .
4. Quality policy is a document developed by management only.

Note: Satisfactory rating – 4 out of 8points Unsatisfactory - below 4 and 8points

Score = _____

Rating: _____



Information Sheet 2 Checking quality services delivered

Checking quality service delivery

Delivering quality service is considered to be an important strategy for success in today's competitive environment. Service quality is commonly defined as a discrepancy between the service quality that is delivered by the organization and the service performance that employees expect. Conceptually, it is a global judgment or attitude relating to the overall excellence or superiority of the service developed the framework for measuring service quality, the gap theory.

Service Quality is an association of two different words: service and quality. Service means any activity or benefit that one party can offer to another that is essentially intangible and does not result in the ownership of anything. Quality has come to be recognized as a strategic tool for attaining operational efficiency and better performance of business.

Service quality, then, is the ability of a service provider to satisfy customer in an efficient manner through which he can better the performance of business. In the service sector too quality is an important element for the success of business.

Thus, the term service quality is the capability of a service firm to hang on to its customer. That is, customer retention is the best measure of service quality. The quality of service as perceived by the customer has two dimensions: technical or outcome dimension and the function of process related dimension. It is the delivery of excellent or superior service relative to customer expectation.

1. Measuring service quality delivered

Every customer has an ideal expectation of the service they want to receive when they go to a restaurant or store. Service quality measures how well a service is delivered compared to customer expectations. Businesses that meet or exceed expectations are considered to have high service quality.

In the case of tangible goods, quality can be assessed by examining the goods. Quality control can be used to check specifications and reject defective goods. But service



quality cannot be assessed in the same way as a tangible product due to particular feature of service such as, intangibility, inseparability etc. As in the case of goods, the service provider cannot undertake quality check before the service is finally delivered to the customer.

In order to assess the service quality the customer judges the expected service quality against the perceived quality when they receive it. There are mainly two methods for measuring service quality: Gap analysis Service and performance measures.

Gap analysis model indicated that customer perception of quality was influenced by a series of five distinct gaps. They are mentioned below:

Gap – 1: Gap between customer expectation and Management perception. The reasons for this gap are lack of adequate market research and lack of upward communication. This gap can be narrowed by adopting adequate research programs to know customer needs and to improve the communication system. It can be measured by using the SERVQUAL scale and comparing the scores obtained from the management and customers.

Gap – 2: Gap between Management perception and service quality specification. This gap exists in service firms because of the lack of whole hearted commitment of management to service quality, inadequate service leadership etc. It can be closed by standardizing service delivery process and setting proper organizational goals.

Gap – 3: Gap between Service quality specification and service delivery. The third gap originates from the discrepancies in the actual service delivery, that is, the service providers or employees do not perform at the level expected by the management. It is because of the ineffective recruitment, lack of proper incentives and motivations etc. This gap can be eliminated by providing the employees with adequate support system, better human resource management system etc.

Gap – 4: Gap between Service delivery and external communication. The gap between service delivery and external communication occurs due to exaggerated promise or ineffective communication to the customer, which raise customer expectations. This can be narrowed by efficient and effective communication system.



Gap – 5: Gap between expected quality and perceived quality. This gap exists because of the inequality in the service expectation of customer and his service perception. This can be overcome by identifying, quantifying and monitoring customer expectations and perceptions through the effective use of marketing and marketing research tools.

In general, there are four key elements for successful service delivery system: service culture, service quality, employee engagement and customer experience.

2. Check against specifications -Conformity to specifications

Quality control inspectors protect the consumer from defective products and the company from damage to its reputation due to inferior manufacturing processes. If the testing process reveals issues with the product, the inspector has the option of fixing the problem himself, returning the product for repairs or tagging the product for rejection. When issues arise, the inspector notifies supervisors and works with them to correct the problem. The inspector needs to use the product specifications as a checklist — typical points are materials, workmanship, appearance, labeling, inner packing, and outer packing.

3. Visual and Physical inspection of final output

Quality inspections are measures aimed at checking, measuring, or testing of one or more product characteristics and to relate the results to the requirements to confirm compliance. This task is usually performed by specialized personnel and does not fall within the responsibility of production workers. Products that don't comply with the specifications are rejected or returned to improve.

Inspection provides a means for monitoring quality. For example, inspection may be performed on incoming raw material, to decide whether to keep it or return it to the vendor if the quality level is not what was agreed on. Similarly, inspection can also be done on finished goods before deciding whether to make the shipment to the customer or not.

Visual inspection is a common method of quality control, data acquisition, and data analysis. And hence, visual inspection is a methodology that requires specialized equipment, training and certification. Quality inspection serves three main purposes:



1. Identification of the quality problem
2. Provision of information to managers
3. Elimination of the problem by managers

Quality inspection can be performed at the end of production process (final inspection) or at several stages of the production (intermediate inspection). Inspection is a major component of quality control, where physical product is examined visually (or the end results of a service are analyzed). Product inspectors will be provided with lists and descriptions of unacceptable product defects such as cracks or surface blemishes for example.

An inspection is the examination of a work product to determine whether it conforms to documented standards. The result of an inspection generally includes measurement and may be conducted at any level.

