Mechanics

Level-III

Learning Guide-47

Unit of Competence: Apply Quality Control

Module Title: Applying Quality Control

Module Code: XXXXX

LG Code: XXXXX

TTLM Code: XXXXX

LO1: Implement quality standards

Instruction Sheet	Learning Guide #47

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

- Introducing quality
- 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 trainees to attain the learning outcome stated in the cover page. Specifically, **upon completion of this Learning Guide, trainees will be able to**:

- Set agree quality standards and procedures
- Provide quality standard and procedures documents
- Establish/Implement quality standards

Learning Instructions:

1. Read the specific objectives of this Learning Guide
2. Follow the instructions described from 3 to 3
3. Read the information written in the information “Sheet 1, Sheet 2, Sheet 3, Sheet 4, and Sheet 5”.

Information Sheet 1	Introducing quality

1.1. Introduction

Quality began during the age of craft production, the 1700s and before. During this period, individual craftsmen produced items for use by others. The craftsmen were totally responsible for the product from start to finish. Consider Paul Revere, an American silversmith in Boston in the late 1700s. He was personally responsible for all aspects of what he produced. He designed the items, obtained supplies, developed production techniques, probably made many of his tools, sold the items to customers, and handled any complaints. He also received any suggestions or requests for custom-made.

The term "**quality**" has a relative meaning. This is expressed by the ISO definition: "The totality of features and characteristics of a product or service that bear on its ability to satisfy stated or implied needs". In simpler words, one can say that a product has good quality when it "***complies with the requirements specified by the client***".

Quality - The prime task of any business is to understand the needs of the customer, then deliver the product or service at the agreed time, place and price, on every occasion. This will retain current customers, assist in acquiring new ones and lead to a subsequent increase in market share.

Quality—*Degree* of *excellence a product or service provides*

It is a simple question, but with a not-so-simple answer

- ✓ The Oxford American Dictionary defines quality as “a degree or level of excellence.”
- ✓ The definition of quality by the American National Standards Institute (ANSI) and the American Society for Quality Control (ASQC) is “the totality of features and characteristics of a product or service that bears on its ability to satisfy given needs.” Quality can be defined in many ways, depending on who is defining it and to what product or service it is related.

- ✓ The oxford dictionary defines quality as “degree of excellence, relative nature or kind or character. General excellence.”

If you ask people about quality, you may get a diverse range of answers. People may say; “Quality” is a perception. Quality could be all things to all people. Quality like beauty lies in the eyes of the beholder. Quality like any other concept begins in the mind. Quality is found in great abundance in our daily life. We live in a quality age, in a quality home, fully of quality furniture. We buy quality goods and drive a quality car and demand quality service from others.

a) More meanings of Quality from the Public:

- Efficient, effective, above average, quality performance
- Flawless or nearly flawless
- The best of what you can get
- Having something that I can depend on
- Goes above and beyond what is considered average
- Quality is functional
- Something dine to the nest of your ability
- Excellence
- Quality is in the eye of the beholder
- Something that will last
- Good workmanship
- Reliable, above standard, better than average, long lasting
- Lives up to what is promised to do
- Taking pride in your performance
- Something tried and true, good reputation
- Better than just normal
- Quality time, giving 100% of ourselves without distractions
- Really listening and responding with caring and respect
- Making the most of your time as though it were truly precious

- Providing training that develops human resources
- Good enough so it won't break and will last a long time
- You have it when you should
- Things are just done right

b) Quality means different to different people and has many meanings:

- Customer-Based: Fitness for use, meeting customer expectations.
- Manufacturing-Based: Conforming to design, specifications, or requirements. Having no defects.
- Product-Based: The product has something that other similar products do not that adds value.
- Value-Based: The product is the best combination of price and features.
- Transcendent: It is not clear what it is, but it is something good...
- Conformance with requirements/specification: measures how well the product or service meets the targets and tolerances determined by its designers.
- The totality of characteristics of an entity that bear on its ability to satisfy
- Stated or implied needs.
- Fitness for use/purpose: focuses on how well the product performs its intended function or use.
- Freedom from defects, imperfections or contamination.
- Delighting customers.

Other meanings associated with the word quality are as follows:

- A good product
- Sturdy/robust
- Durable
- Made of best materials
- Easy to operate
- Nice in appearance and touch
- Produced with care

Quality, therefore, can be described as, “Meeting the stated and implied needs of the customer.” Kordupleski et al. (1993) proposes that it would help in the understanding of quality if we differentiate between customer-perceived quality, which they term “true quality” and business process quality, which they term “internal quality.”

Why Quality?

Reasons for quality becoming a cardinal priority for most organizations:

- Competition – Today’s market demand high quality products at low cost. Having `high quality’ reputation is not enough! Internal cost of maintaining the reputation should be less.
- Changing customer – The new customer is not only commanding priority based on volume but is more demanding about the “quality system.”
- Changing product mix – The shift from low volume, high price to high volume, low price have resulted in a need to reduce the internal cost of poor quality.
- Product complexity – As systems have become more complex, the reliability requirements for suppliers of components have become more stringent.
- Higher levels of customer satisfaction – Higher customers’ expectations are getting spawned by increasing competition.

Relatively simpler approaches to quality viz. product inspection for quality control and incorporation of internal cost of poor quality into the selling price, might not work for today’s complex market environment.

1.2. Benefits of Quality

The benefits of quality in project performance are many. First, a quality project and product will yield customer satisfaction. If you meet or exceed requirements and expectations, customers will not only accept the results without challenge or ill feeling, but may come back to you for additional work when the need arises.

A satisfied customer may perceive greater value than originally anticipated, which goes beyond customer satisfaction to customer delight. Reduced costs are another benefit. Quality processes can reduce waste, improve efficiency, and improve supplies, all things that mean the project may cost less than planned. As costs go down, profits may go up (depending

on the pricing arrangement in the contract on which the project is based) or reduced costs may mean more sales to an existing customer within existing profit margins.

Finally, better products, better project performance, and lower costs translate directly into increased competitiveness in an ever-more-global market- place.

“Quality is that elusive/indefinable entity that everyone is talking about. Customers want it! The media promote it! Manufacturers, developers, providers, suppliers, etc, seek it! Unfortunately, to paraphrase true (quality) is like ghosts, who everyone talks about and few have seen.”

Customer satisfaction oriented benefits of TQM are;

1. Improvement in product quality
2. Improvement in product design
3. Improvement in production flow
4. Improvement in employee morale and quality consciousness
5. Improvement in product service
6. Improvement in market place acceptance

Economic improvement oriented benefits of TQM are,

1. Reduction in operating costs
2. Reduction in operating losses
3. Reduction in field service costs
4. Reduction in liability exposure

Quality is an endless journey. It is like walking toward the horizon. No matter how much far you walk, it does not change where the horizon is.