The Role of quality control inspectors

Quality control inspectors protect the consumer from defective products and the company from damage to its reputation due to inferior manufacturing processes. If the testing process reveals issues with the product, the inspector has the option of fixing the problem himself, returning the product for repairs or tagging the product for rejection. When issues arise, the inspector notifies supervisors and works with them to correct the problem.

**Self-Check 2****Written Test**

Name: _____

Date: _____

Instruction: Answer all the questions listed below, if you have some clarifications- feel free to ask your teacher.

III. Direction: True or False. write “True” if the statement is correct or “False” if the statement is incorrect on the space provided.(each 2pts)

1. Service Quality is an association of two different words: service and quality.
2. Service quality can be assessed in the same way as a product quality.
3. Quality control inspectors protect the consumer from defective products.
4. Inspection provides a means for monitoring quality.

IV. DIRECTION: CHOOSE THE BEST ANSWER AND ENCIRCLE THE CORRECT LETTER OF YOUR CHOICE (each 1 point)

1. Which of the following is the main purposes quality inspection?
 - A. Provision of information to managers
 - B. Identification of the quality problem
 - C. Elimination of the problem by managers
 - D. All of the following
2. Which one of the following is NOT the role of an inspector?
 - A. Notifies supervisors
 - B. fixing the problem himself,
 - C. returning the product for repairs
 - D. None of the following

Note: Satisfactory rating – 5 out of 10points

Unsatisfactory - below 5 and 10points



Information Sheet 3 Evaluating service delivered using quality parameters

Evaluation of service quality

The provision of high quality services is a prerequisite for the success of service organizations since service quality influences customers' perceived value, their satisfaction and faithfulness. Therefore, the improvement of service quality has been on management agenda. Growth in demand for services, increased costs, limited resources, and the variety of interventions have led many organizations in the world to focus on measuring and improving the quality of services. The first step to this end is to define the concept of quality that has long been a topic of much controversy.

Service quality is a unique and abstract concept which is difficult to define and measure. Researchers have provided different definitions. It has been described as the judgment or overall attitudes of customers towards the provided services and refers to the differences and mismatches between customers' expectations and their perceptions of service performance.

For example, quality in social services includes technical quality and functional quality. The former focuses on the skills, accuracy of procedures and while the latter refers to the way that social service are provided to the customers.

Constant monitoring of social services is very important, thus measuring customers' perception of service quality, as a key element in quality assessment, has gained much attention in recent years. Monitoring provides important information about service quality which cannot be obtained through traditional means for performance evaluation.

1. Standard specifications

Quality- degree of perfection- is not absolute but it can only be judged or realized by comparing with standards. It can be determined by some characteristics namely, design, size, material, chemical composition, mechanical functioning, workmanship, finish and other properties. Thus, quality of any product is regarded as the degree to which it fulfills the requirements of the customer.

In order to implement an effective Quality Control program, business organization must first decide which specific quality standards the product or service must meet. Then the



extent of QC actions must be determined -- for example, the percentage of units to be tested from each lot.

Next, real-world data must be collected -- such as the percentage of units that fail -- and the results reported to management personnel. After this, corrective action must be decided upon and taken. For example, defective units must be repaired or rejected, and poor service repeated at no charge until the customer is satisfied. If too many unit failures or instances of poor service occur, a plan must be devised to improve the production or service process; then that plan must be put into action.

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

2. Procedures

A procedure is a documented series of actions, performed in an orderly manner, to achieve a desired outcome. This will ensure that all concerned undertake the task in an agreed and consistent way. A standard procedure gives a set of instructions for performing operations or functions. For example, there are detailed standard operating procedures for operation of a nuclear power plant

Procedures are the specific activities of a process. A procedure is easily described as the performance of a test. It tells "how to do it", and shows the step-by-step instructions that laboratory staff should meticulously follow for each activity. The term Standard Operating Procedure (SOP) is often used to indicate these detailed instructions on how to do it.

Job aids, or work instructions, are shortened versions of SOPs that can be posted at the bench for easy reference on performing a procedure. They are meant to supplement, not replace, the SOPs.

**Self-Check 3****Written Test**

Name: _____

Date: _____

Instruction: Answer all the questions listed below, if you have some clarifications- feel free to ask your teacher.

I. Direction: True or False. write “True” if the statement is correct or “False” if the statement is incorrect on the space provided.(each 2pts)

1. Service quality can be a prerequisite for the success of any organizations.
2. Quality is absolute and it cannot be judged or realized by comparing with standards.
3. Procedures are the specific activities of a process.