1.3. Factors Affecting Quality

The quality of products and services are directly affected by many base factors. In today's, world these factors play a crucial role in an organization are listed below.

a) Markets

New products are hitting the market at an explosive rate. Many of these products are manufactured by material and methods unheard till a few years back. Customers demand and get better products today.

b) Money

As competition has increased, profit margins have decreased. Automation forced companies to spend heavily on new equipment's and processes.

c) Man

The rapid growth of technology and opening of new fields have created a great demand for workers with specialized knowledge. This specialization of people has created a need for persons who can bring together this knowledge to plan and create operating systems that will bring the desired results.

d) Materials

Due to high material costs engineers have to constantly keep coming up with ways to bring down the cost of material used. They also need to come up with new alternate materials that can replace costlier older material.

e) Machines

The demand to cut costs is forcing companies to use newer machines, which will deliver better quality and product using lesser cycle times. Further the machines need to deliver higher quantities also to keep production costs low. This means maintaining of these machines also becomes critical as any and only down time of these machines leads to increased costs.

f) Management

Today responsibility for product quality has to be distributed among, various functions. For example, design of design for quality of product design. Manufacturing for process quality, service for after sales quality and marketing for establishing the quantity of the new product required. This means that top management should ensure proper allocation of responsibilities to all to achieve the organization goals.

g) Motivation

The increased complexity of the product means that every employee has to give his best if quality is to be maintained. This requires that quality conscious nesses among employees are high. This can be achieved only through continuous education and motivation of the work force. Motivation, therefore, needs to be on the top of the agenda for any management team of an organization.

Information Sheet 2	Acquiring and confirming agreed quality standard and procedures

2.1. Quality Control/Quality Assurance

Quality control (QC) is a process through which a business seeks to ensure that product quality is maintained or improved with either reduced or zero errors. Quality control requires the business to create an environment in which both management and employees strive for perfection. This is done by training personnel, creating benchmarks for product quality and testing products to check for statistically significant variations.

Quality Control/Quality Assurance (QC/QA) can be defined as the set of planned and systematic activities focused on providing confidence that quality requirements will be fulfilled. It covers a wide range of matters that influence the quality of a product or service. In a medical laboratory, the quality can be defined as accuracy, reliability, and timeliness of the reported test results (1). QC refers to those measures that must be included in each assay to verify that the test is working properly. QA is defined as the overall program that ensures that the final results reported by the laboratory are as correct and accurate as possible.

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

Information Sheet 3	Introducing standard procedures

3.1. Standard procedures definition

Standard procedure is defined as a prescribed **procedure** to be followed routinely; "rote memorization has been the educator's **standard** operating **procedure** for centuries" **standard** operating **procedure** (SOP).

A **Standard Operating Procedure** is a document which describes the regularly recurring operations relevant to the quality of the investigation. The purpose of a **SOP** is to carry out the operations correctly and always in the same manner. ... Several categories and **types of SOPs** can be distinguished.

Purpose of standard operating procedures

The **purpose** of a **SOP** is to provide detailed instructions on how to carry out a task so that any team member can carry out the task correctly every time. The **purpose** or objective of a **SOP** should restate and expand a well-written title. A well-written **SOP** will facilitate training.

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

Information Sheet 4	Providing quality standard and procedures documents

4.1 Quality Standards

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

Who Uses Quality Standards?

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

- Satisfying their customers' quality requirements
- Ensuring their products and services are safe
- Complying with regulations
- Meeting environmental objectives
- Protecting products against climatic or other adverse conditions
- Ensuring that internal processes are defined and controlled

Use of quality standards is voluntary, but may be expected by certain groups of stakeholders. Additionally, some organizations or government agencies may require suppliers and partners to use a specific standard as a condition of doing business.

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

Figure 1: quality standard elements

Quality standards are:

- Consensus (agreement) Standard:
  - A set of quality attributes which, through consensus of its developers, provides a consistent process for producing the exact same product each time, e.g., ISO 9000.
  - Standards may be adopted voluntarily or by regulation and should be reviewed regularly for ways to update or improve process.
- Benefits of standards include:
  - Documenting quality standards forces you to review all aspects of your process.
  - Providing a way to assure that an item complies with contract specifications.
  - Attracting buyers, including the government, because of its repeatable quality.
  - Saving money by providing the necessary indicators and tools to identify problem areas and ways to correct those areas.

ISO 9000 Standards

- ISO 9000 is a family of standards for quality management systems.
  - They were developed by International Organization for Standardization (ISO), patterned from a British quality program and first published in 1987.
  - The American Society for Quality (ASQ) and the American National Standards Institute (ANSI) also produce standards and work with ISO.
- ISO standards are:
  - Based on need to meet customer's requirements, regulations, and satisfaction.
  - Adopted by organizations and then they must become accredited.
  - Used worldwide—new edition is ISO 9001:2008.
  - Applied broadly to all products; doesn't differentiate between picture frames and nuclear components.

Six Sigma Basics

- Six Stigmas is the methodology for improving the performance of any organization by minimizing the defects in its products or services.
- **Every error committed has a cost associated with it including:**
  - Losing customers
  - Redoing a task
  - Replacing a part
  - Wasting time/efficiency
- Most of the organizations around the world deliver results in the Three to Four Sigma band which implies that they are losing around a quarter of total revenue due to defects in their organizations.

Applying Six Sigma

- **Define, Measure, Analyze, Improve** and **Control** (DMAIC) and Define for Six Sigma (DFSS) are the elementary methodologies that exist for two potential scenarios.
  - **DMAIC:** This methodology is required to modify an existing process and make it Six Sigma compliant and more efficient. DMAIC is an acronym for:

- **Define** the goals for process improvement in coherence with the customer's demand and the organization's strategies
- **Measure** the current performance and collect relevant data for the future
- **Analyze** the current setting and observe the relationship between key parameters and performance
- **Improve** the process based on the analysis to further optimize the process
- **Control** the parameters before they affect the outcome

Quality Assurance (QA): Planned actions (programmatic) necessary to provide adequate confidence or a performance guarantee that a product will perform satisfactorily:

- Following defined processes before production.
- Systematic approach for evaluation, inspection, testing, calibration, or whatever is needed to monitor and assure the quality of your product.
- Use of checklists, company audits, and project audits.

When Implementing a QA Program

Begin by identifying the critical business tasks, processes, or systems and documenting instructions. Use the instructions for training and day-to-day reference. A quality assurance program will reduce the:

- Number of errors
- Waste of time and materials associated with errors
- Number of customer complaints
- Number of problems to fix
- Time spent on giving day-to-day instructions
- Time needed to improve processes and systems (by establishing a stable base)

Following a widely-accepted quality standard program, such as the ISO 9000 system, initially will save you time and money if you become certified. The implementation plan should include:

- Quality coordinator
- Discipline task teams
- Quality team
- Policy development—quality and operational
- GAP analysis
- Map processes
- Quality manual development
- Communication/education/training
- Audit procedures
- Accreditation (optional)

Evaluating a Quality Control Approach in a Proposal

The government evaluation will consider several factors to evaluate your Quality Control Approach in a proposal:

- The degree to which your approach to quality control identifies processes, procedures, and metrics which, are likely to predict successful outcome within cost and on schedule.
- Specific considerations of whether your proposal addresses a Quality Control Approach or identifies specific processes and procedures that are logical predictors of successful realization of stated mission objectives.
- Other areas evaluated are:
    - Metrics identified in the Quality Control Approach that will logically predict success on the task.
    - Methods and procedures in the Quality Control Approach that will reliably collect the specified metrics.