II. Direction: choose the best answer and encircle the correct letter of your choice (each 2pts)

1. Which one of the following is not a Quality in social services?
 - A. Functional quality
 - B. technical quality
 - C. customer perception
 - D. A & B

2. One of the following is described as the performance of a test:
 - A. Specifications
 - B. Procedures
 - C. Standards
 - D. Policies

Note: Satisfactory rating – 5 out of 10points

Unsatisfactory - below 5 and 10points



Information Sheet 4 Identifying causes of any faults

Identify causes of any faults

Fault can be defined as a physical or intellectual imperfection or impairment. It is an error in service. The common causes of service faults, malfunctions and work related errors can be listed as follows.

i. The most common causes of service failures or faults:

- ❖ Incorrect operation
- ❖ Poorly performed or inadequate maintenance
- ❖ Incorrect installation and bad workmanship
- ❖ Incorrect repair introducing new defects
- ❖ Poor quality manufacture leading to substandard components Poor design

ii. Malfunction caused by:

- ❖ Design errors
- ❖ Implementation errors
- ❖ Human operator errors
- ❖ Wear
- ❖ Aging
- ❖ Environmental aggressions
- ❖ part misapplication

iii. CAUSES OF –WORK RELATED ERRORS/ FAULTS

A. Quantity of work (Factors that affect quantity of work are:

- ❖ Poor prioritizing, timing, scheduling
- ❖ Lost time due to: 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

B. Preventable accidents

- ❖ 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

Method of Preventing Faults

Faults in any systems may be prevented by one of the following methods:

- i. Fault identification: to estimate the size and type or nature of the fault.
- ii. Fault detection: Detect malfunctions in real time, as soon and as surely as possible
- iii. Fault isolation: Find the root cause, by isolating the system component(s) whose operation mode is not nominal
- iv. Fault Tolerance: - Provide a system an allowable amount of variation of a specified quantity to accept faults as normal events.



Self-Check 4	Written Test
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Name: _____

Date: _____

Instruction: Answer all the questions listed below, if you have some clarifications- feel free to ask your teacher.

I. Direction: True or False. Write “True” if the statement is correct or “False” if the statement is incorrect. (each 2pts)

- 1. Human operator errors is an example for cause of malfunction.
- 2. Poor prioritizing can be a factors that affects quality of work.
- 3. Fault Tolerance is NOT method of Preventing Faults.
- 4. Fault identification estimates the size and type or nature of the fault.

Note: Satisfactory rating – 4 out of 8points Unsatisfactory - below 4 and 8points



Information Sheet 5 Taking corrective actions.

Taking corrective action

When opportunities for improvement come up, this is the true test of your processes. Quality depends on continuous improvement, and—though they can be stressful and unwanted—problems are a way of making the company and the team even better. This is all just theory, however, until an audit brings issues to light. That’s when corrective actions come into play.

Corrective actions (CARs) are a way to make the problem go away. In addition, they can also teach your company how to improve your manufacturing processes. In that way, they are at the heart of a continuous improvement program.

As ISO 9001:2015 made clear, the priority is to prevent problems, but if that fails, corrective action is the next best thing. Corrective action is defined as “action to eliminate the cause of a nonconformity and to prevent its recurrence,” according to ISO.

Though the ISO 9001:2015 version did make changes regarding corrective and preventive action, the requirements have not disappeared. Despite these changes, the theory behind them holds true. If it’s not possible to prevent a problem—always the ideal method—then at least the solution should address how to avoid it in the future.

As Jack West and Charles A. Cianfrani write in ASQ’s Quality Progress, “Correction and corrective action are still required in ISO 9001:2015 and are addressed in clauses 9 and 10. In simple terms, an organization is required to react to nonconformity and take action to control and correct it, and to deal with the consequences.”

A nonconformity, as stated by ISO, would be any failure to meet a requirement. This could be a requirement from a customer, regulatory body, ISO, or your organization. Audits, whether internal or external, will uncover these issues. Keep in mind that audits are there to improve an organization and lead the way to a better version of the company, so addressing any nonconformities is a necessary step on the road to improvement.



While the terminology has changed in the ISO 9001:2015 standard—preventive action is now known as risks and opportunities—the idea has not. Better to prevent than fix a problem, as Benjamin Franklin would say. It seems that “an ounce of prevention” applies to colonial era projects just as much as today’s nonconformities.

The process can be daunting, however. To answer your questions, it might help to look at some guidelines summarized by SGS. In “The Route to ISO 9001:2015,” SGS lays out what an organization should do regarding nonconformities and summarizes the requirements of clause 10.2 this way: “When a nonconformity occurs does the organization:

React to the nonconformity and take action to control and correct it; deal with the consequences?

Evaluate the need for action to eliminate the causes of the non-conformity so that it does not recur or occur elsewhere by: reviewing and analyzing the nonconformity; determining the causes of the nonconformity; determining if similar nonconformities exist or could potentially occur?

- Implement any action needed?
- Review the effectiveness of corrective action taken?
- Update risks and opportunities determined during planning?
- Make changes to the QMS?”

In addition, SGS says, companies should ask, “Are corrective actions appropriate to the effects of the nonconformities encountered? Is documented information retained as evidence of:

- The nature of the nonconformities and any subsequent actions taken?
- The results of any corrective action”

Getting the hang of this can be difficult. If you’ve asked yourself these questions and not been happy with the answers, perhaps a change of perspective is needed.



If you're looking for more guidance, Mark Ames described some misunderstandings related to corrective action during an ASQ webcast. He notes that common sense should play a central role in corrective actions, though it often doesn't. He notes that it is important not to overlook the needs of the customer, needs of the organization, identified and potential risks, regulatory requirements, and the cost/benefit tradeoffs.