How to Get Technical in a Proposal

- Your Quality Assurance model and approach should illustrate processes which are likely to predict successful outcome of projected deliverables within cost and on schedule. The technical evaluation will review Quality Assurance from a risk management perspective to address the risk of noncompliance and the risk of missing the project objectives. Thus a Quality

Assurance framework is essentially a component of your overall risk management framework. Quality Assurance Risk Management poses risk and opportunities to an organization.

- Leading organizations define Quality Assurance as a continuous process of verifying or determining whether products or services meet or exceed customer expectations. This process considers design, development, production, and service. Your toolset for Quality Assurance should include evaluator accuracy, data processing, and report generation.
- Your Quality Assurance model should address measures to **Plan-Do-Check-Act(PDCA)** as a four stage cycle which you must go through to get from 'problem-faced' to 'problem solved.' All phases incorporate activities for continuous improvement to refine the scope to which PDCA is applied until there is a plan that involves improvement.

Quality Control Approach

- The concept of the PDCA Cycle was originally developed by Walter Shewhart, the pioneering (new) statistician who developed statistical process control in the US Bell Laboratories during the 1930s.
- **Plan:** Establish the objectives and processes necessary to deliver results in accordance with the expected output. Making the expected output the focus, differs from what would otherwise be. The completeness and accuracy of the specification is part of the improvement.
- **Do:** Implement the process developed. Perform tasks as designed and expected by management, reinforced by training and guidance from key stakeholders.
- **Check:** Measure, monitor and evaluate the implemented process by testing the results against the predetermined objectives and compare the results to ascertain any differences.
- **Act:** Analyze the differences to determine their cause. Apply actions necessary for improvement if the results require changes. Determine where to apply changes that will include improvement.

- **Improve:** Improvement incorporates the tracking of individual processes with statistics on performance compared to stated objectives. This information can be used to work with internal stakeholders, customers, and suppliers to improve interconnected processes to enhance overall business performance.

☞ When a pass through of these four steps does not result in the need to improve, refine the scope to which PDCA is applied until there is a plan that involves improvement.

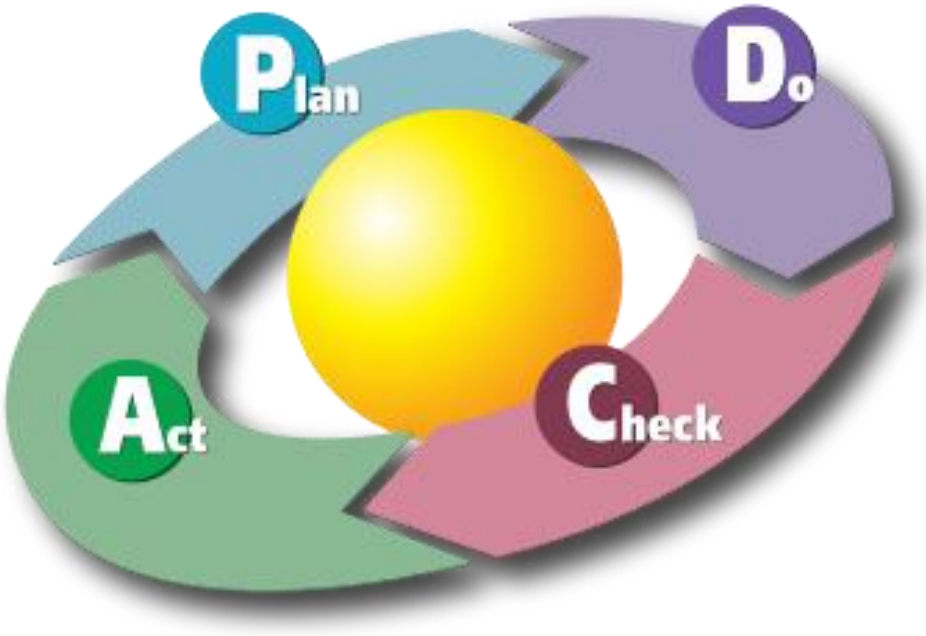

Figure: Quality Control Approach

Information Sheet 5	Revising / updating standard procedures

5.1. Improve Quality Standards

Quality improvement (for better control) is a process for changing **standards**. It is not a process for maintaining or creating new **standards**. **Standards** are changed through a process of selection, analysis, corrective action on the **standard** or process, education and training.

Ways to updating quality standard procedures

1. Assess the current **Quality Standards** and ensure they are accessible.
2. Consistency is a critical consideration for **quality standards improvement**.
3. Data is Everywhere:
4. Create a Culture of **Quality** Ownership.
5. Continuous Customer-Centricity.
6. Utilize Quality Management System Software.

Mechanics

Level-III

Learning Guide-48

Unit of Competence: Apply Quality Control

Module Title: Applying Quality Control

Module Code: XXXXX

LG Code: XXXXX

TTLM Code: XXXXX

LO2: Assess quality of service delivered

Instruction Sheet	Learning Guide #48

This learning guide is developed to provide trainees 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 trainees to attain the learning outcome stated in the cover page. Specifically, **upon completion of this Learning Guide, trainees will be able to**:

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

Learning Instructions:

1. Read the specific objectives of this Learning Guide
2. Follow the instructions described from 3 to 3
3. Read the information written in the information “Sheet 1

Information Sheet 1	Quality standards and specifications

1.1. Introduction

Services delivered are quality checked against organization quality standards and specifications.

Unlike a code or **standard**, which can apply broadly to an industry and region, **specifications** outline the requirements of a specific company or product. A **specification** provides specific requirements for the materials, components or services used **in an** application

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

Specification and its types

A **specification** is often a **type** of technical standard. There are different **types** of technical or engineering **specifications** (specs), and the term is used differently in different technical contexts. They often refer to particular documents, and/or particular information within them.

The three types of **construction** specifications are prescriptive, **performance**, and proprietary.

Methods of specifications

The following are common types of specification:

- Requirement Specifications. Documentation of a business need.
- Design Specifications.
- Material Specifications.
- Standard Specifications.
- Interface Specifications.
- Test Specifications.

- Performance Specifications.
- Quality Specifications.

1.2. Importance /Benefits of Quality Control | Production Management

1. Encourages quality consciousness:

The most important advantage derived by introducing quality control is that it develops and encourages quality awareness among the workers in the factory which is greatly helpful in achieving desired level of quality in the product.

2. Satisfaction of consumers:

Consumers are greatly benefited as they get better quality products on account of quality control. It gives them satisfaction.