Ultimately, corrective actions should be a satisfying way to get something out of a problem. Knowing that you won't have to face the same issue again—or at least that's the idea—should be a relief. To ensure that your corrective action process is robust, ISO requires organizations to review the effectiveness of actions taken. For example, this could take the form of a meeting or just a follow-up with those involved. Continual improvement takes work, and it also takes corrective action.

**Self-Check 5****Written Test**

Name: _____

Date: _____

Instruction: Answer all the questions listed below, if you have some clarifications- feel free to ask your teacher.

I. Direction: True or False. write “True” if the statement is correct or “False” if the statement is incorrect on the space provided.(each 2pts)

1. The priority is to prevent problems, but if that fails, corrective action is the next best thing.
2. Quality depends on continuous improvement.
3. According to Benjamin Franklin Better to prevent than fix a problem.
4. If it's not possible to prevent a problem—always the ideal method—then at least the solution should address how to avoid it in the future.

Note: Satisfactory rating – 4 out of 8points Unsatisfactory - below 4 and 8points



L # 39

LO #3- Recording Information

Instruction sheet

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 outcomes 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:

Read the specific objectives of this Learning Guide.

1. Read the specific objectives of this Learning Guide.
2. Follow the instructions described below.
3. Read the information written in the “Information Sheets”. Try to understand what are being discussed. Ask your trainer for assistance if you have hard time understanding them.
4. Accomplish the “Self-checks” which are placed following all information sheets.
5. Ask from your trainer the key to correction (key answers) or you can request your trainer to correct your work. (You are to get the key answer only after you finished answering the Self-checks).
6. If your performance is satisfactory proceed to the next learning guide,
7. If your performance is unsatisfactory, see your trainer for further instructions or go back to “information sheets”.



Information Sheet 1 Recording basic information on the quality performance

Recording basic information on the quality performance

The management of documents and records is one of the essential elements of the quality control system. The management system addresses both use and maintenance of documents and records. A major goal of keeping documents and records is to find information whenever it is needed. It provides written information about policies, processes, and procedures.

Characteristics of documents are that they:

- communicate information to all persons who need it, including laboratory staff, users, and laboratory management personnel;
 - need to be updated or maintained;
 - must be changed when a policy, process, or procedure changes;
 - establish formats for recording and reporting information by the use of standardized forms.
- Once the forms are used to record information, they become records.

Some examples of documents include a quality manual, standard operating procedures, and job aids.

Documents include written policies, processes, and procedures, and provide a framework for the quality system. They need to be updated and maintained.

Records include information captured in the process of performing and reporting a laboratory test. This information is permanent, and does not require updating.

Having a good document control program assures that the most current version of a document is used, and ensures availability and ease of access when a document is needed. Quality Records is a completed form or Table that proves the action took place. Nonconforming product did not meet customer requirements.



Documented information is broken up into two types, documents and records. A form is a kind of document. When the form is filled out it becomes a record. Quality manual, policy, procedure or work instructions are other kinds of documents.



Self-Check 1	Written Test
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Name: _____

Date: _____

Instruction: Answer all the questions listed below, if you have some clarifications- feel free to ask your teacher.

V. Direction: True or False. write “True” if the statement is correct or “False” if the statement is incorrect on the space provided.(each 2pts)

1. The goal of keeping documents and records is to find information whenever it is needed.
2. Documents need NOT to be updated or maintained.

ii. Direction: choose the best answer and encircle the correct letter of your choice on (3pts)

1. Which one of the following is an example of record?
 - A. work instructions
 - B. written policies
 - C. procedures
 - D. Information

Note: Satisfactory rating – 3 out of 5points Unsatisfactory - below 3 and 5points



Information Sheet 2 Maintaining records of work quality

Maintaining records of work quality

Recorded documents include all the written policies, processes, and procedures. So maintaining must be given careful consideration, as the main goal of documentation is finding the information when it is needed. We have to keep documents and records properly.

i. Using a paper system:

It is important to consider the following when using a paper system for records.

- **Permanence**—paper records must last for as long as needed. This should be ensured by binding pages together, or using a bound book (log register). Pages should be numbered for easy access, and permanent ink used.
- **Accessibility**—paper systems should be designed so that information can be easily retrieved whenever needed.
- **Security**—documents and records must be kept in a secure place. Care should be taken to keep documents safe from any environmental hazards such as spills. Consider how records can be protected in the event of fires, floods, or other possibilities.
- **Traceability**—it should be possible to trace a sample throughout all processes in the laboratory, and later to be able to see who collected the sample, who ran the test, and what the quality control results were for the test run including issuing of the report.

i. Using an electronic system:

Electronic systems have essentially the same requirements as paper systems. However, the methods for meeting these requirements will be different when using computers. The following are factors to consider.



- **Permanence**—backup systems in case the main system fails are essential. Additionally, regular maintenance of the computer system will help to reduce system failures and loss of data..
- **Security**—it is sometimes more difficult to assure confidentiality with a computer system, as many people may have access to the data.
- **Traceability**—electronic record systems should be designed in a way that allows for tracing the specimen throughout the entire process in the laboratory. Six months after performing an examination, it should be possible to look at the records and determine who collected the specimen and who ran the test.