3. Reduction in production cost:

By undertaking effective inspection and control over production processes and operations, production costs are considerably reduced. Quality control further checks the production of lower wastages thereby bringing down the cost of production considerably.

4. Most effective utilization of resources:

Quality control ensures maximum utilization of available resources thereby minimizing wastage and inefficiency of every kind.

5. Reduction in inspection costs:

Quality control brings about economies in inspection and considerably reduces cost of inspection.

6. Increased goodwill:

By producing better quality products and satisfying customer's needs, quality control raises the goodwill of the concern in the minds of people.

7. Higher morale of employees:

An effective system of quality control is greatly helpful in increasing the morale of employees, and they feel that they are working in the concern producing better and higher quality products.

8. Improved employer-employee relations:

Quality control develops to better industrial atmosphere by increasing morale of employees which ensures cordial employer-employee relations leading to better understanding and closeness between them.

9. Improved techniques and methods of production:

By supplying technical and engineering data for the product and manufacturing processes, improved methods and designs of production are ensured by quality control.

10. Effective advertisement:

Organizations producing quality products have effective advertisement. They win the public confidence by supplying those better quality products.

11. Facilitates price fixation:

By introducing quality control measures, uniform products of same quality are produced. This greatly facilitates the problem of price fixation. One price of standard products becomes prevalent in the market.

12. Increased sales:

Quality control ensures production of quality products which is greatly helpful in attracting more customers for the product thereby increasing sales. It is greatly helpful in maintaining existing demand and creating new demand for the product. It has been rightly pointed out that quality control is a powerful instrument with the help of which markets both at home and abroad can be expanded.

Service delivered are evaluated using the appropriate evaluation quality parameters and in accordance with organization standards.

Product Quality: Product quality is defined as the collection of features and characteristics of a product that contribute to its ability to meet given requirements.

The characteristic of a product or service that satisfies the customer's wants and needs in exchange for monetary considerations. If the consumer is satisfied that he/she had a fair exchange, then the quality is acceptable. A perception of high quality or that which is above expectations can help to create high brand loyalty and in turn helps create brand equity for the company.

If a consumer buys Maytag washers due to past exceptional service, then this quality level has helped create brand loyalty.

Suggested eight dimensions of product quality which are very important to customers include; Performance- primary operating characteristics of a product,

- **Features**- 'bells and whistles' of a product,
- **Reliability**- probability of a product failing within a specified period of time;
- **Durability**- measure of a product life;
- **Conformance**- degree that a product's design matches established standards;
- **Serviceability**- speed and competency of repair;
- **Aesthetics**- subjective measure of how a product looks, feels, sounds, smells or tastes;
- **Perceived quality**- subjective measure of how the product measures up against a similar product.

1.3. Customer specifications

A customer specification is a document issued by a **customer** that describes the requirements of a system and the expected services of a contractor.

The most important asset of an organization is its customer. An organization's success depends on how many customers it has, how much they buy and how often they buy. Customers that are satisfied will increase in number, buy more and buy more frequently.

Increasingly, manufacturing and service organizations are using customer satisfaction as the measure of quality. The importance of customer satisfaction is not only due to national competition but also due to worldwide competition.

Total Quality Management (TQM) implies an organizational obsession with meeting or exceeding customer expectations, so that customers are delighted. Understanding the customer's needs and expectations is essential to winning new business and keeping existing business. An organization should give its customers a quality product or service

that meets their needs at a reasonable price, which includes on-time delivery and outstanding service. To attain this level, the organization needs to continually examine their quality system to see if it is responsive to ever-changing customer requirements and expectations.

The most successful TQM programs begin by defining quality from the customer's perspective. Quality means meeting or exceeding the customer's expectations. Dr. Deming added that quality also means anticipating the future needs of the customer. Customer satisfaction, not increasing profits, should be the primary goal of the organization. It is the most important consideration because satisfied customers will lead to increased profits.

The customer as satisfying perceives that part of the square that lies within the circle and the part of the square outside the circle is perceived as unnecessary. It is important that the organization listens to the "voice of the customer" and ensures that its marketing, design, production and distribution processes truly meet the expectations of the customer.

Customer satisfaction seems simple enough and yet it is far from simple. Customer satisfaction is not an objective statistic but more of a feeling or attitude. Although certain statistical patterns can be developed to represent customer satisfaction, it is best to remember that people's opinions and attitudes are subjective by nature. Because customer satisfaction is subjective, it is hard to measure. There are so many facets to a customer's experience with a product or service that need to be measured individually to get an accurate total picture of customer satisfaction.

Since customer satisfaction is hard to measure, the measurement of ten is not precise. As with most of the attitude, there is variability among people and often within the same person at different times often due to the difficulty of measuring feelings.

Customer satisfaction should not be viewed in a vacuum. For example, a customer may be satisfied with a product or service and therefore rate the product or service highly in a

survey and yet that same customer may buy another product or service. It is of little benefit to understand a customer's views about a product or service if the customer's views about competitors' product or service are not understood. The value customers place on one product compared to another may be a better indicator of customer loyalty. Customer loyalty can be sustained only by maintaining a favorable comparison when compared with competitors. As mentioned before, customer satisfaction is not a simple concept to understand or to measure.

Who Are the Customers?

Customers are the individuals and businesses that purchase goods and services from another business. To understand how to better meet the needs of its customers, some businesses closely monitor their customer relationships to identify ways to improve service and products.

There are two distinct types of customers-- external and internal. An external customer can be defined in many ways, such as the one who uses the product or service, the one who purchases the product or service, or the one who influences the sale of the product or service. For instance, McDonald's determined the customer to be the child when they introduced their "happy meals." The child never paid for the meals but the child influenced the sale. Oftentimes, parents purchase lawnmowers and yet the teenage children use the lawnmowers. The identity of the external customer is not always easy to determine.

An external customer exists outside the organization and generally falls into three categories-- **current, prospective and lost customers**. Each category provides valuable customer satisfaction information for the organization. Every employee in an organization should know how his or her job enhances the total satisfaction of the external customer. Performance should be continually improved in order to retain existing customers and to gain new ones.

An internal customer is just as important. Every function, whether it is engineering, order processing, or production, has an internal customer-- each receives a product or service

and, in exchange, provides a product or service. Every person in a process is considered a customer of the preceding operation. Each worker's goal is to make sure that the quality meets the expectations of the next person. When that happens throughout the manufacturing, sales and distribution chain, the satisfaction of the external customer should be assured.

All processes have outputs which are used by internal or external customers and inputs which are provided by internal or external suppliers. Each supplier performs work that produces some service or product that is used by another customer.

The leader's role is to process work through the internal customer-supplier chain by helping workers guarantee that the end product or service fully satisfies the end user. Rather than strive for personal objectives, each individual or group should identify and satisfy the internal customer(s) while fostering a team effort where all people help the organization. Each department should determine what activities are important to both external and internal customers and manage quality every step of the way. All quality management systems start with the basic need of ensuring that the external customer's requirements are adequately documented. Similarly, the organization should document explicitly what each internal customer expects. In addition, a clear criterion should be provided for measuring success in meeting the expectations of both internal and external customers.

4.2 Customer Perception of Quality

One of the basic concepts of the TQM philosophy is continuous process improvement. This concept implies that there is no acceptable quality level because the customer's needs, values and expectations are constantly changing and becoming more demanding.

The factors of performance, features, service and warranty are the parts of a product or service quality. Therefore, it is evident that product quality and service are more important than price.

a) Performance

Performance involves “fitness for use.” It is a phrase that indicates that the product and service is ready for the customers use at the time of sale. Other considerations are as follows:

- Availability which is the probability that a product will operate when needed
- Reliability which is freedom from failure over time
- Maintainability which is the ease of keeping the product operable

b) Product Features

Identifiable features or attributes of a product or service are psychological, time-oriented, contractual, ethical and technological. Features are secondary characteristics of the product or service. For example, the primary function of an automobile is transportation, whereas a car stereo system is a feature of an automobile.

c) Service

An emphasis on customer service is emerging as a method for organizations to give the customer-added value. However, customer service is an intangible, i.e. it is made up of many small things, all geared to changing the customer’s perception. Intangible characteristics are those traits that are though not quantifiable yet contribute greatly to customer satisfaction. Providing excellent customer service is different from and more difficult to achieve than excellent product quality.

d) Warranty

A product warranty represents the organization’s public promise of a quality product backed up by a guarantee of customer satisfaction. Ideally, it also represents a public commitment to guarantee a level of service sufficient to satisfy the customer. A warranty forces the organization to focus on the customer’s definition of product and service quality. An organization has to identify the characteristics of product and service quality and the importance the customer attaches to each of those characteristics. A warranty

generates feedback by providing information on the product and service quality. It also forces the organization to develop a corrective action system.

Finally, a warranty builds marketing muscle. The warranty encourages customers to buy a service by reducing the risk of the purchase decision and it generates more sales from existing customers by enhancing loyalty.

e) Price

Today's customer is willing to pay a higher price to obtain value. Customers are constantly evaluating one organization's products and services against those of its competitors to determine who provides the greatest value. However, in our highly competitive environment, each customer's concept of value is continually changing. Ongoing efforts should be made by everyone having contact with customers to identify, verify and update each customer's perception of value in relation to each product and service.

f) Reputation

Most of us find ourselves rating organizations by our overall experience with them. Total customer satisfaction is based on the entire experience with the organization, not just the product.

What is Customer Satisfaction?

It is a measure of how products and services supplied by a company meet or exceed customer expectation. Customer satisfaction is defined as "the number of whose reported experience with a firm, its products, or its services exceeds specified satisfaction goals.
Customer satisfaction is defined as a measurement that determines how happy customers are with a company's products, services, and capabilities. Customer satisfaction information, including surveys and ratings, can help a company determine how to best improve or changes its products and services.

There are two important questions to ask when establishing customer satisfaction:

1. Who are the customers?
2. What does it take to satisfy them?

Why customer satisfaction is important?

1. A Loyal customer is a treasure you should keep and hide from the world. ...
2. They can stop being your clients in a heartbeat. ...
3. It's (all) about the money, too. ...
4. Customer satisfaction is a factor that helps you stand out of the competition. ...
5. Great customer experience can take your brand places.

4.3 Dissatisfied, Satisfied and Delighted Customers

Depending on the extent to which his requirements are met, a customer may be classified as dissatisfied, satisfied or delighted. If his requirements are not adequately met, a customer will be dissatisfied. If his requirements are just met, he will be satisfied. If, however, his requirements have been exceeded, he will be delighted. Thus, the dissatisfaction, satisfaction and delight of a customer are dependent on his expectations and the performance of the product or service.

A dissatisfied customer is sure to go to the competition at the earliest opportunity. A satisfied customer will be retained as long as no alternative choice's available. He can be lured away by an aggressive competitor offering a more attractive choice. A delighted customer is a loyal customer and will be retained even if he has an alternative available to him.

4.4 Checking of Customer Satisfaction

a) Feedback

Customer feedback should be continually solicited and monitored as customers continually change. They change their minds, their expectations and their supplier. Customer feedback is not a one-time effort. In fact, it is an ongoing and active probing of the customers' mind. Feedback enables the organization to do the following:

- Discover customer dissatisfaction
- Discover relative priorities of quality
- Compare performance with the competition
- Identify customers' needs
- Determine opportunities for improvement

Even in service industries, such as insurance and banking, customer feedback has become so important that it drives new product development. There are programs to identify and analyze errors, take corrective action and make ongoing enhancements. All these efforts are justified when the consumers' expectation levels are very high. Effective organizations take time out to listen to the voice of the customer and feed that information back to the idea stage.

Listening to the voice of a customer can be accomplished by numerous information collecting tools. The principal ones are the following:

- Comment cards
- Questionnaires
- Focus groups
- Toll free telephone lines
- Customer visits

b) Comment Card

A low-cost method of obtaining feedback from customers involves a comment card. It can be attached to the warranty card and included with the product at the time of purchase. The intent of the card is to get simple information, such as name, address, age, occupation and what influenced the customer's decision to buy the product.

A customer questionnaire is a popular tool for obtaining opinions and perceptions about an organization and its products and services. However, they can be costly and time consuming. Surveys may be administered by mail or telephone. In the form of questionnaires, the customer is asked to furnish answers relating to the quality of products and services.

Focus Groups Customer focus groups are a popular way to obtain feedback, but they too can be very expensive. These groups are very effective for gathering information on customer expectations and requirements.

c) Customer Visits

Visits to a customer's place of business provide another way to gather information. An organization can proactively monitor its product's performance while it is in use and thereby identify any specific or recurring problems. Senior managers should be involved in these visits and not delegate them to someone else.

d) Customer Care

An organization should revolve around the customer because customers are the key to any business. A customer, any customer, should be valued and treated like a friend. Responses to customer complaints should be immediate and should be more than the customer expected to receive.

e) Communication

An organization's communication to its customers should be consistent with its level of service quality. A customer will become dissatisfied if there is a difference between what has been advertised and what has been received. An organization communicates to its customers in many subtle ways. For instance, an organization communicates to its customers even by such means as an employee's telephone manners, or an automated voice response system that is fast and easy for the customer to use. Customer relationships are based on communication**.** An organization should listen to its customers and establish a level of trust.

f) Customer Retention

Customer retention is more powerful and effective than customer satisfaction. It represents the activities that produce the necessary customer satisfaction which creates customer loyalty and which actually improves the bottom line. Customer satisfaction surveys, focus

groups, interviews and observations can help determine what customers think of a service or a product.

Why should YOU care about managing customers?

- Times have changed
- Customers have escalating needs
- Competitors are delivering on these demands
- If you don't, you will be out of business
- Computer technology has contributed to this new world
- Business Case
- Dissatisfied customers usually don't complain
- Dissatisfied customers usually do defect
- Dissatisfied customers tell everyone they know
- Dissatisfied customers encourage others to defect

Why should you care about managing customers?