Maintenance times for records should be determined in each organization, based on a number of factors:

- the length of time the organization will need to have access to its records;
- organization requirements or standards that dictate record retention times;
- whether the organization is engaged in ongoing research requiring many years of data.
- the time interval between the organization's assessments or audits.

**Self-Check 3.2****Written Test**

Name: _____

Date: _____

Instruction: Answer all the questions listed below, if you have some clarifications- feel free to ask your teacher.

I. Direction: True or False. Write “True” if the statement is correct or “False” if the statement is incorrect on the space provided.

1. Recorded documents include all the written policies, processes, and procedures.
2. Regular maintenance of the computer system will help to reduce system failures.
3. Electronic record systems have the requirements as that of paper record system.

II. Direction: choose the best answer and encircle the correct letter of your choice.

1. Which one of the following is not considered when using electronic system for records?
 - A. Traceability
 - B. Permanence
 - C. Security
 - D. None of the above



L #40

LO #4- Study causes of quality deviations

Instruction sheet

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 outcomes stated in the cover page. Specifically, upon completion of this learning guide, you will be able to:

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

Learning Instructions:

Read the specific objectives of this Learning Guide.

- Read the specific objectives of this Learning Guide.
- Follow the instructions described below.
- Read the information written in the “Information Sheets”. Try to understand what are being discussed. Ask your trainer for assistance if you have hard time understanding them.
- Accomplish the “Self-checks” which are placed following all information sheets.
- Ask from your trainer the key to correction (key answers) or you can request your trainer to correct your work. (You are to get the key answer only after you finished answering the Self-checks).
- If your performance is satisfactory proceed to the next learning guide,
- If your performance is unsatisfactory, see your trainer for further instructions or go back to “information sheets”.



Information Sheet 1 Study causes of quality deviations

Study causes of quality deviations

Investigating quality Deviations and its Causes

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.

Types of Deviations

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

1. **Production Deviation** - usually rose during the manufacture of a batch production.
2. **Quality Improvement Deviation** - may be raised if a potential weakness has been identified and the implementation will require project approval.
3. **Audit Deviation** - raised to flag non-conformance identified during internal, external, supplier or corporate audits.
4. **Customer Service Deviation** - rose to track implementation measures related to customer complaints.
5. **Technical Deviation** - can be raised for validation discrepancies. For example: changes in Manufacturing Instruction.
6. **Material Complaint** - rose to document any issues with regards to non-conforming, superseded or obsolete raw materials/components, packaging or imported finished goods.
7. **System Routing Deviation** - rise to track changes made to Bill of materials as a result of an Artwork change.

When to Report Deviation

A Deviation should be raised when there is a deviation from methods or controls specified in manufacturing documents, material control documents, standard operating procedure for products and confirmed out of specification results and from the



occurrence of an event and observation suggesting the existence of a real or potential quality related problems.

Different Levels of deviation risks:

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

Level 1: Critical deviation

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

Level 2: Serious deviation

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

Level 3: Standard deviation

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



Self-Check 1	Written Test
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Name: _____

Date: _____

Instruction: Answer all the questions listed below,

I. Direction: true or False. Write “True” if the statement is correct or “False” if the statement is incorrect on the space provided.(each 2pts)

1. Deviation is a departure from specifications resulting in non-conforming processes.

2. Quality deviation should NOT be reported when there is a deviation from methods.

II. Direction: choose the best answer and encircle the correct letter of your choice (3 points)

1. Which one of the following deviation level provides immediate and significant risk to product quality?

- A. Serious Deviation
- B. Critical Deviation
- C. Standard Deviation
- D. None of the above

Note: Satisfactory rating – 3 out of 6 points

Unsatisfactory - below 3 and 6 points



Information Sheet 2

Recommending suitable preventive action

Recommending suitable prevention action

Quality Assurance 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 Quality Assurance Manager. Quality Assurance Manager has to justify whether the deviation is a Critical, Serious or Standard in nature. For a deviation of either critical or serious nature Quality Assurance delegate has to arrange a Cross Functional Investigation.

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, equipment's, 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.

Considerations for Deviation Management

- Develop policy on deviation
- Determine approach i.e. differentiation among various deviations
- Tracking of deviation
- Trending of deviation
- Create database (software based or manual system) to assist in tracking and trending of deviations.



Self-Check 2	Written Test
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Name: _____

Date: _____

Instruction: Answer all the questions listed below, if you have some clarifications- feel free to ask your teacher.

I, Direction: True or False. write “True” if the statement is correct or “False” if the statement is incorrect on the space provided.(each 2pts)

1. Developing policy is one method to prevent quality deviation.
2. Creating database helps for trending of deviations.

Note: Satisfactory rating – 2 out of 4points Unsatisfactory - below 2 and 4points



Information Sheet 3 Recommending suitable preventive action

Recommending suitable preventive action

Preventive action – the ISO 9001 Standard requirements

Within the most basic requirement, the purpose of the preventive action is to:

- Eliminate problems/Non conformities
- Achieve improvement within processes

In this article we will review only the requirements for PA (preventive action) out of the CAPA. The CA (preventive action) would be reviewed within another article. The organization is required to take actions to eliminate potential Nonconformities – this is improvement. Why? Something could go wrong; you detected it, eliminated it and made sure it would not happen. How to achieve? With the PA (from the CAPA). The ISO 9001 Standard requires you to locate the potential Nonconformities and to eliminate the cause. The purpose is to prevent them from happening before they occurred. And yes, you are required to maintain a procedure describing the process of preventing the Nonconformities and to document the process itself. It is not a recommendation but an ISO 9001 Standard requirement.