- Management Case
- Wants to see data
- How to know that customers are satisfied?
- Why should provide a choice?
- What is your plan to meet future customer needs?
- Government Case
- Should be the sole source of products/services
- Can others (gov or private) be providers
- Cost important but also value
- Government Performance and Results Act (GPRA)
- Explain in quantifiable terms how serving customers
- Value provided in fulfilling Agencies' missions
- Why we should continue to receive funding and support

The 10 Steps in Managing Customer

1. Select the service area to measure

2. Define products/services delivered to customers
3. Identify customer segments
4. Conduct targeted customer interactions
5. Research competitors
6. Select measures
7. Plan data collection
8. Gather and analyze customer data
9. Discuss findings and recommendations
10. Take action

Performance Measures

Performance measure includes the following criterion:

- Customer satisfaction/retention
- Market share, new market development
- Product and service quality
- Productivity, operational effectiveness and responsiveness
- Human resource performance/development
- Supplier performance/development
- Public responsibility/corporate citizenship

1.4. Customer Satisfaction Control Approach

Objective/s:

1. Define customer/ product;
2. Explain two dimensions for customer satisfaction;
3. Manage customer;

Understand the principles of TQM for customer satisfaction;

- What is a customer?

Anyone who is impacted by the product or process delivered by an organization.

External customer: The end user as well as intermediate processors. Other external customers may not be purchasers but may have some connection with the product.

Internal customer: Other divisions of the company that receive the processed product.

- What is a product?

The output of the process carried out by the organization. It may be goods (e.g. automobiles, missile), software (e.g. a computer code, a report) or service (e.g. banking, insurance)

- How is customer satisfaction achieved?

Two dimensions: Product features and Freedom from deficiencies.

- Product features – Refers to *quality of design*.

Examples in manufacturing industry: Performance, Reliability, Durability, Ease of use, Esthetics etc.

Examples in service industry: Accuracy, Timeliness, Friendliness and courtesy, Knowledge of server etc.

- Freedom from deficiencies – Refers to *quality of conformance*.

Higher conformance means fewer complaints and increased customer satisfaction. (This is related to free from defects.)

Customer measurement a piece of CRM

- Describes the many activities in managing relationships with customers
- What is a relationship?
- Continuing series of collaborative interactions
- Occurs over time
- Develops based on successive interactions
- Unique for each customer
- Why management?
- Each interaction offers:
- Ability to customize products/services to customers
- Opportunity to influence customers' percpetions
- Learn more about customers for the future
- Management of relationship encourages loyalty

Why should YOU care about managing customers?

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- Computer technology has contributed to this new world
- Business Case
- Dissatisfied customers usually don't complain
- Dissatisfied customers usually do defect
- Dissatisfied customers tell everyone they know • Dissatisfied customers encourage others to defect
- Result --- lost business…..forever!!

Why should you care about managing customers?

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- How to know that customers are satisfied?
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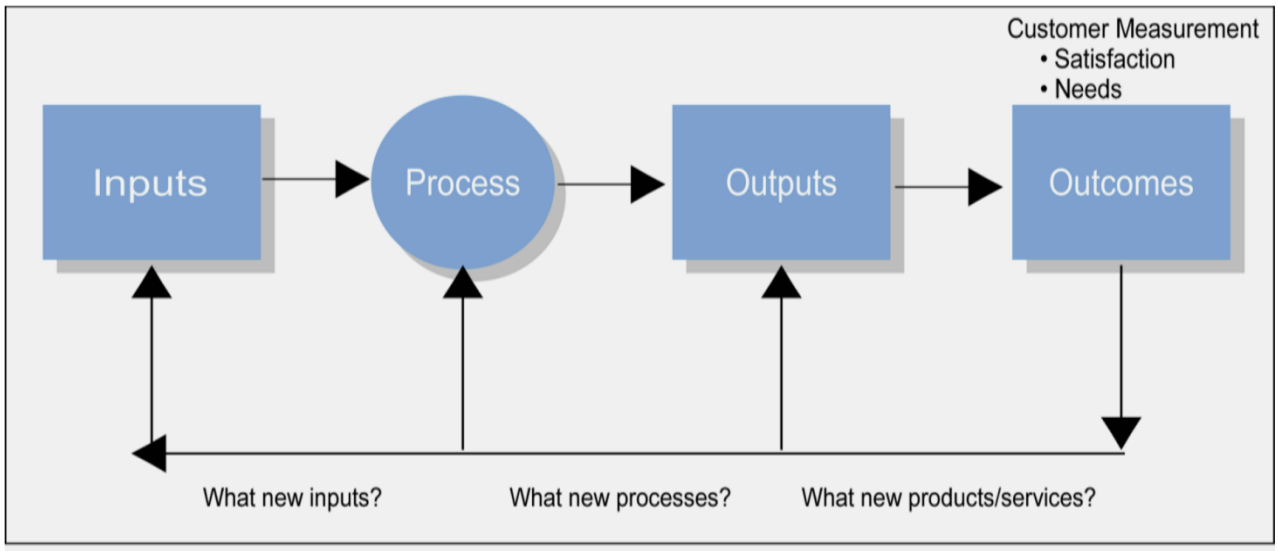
- Explain in quantifiable terms how serving customers
- Value provided in fulfilling Agencies' missions

Why we should continue to receive funding and support

Performance Measurement Model



If you can't measure it, you can't manage it.

The 10 Steps in Managing Customer

1. Select the service area to measure
2. Define products/services delivered to customers
3. Identify customer segments
4. Conduct targeted customer interactions
5. Research competitors
6. Select measures
7. Plan data collection
8. Gather and analyze customer data
9. Discuss findings and recommendations
10. Take action

Principle of TQM

The central idea is that it is more efficient to do all the activities at once. This saves the organization time corrections, failed products and service (including warranty repairs). This would ultimately save the organization costs. It is applicable both in

manufacturing companies and within service organizations. The goal of TQM is to do the right things the best time and again. Hammet describes 7 basic principles of TQM.

- The customer determines the quality.
- Improving quality requires the creation of effective quality measurement systems. Pure data is required and personal opinions should be excluded.
- People who work within systems create quality.
- Quality is a moving goal. It requires dedication to continuous improvement.
- Prevention rather than detection is the key to producing high quality.
- Quality must be in design and variations should be excluded as much as possible.
- Top management must provide leadership and support all quality initiatives.

A number of TQM currents use quality circles, such as Deming's. Unlike the radical Business Process Reengineering, TQM offers incremental changes.

The complaint management process

The complaint management process involves six steps that organizations can use to influence effective service recovery:

1. encourage complaints as a quality improvement tool;
2. establish a team of representatives to handle complaints;
3. resolve customer problems quickly and effectively;
4. develop a complaint database;
5. commit to identifying failure points in the service system; and 6. track trends and use information to improve service processes.

Customer retention is enhanced when an organization can reclaim customer complains through the development of effective service recovery programs. The organizations can become more customers oriented by taking advantage of the information provided by customer complaints, increasing customer satisfaction and retention in the process.

Summary: Assess quality of service delivered

1. *Check* Services delivered against organization *quality standards* and specification

Checklists

- Many activities use checklists to ensure that steps are followed in order. Checklists are also used to document completed actions. Any checklists or forms included as part of an activity should be referenced at the points in the procedure where they are to be used and then attached to the SOP.
- In some cases, detailed checklists are prepared specifically for a given activity. In those cases, the SOP should describe, at least generally, how the checklist is to be prepared, or on what it is to be based. Copies of specific checklists should be then maintained in the file with the activity results and/or with the SOP.

☞ Remember that the checklist is not the SOP, but a part of the SOP.

2. Evaluate Service delivered

Dimensions of Service Quality

- Reliability
- Responsiveness
- Assurance
- Empathy
- Tangibles

Reliability

- **Service is accomplished:**
  - On time
  - In the same manner (consistently)
  - Without errors

Responsiveness

- Willingness of employees to help customers and to provide prompt service

Assurance

- Knowledge and courtesy of employee
- Ability of the employee to convey trust and confidence

Empathy

- Provision of caring and individualized attention to the customer

Tangibles

- Appearance of the physical facility
- Appearance of employees
- Appearance of communication materials

Service Quality

- For services, the assessment of quality is made during the service delivery process.
- Customer satisfaction can be measured as the difference between the customer's service expectation and the service actually received.

Gaps in Service Quality

- Measuring the gap between expected service and perceived service is a routine customer feedback process practiced by many companies

Cost of Quality

- Insuring quality in a service delivery system may seem costly, but it is more costly to ignore quality
- Prevention of poor quality is less costly than fixing problems that result because of poor quality

Service Quality Gap

The gap between expected and perceivedservice is a measure of service quality

- Expectation **>** Service perceived (supposed) = Exceptional (excellent) Quality,
- Expectations **<** Service perceived = Unacceptable quality.
- Expectations **=** Service perceived = Satisfactory Quality.

Challenges of Measurements in Service Quality

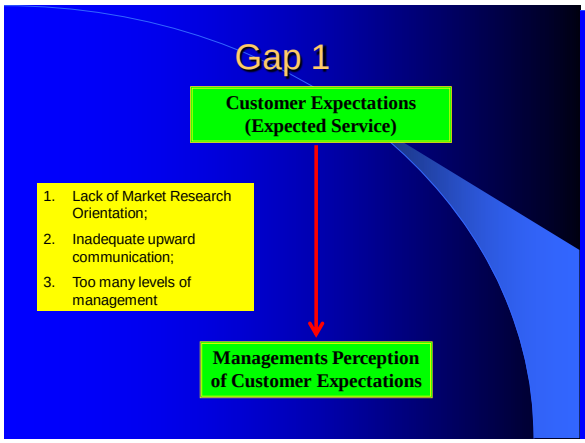
Definition of Dimensions

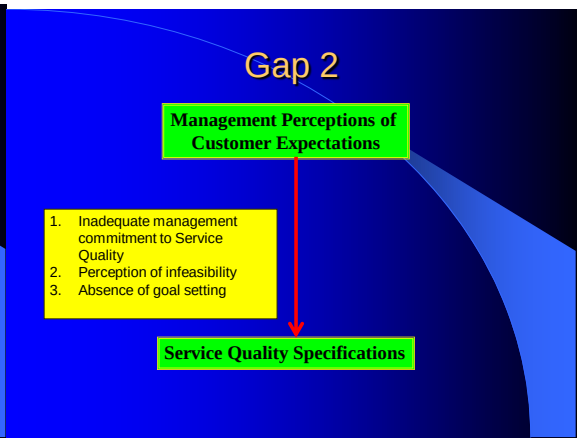
Dimension Measurements

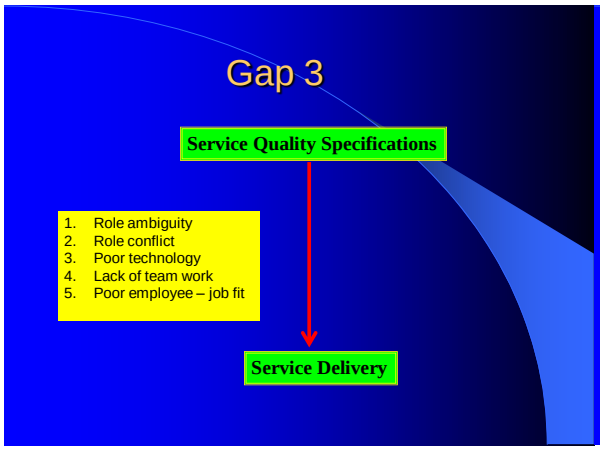
- Reliability – On time delivery performance, Errors in invoices
- Responsiveness – Cycle time (speed)
- Access – Availability (24x7), Downtime of web
- Credibility – Financial Ratings, Image

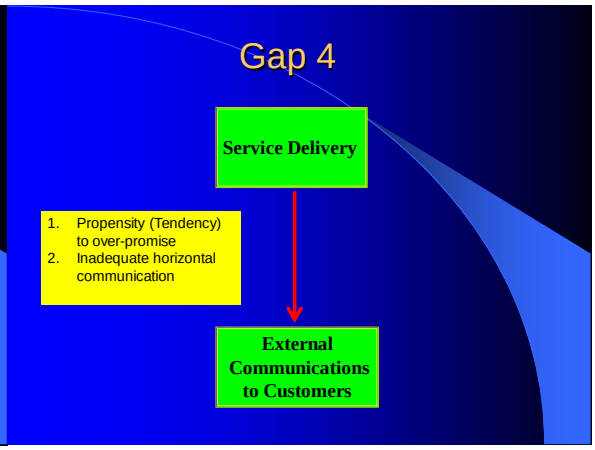
3. Identify and correct Causes of any faults and take actions

Causes of Service Quality Gaps (Customer Dissatisfaction)