The preventive action documentation

The description for Preventive action – an action taken to eliminate a potential event that might cause Nonconformity. In this case the Nonconformity has not occurred yet. After you identified the cause that would generate Nonconformity, you are required to initiate an action to eliminate it: The Preventive action. You must also document it. Why must you document it? For supervision. After a defined period of time (documented within a procedure) you must examine whether the Preventive action was sufficient, effective and the Nonconformity had not occurred like expected.



Preventive action objectives – you must define what is required by the preventive action taken. The objective could be a numerical, quantitative or a quality requirement – whatever is appropriate for your organization. It is not a recommendation but an ISO 9001 Standard requirement. Before executing the preventive action, it is required to consider cost effective of the preventive action. Some action may cost a lot. You must examine whether it is cost effective to carry out the action. Sometimes it would not be worth taking an action. It would be too expensive. The organization would rather live with the nonconformity – as long as the customer's requirements are maintained!! But, you must document the fact that you initiated a preventive action, examined it and decided to withdraw. Again, documentation here is required by the ISO 9001 Standard.

Closing date for the preventive action – All preventive actions should be limited within time frames in order to measure its effectiveness. You performed a preventive action. That is good but not enough. According to the ISO 9001 Standard requirements, you must define time frames (according to your needs) to examine its effectiveness. The date indicates when the preventive action would be examined.

The preventive action results – the ISO 9001 Standard requires you to observe the preventive action taken and to verify its objectives. You must indicate (and document) the preventive action's status. You must document what are its results: success, failure or perhaps more time is required to examine its effectiveness – that is also possible. Bottom line, you must examine (and document) that the predicted nonconformity was indeed prevented. Then and only then, you may close the preventive action. When a preventive action was found as not successful it is recommended to open a new one. It is not required by the ISO 9001 Standard but an unsuccessful preventive action indicates that a potential Nonconformity is still hanging over your heads – and that is forbidden by the ISO 9001 Standard (unless you defined it otherwise – that you considered and reached a decision – the cost effective topic). We remind you again; you must maintain a documented procedure defining the process of initiating a preventive action:

- Identifying a potential Nonconformity



- Where and how to document it
- The investigation of the cause
- The action taken
- The closing

This procedure would be one of your Quality procedures required to be maintained by the ISO 9001 Standard. You must also maintain documentation of the process itself:

- The nonconformity detected
- The cause
- The preventive action taken
- Its objectives (including time frames)
- The results

So, two types of documentations are required; a procedure and the records. We refer you to the next site: QualityManualTemplates.com – they provide an effective template solution that holds against the ISO 9001:2008 Standard requirements.



Self-Check 4.3	Written Test
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Name: _____

Date: _____

Instruction: Answer all the questions listed below, if you have some clarifications- feel free to ask your teacher.

I. Direction: True or false. write “True” if the statement is correct or “False” if the statement is incorrect on the space provided.(each 2pts)

1. The purpose of the preventive action is to eliminate problems/Non conformities.
2. The preventive action results the ISO 9001 Standard requires you to observe the preventive action taken and to verify its objectives

Note: Satisfactory rating – 4out of 4points Unsatisfactory - below 4and 4points



L #41

LO #5- Complete documentation

Instruction sheet

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 outcomes 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:

Read the specific objectives of this Learning Guide.

- Read the specific objectives of this Learning Guide.
- Follow the instructions described below.
- Read the information written in the “Information Sheets”. Try to understand what are being discussed. Ask your trainer for assistance if you have hard time understanding them.
- Accomplish the “Self-checks” which are placed following all information sheets.
- Ask from your trainer the key to correction (key answers) or you can request your trainer to correct your work. (You are to get the key answer only after you finished answering the Self-checks).
- If your performance is satisfactory proceed to the next learning guide,
- If your performance is unsatisfactory, see your trainer for further instructions or go back to “information sheets”.



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

Recording information on quality and other indicators of service performance

Documentation is any communicable material that is used to describe, explain or instruct regarding some attributes of an object, system or procedure, such as its parts, assembly, installation, maintenance and use. Documentation can be provided on paper, online, or on digital or analog media, such as audio tape or CDs.

The presence of documentation helps keep track of all aspects of an application and it improves on the quality of a software product. Its main focuses are development, maintenance and knowledge transfer to other developers. The purpose of documentation is to: Describe the use, operation, maintenance, or design of software or hardware through the use of manuals, listings, diagrams, and other hard- or soft-copy written and graphic materials.

Documented information is broken up into two types, documents and records. A form is a kind of document. When the form is filled out it becomes a record. Quality manual, policy, procedure or work instructions are other kinds of documents.

The specific documents and records you are required to control are listed in the table below

Topic	Type of documented information	Requirement
Determining the scope of the QMS	Document	The scope of the organization's QMS shall be available and be maintained as documented information.
QMS and its processes	Document	To the extent necessary, the organization shall maintain documented information to support the operation of its processes.
QMS and its processes	Record	To the extent necessary, the organization shall retain documented information to have confidence that the processes are being carried out as planned.



Communicating the quality policy	Document	The quality policy shall be available and maintained as documented information.
Quality objectives and planning to achieve them	Document	The organization shall maintained documented information on the quality objectives.
Monitoring and measuring resources	Record	The organization shall retain appropriate documented information as evidence of fitness for purpose of the monitoring and measurement resources.
Measurement traceability	Record	Measuring equipment shall be calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; when no such standard exists, the basis for calibration or verification shall be retained as documented information.
Competence	Record	The organization shall retain appropriate documented information as evidence of competence.
Documented information	Document	The organization's QMS shall include documented information determined by the organization as being necessary for the effectiveness of the QMS.
Review of the requirements for products and services	Record	The organization shall retain documented information, as applicable, on the results of review and on any new requirements for products and services.
Design and development planning	Record	The organization shall consider the documented information needed to demonstrate that design and development requirements have been met.
Design and development inputs	Record	The organization shall retain documented information on design and development inputs.
Design and development controls	Record	The organization shall apply controls to the design and development process to ensure that documented information of these activities is retained.
Design and development outputs	Record	The organization shall retain documented information on the design and development outputs.



Design and development changes	Record	The organization shall retain documented information on design and development changes and the results of reviews.
Control of externally provided process, products and services	Record	The organization shall retain documented information of these activities and any necessary actions arising from the evaluations.
Identification and traceability	Record	The organization shall control the unique identification of the outputs when traceability is a requirement, and shall retain documented information necessary to enable traceability.
Property belonging to customers or external providers	Record	When the property of a customer or external provider is lost, damaged or otherwise found to be unsuitable for use, the organization shall report this to the customer or external provider and retain documented information on what has occurred.
Control of changes	Record	The organization shall retain documented information describing the results of the review of changes, the person(s) authorizing the change, and any necessary actions arising from the review.
Release of products and services	Record	The organization shall retain documented information on the release of products and services. The documentation shall include evidence of conformity with the acceptance criteria and traceability to the person(s) authorizing the release.
Control of nonconforming outputs	Record	The organization shall retain documented information that describes the nonconformity, actions taken, any concessions obtained and identifies the authority deciding the action in respect of the nonconformity.
Monitoring, measurement, analysis and evaluation	Record	The organization shall retain documented information as evidence of the results [of QMS performance evaluation].
Internal audit	Record	The organization shall retain documented information as evidence of the implementation of the audit program and the audit results.
Management review outputs	Record	The organization shall retain documented information as evidence of the results of management reviews.
Nonconformity and	Record	The organization shall retain documented



corrective action		information as evidence of the nature of the nonconformities and any subsequent actions taken and the results of any corrective action.
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The documented information listed above is required because it confirms that your Quality Management System is maintained and effective. Documented information is also used as evidence of conformance, provides consistency in how a process is executed, assists with training and prevents loss of knowledge.

All documented information must be controlled. This means that you have a process for identifying, reviewing and approving documents as well as using an appropriate format and media for the contents of the documented information. You need to ensure the documented information is available for those that need to access it, is protected, version controlled and inactive/old versions are disposed of properly. In addition, a retention policy needs to be established for specifying the length of time you will retain your required records

**Self-Check 1****Written Test**

Name: _____

Date: _____

Instruction: Answer all the questions listed below, if you have some clarifications- feel free to ask your teacher.

Direction: True or False. Write “True” if the statement is correct or “false” if the statement is incorrect on the space provided.(each 2pts)

1. Documentation can be provided on digital or analog media basis.
2. The quality policy shall be available and maintained as documented information.
3. Documented information is NOT used as evidence of conformance.

Direction: choose the best answer and encircle the correct letter of your choice (each 3pts)

1. Which one of the following is not a document?
 - A. QMS and its processes
 - B. QMS and its processes
 - C. Communicating the quality policy
 - D. Quality objectives and planning to achieve them
2. Which one of the following is not a record?
 - A. Internal audit
 - B. Management review outputs
 - C. Measurement traceability
 - D. Determining the scope of the QMS

Note: Satisfactory rating – 3 out of 6 points

Unsatisfactory - below 3 and 6 points



Information Sheet 2 Recommending suitable preventive action

Record all services and process

The management of documents and records is one of the essential elements of the quality control system. The management system addresses both use and maintenance of documents and records. A major goal of keeping documents and records is to find information whenever it is needed. It provides written information about policies, processes, and procedures.

Records are information, either written by hand or computer printed. They are permanent, and are not revised or modified. They should be complete, legible and carefully maintained, as they are used for many purposes, such as:

Continuous monitoring—without access to all the data collected as a part of a quality system process, continuous monitoring cannot be accomplished;

- **tracking of samples**—well-kept records allow for tracking of samples throughout the entire testing process; this is essential for troubleshooting, looking for sources of error in testing, and investigating identified errors;

- **evaluating problems**—well-kept equipment records will allow for thorough evaluation of any problems that arise;

- **Management**—good records serve as a very important management tool.

Never change a record. If new information needs to be added to a record, it should be noted as an addition, with a date, and signature or initials.

Documents include written policies, processes, and procedures, and provide a framework for the quality system. They need to be updated and maintained. Records include information captured in the process of performing and reporting a laboratory test. This information is permanent, and does not require updating.

Having a good document control program assures that the most current version of a document is used, and ensures availability and ease of access when a document is needed. Quality Records is a completed form or Table that proves the action took place.



Self-Check 5.2	Written Test
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Name: _____

Date: _____

Instruction: Answer all the questions listed below, if you have some clarifications- feel free to ask your teacher.

I. Direction: True or False. write “true” if the statement is correct or “False” if the statement is incorrect on the space provided.(each 2pts)

1. Records are information that can be revised or modified.
2. Quality Records is a completed form that proves the action took place.
3. The management of records is an essential element of the quality control system

Note: Satisfactory rating – 3 out of 6points Unsatisfactory - below 3 and 6points



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This curriculum was developed on September 2020 at Bishoftu

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Answer Key for self-check
Module Title: Applying Quality Control

LO #1-Acquiring and confirming agreed quality standard and procedures

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

Self-Check 1	Written Test
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Answer keys:

Direction: True or False. Write “True” if the statement is correct or “False” if the statement is incorrect on the space provided.

1. True
2. False
3. True
4. True
5. False

Self-Check 2	Written Test
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Answer keys:

Direction 1. : true or false. write “true” if the statement is correct or “false” if the statement is incorrect on the space provided.

1. True
2. False
3. False

Direction 2. choose the best answer and encircle the correct letter of your choice

3. C
4. D

Self-Check 3	Written Test
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Answer keys:

Direction: True or False. write “true” if the statement is correct or “False” if the statement is incorrect on the space provided.

1. True



2. True
3. True

Direction: choose the best answer and encircle the correct letter of your choice

1. D
2. C

Self-Check 4	Written Test
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Answer keys:

Direction: explain the following

3. Improved product reliability
Improved process control and flow
Improved documentation of processes
Greater employee quality awareness
Reduction in waste, reworks, and rejections of products

4. Customer Focus
Leadership
Engagement of People
Process Approach
Improvement
Evidence-Based Decision Making
Relationship Making

5. Leadership Involvement
Quality Policy, Objectives, and Planning
Risk Based Thinking
Corrective and Preventative Actions
Continual Improvement

LO #2-Assess quality of service delivered

Self-Check 1	Written Test
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Answer keys:

Direction: True or False. write “True” if the statement is correct or “False” if the statement is incorrect on the space provided



1. True
2. True
3. False
4. False

Self-Check 2	Written Test
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Answer keys:

Direction: True or False. write “true” if the statement is correct or “False” if the statement is incorrect on the space provided.

1. True
2. False
3. True
4. True

Direction: choose the best answer and encircle the correct letter of your choice

- E. d
- F. D

Self-Check 3	Written Test
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Answer keys:

Direction: True or False. write “True” if the statement is correct or “False” if the statement is incorrect on the space provided.

1. True
2. False
3. True
4. True

Self-Check 4	Written Test
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Answer keys:

I. Direction: True or False. write “true” if the statement is correct or “False” if the statement is incorrect on the space provided.



1. True
2. True
3. False
4. True

Self-Check 5	Written Test
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Answer keys:

Direction: True or False. write “True” if the statement is correct or “False” if the statement is incorrect on the space provided.

1. True
2. True
3. False

LO #3-Record information

Self-Check 1	Written Test
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Answer keys:

I. Direction: True or False. write “True” if the statement is correct or “False” if the statement is incorrect on the space provided.

1. True
2. False

II. Direction: choose the best answer and encircle the correct letter of your choice on

1. D

Self-Check 2	Written Test
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Answer keys:

- I. Direction: True or False. write “True” if the statement is correct or “False” if the statement is incorrect on the space provided.**



1. True
2. True
3. True

II. Direction: choose the best answer and encircle the correct letter of your choice on

1. D

LO #4-Study causes of quality deviations

Self-Check 1	Written Test
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Answer keys:

I. direction: true or false. write “true” if the statement is correct or “false” if the statement is incorrect on the space provided.

1. True
2. False

II. Direction: choose the best answer and write the correct letter of your choice on the space provided

1. B

Self-Check 2	Written Test
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Answer keys:

direction: True or False. write “True” if the statement is correct or “False” if the statement is incorrect on the space provided.

1. True
2. True



Self-Check 3	Written Test
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Answer keys:

Direction: True or False. write “True” if the statement is correct or “False” if the statement is incorrect on the space provided.

1. True
2. True

LO #5-Study causes of quality deviations

Self-Check 1	Written Test
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Answer keys:

I. Direction: True or False. write “True” if the statement is correct or “False” if the statement is incorrect on the space provided.

3. True
4. True
5. False

II. Direction: choose the best answer and write the correct letter of your choice on the space provided

2. B
3. D

Self-Check 2	Written Test
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I. Direction: True or False. write “True” if the statement is correct or “False” if the statement is incorrect on the space provided.

1. True
2. True-
3. True



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