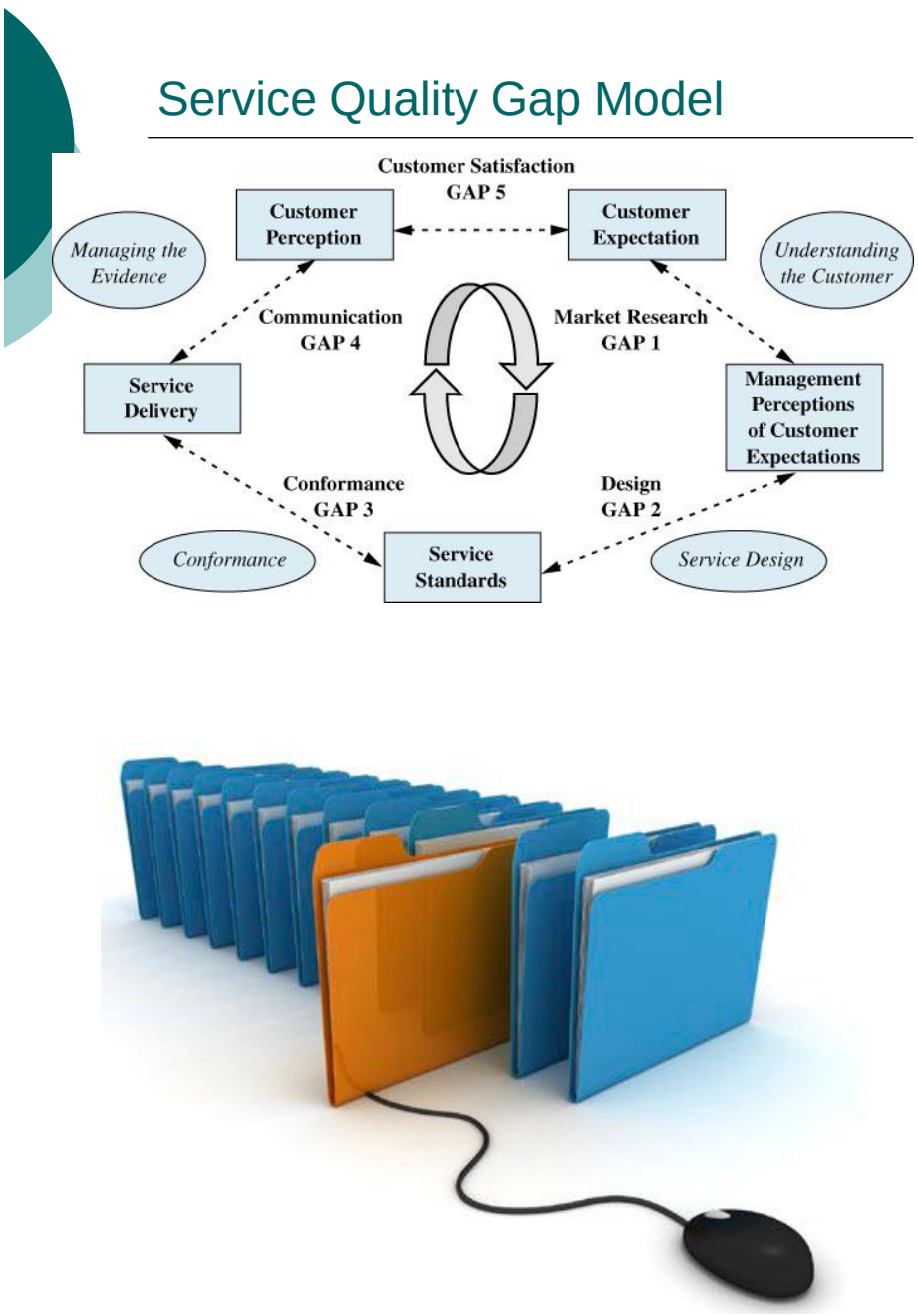


Figure: Identification of Causes of any faults and take actions

Mechanics

Level-III

Learning Guide-49

Unit of Competence: Apply Quality Control

Module Title: Applying Quality Control

Module Code: XXXXX

LG Code: XXXXX

TTLM Code: XXXXX

LO3: Record information

Instruction Sheet	Learning Guide #49

This learning guide is developed to provide trainees 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 trainees to attain the learning outcome stated in the cover page. Specifically, **upon completion of this Learning Guide, trainees will be able to**:

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

Learning Instructions:

1. Read the specific objectives of this Learning Guide
2. Follow the instructions described from 1 to 3
3. Read the information written in the information “Sheet 1, Sheet 2,

Information Sheet 1	Recording basic information on the quality performance

3.1. Record information

Basic information on the quality performance is recorded in accordance with organization procedures.

3.1.1 Quality records

Quality Records means Documents containing recorded information, regardless of the medium or characteristic, which demonstrate the effectiveness of the **quality** management system and that provide evidence that products meet regulatory requirements and comply with specified product requirements.

A Quality Record is quality management system documentation recording specific information that relates to a procedure or work instruction. Quality information records are used to manage the supplier relation in an organization.

When there is continuous defect in the material supplied by a vendor, you can use **Quality Info Records** to block a vendor.

When you create a purchase order, SAP system performs a check to find if a **Quality Info Record** is required and is available for combination of material and vendor.

3.1.2 Quality records Procedure

4. PURPOSE AND SCOPE

Purpose- define and describe the manner in which Quality Records are prepared, collected, identified, controlled, stored, corrected, dispositioned, retrieved and disposed

Scope- the scope of this procedure is applicable to our Company's Quality Management System quality records.

5. APPLICABLE DOCUMENTS

The following documents are applicable as to the extent specified herein:

Industrial/Commercial/Government Documents

ISO 9001:2008 Quality Management System Requirements

Internal

Document(s)

Form(s)

None

6. RESPONSIBILITIES

General

Quality Assurance - shall be responsible for preparing, complying with and maintaining this procedure.

Other Functional Departments - that prepare, use and retain Quality Records shall be responsible for adhering to this procedure.

7. PROCEDURE

General

- Our Quality Assurance Department ensures that records are established and maintained to

- provide evidence of conformity to requirements and of the effective operation of the quality
- management system. Records remain legible, readily identifiable and retrievable.

This procedure defines the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records.

Once Quality Records have been completed in accordance with applicable operating procedures, and served their purpose, they are retained in approved Quality Assurance locations and as specified in this document.

There are two types of media used to record Quality Records. The media types are:

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

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

Identification

Each record type is identified with the following information:

1. Record Type Name/Description
2. Record Type Part Number (When applicable)
3. Originator Name (Person who issued and/or recorded the data)

4. Date (The date the data was recorded)
5. Status of the Item: Pass/Accept or Fail/Reject (When applicable)
6. When applicable, the following shall also be recorded (when applicable):
    a. Serial Number/Lot Number/Date Code, and/or Quantity
    b. Product Part Number **Revision of Record**

Documentation Retention

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

Legibility

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

Changing Records

When changes are required in order to make the Quality Record accurate, the change shall be performed by the person who initially recorded the original data.

Quality Assurance and the employee's supervisor/management are also authorized to make necessary corrections and initial/date each change.

All changes shall be performed in a manner that does not make the old data un-readable.

A single line shall be drawn through the old data, the new data shall be recorded next to it, and initialed/dated by the approved person who made the change. Old data shall not be thrown away, and shall be kept with the new data. **Whiting out old text using liquid white-out is not acceptable**.

Receiving Inspection, Test or In-process/Final/Shipping Inspection results shall not be altered or modified in a manner that allows nonconforming material to be accepted by Quality Assurance as acceptable product.

Disposition of Records

Quality Records that have been damaged/missing/illegally altered/not legible/incomplete are brought to the attention of Quality Assurance for disposition in accordance with

QAP-1005, Nonconforming Material System.

Records Disposal

- Quality Records shall not be disposed of unless approved by Quality Assurance unless the minimum retention period(s) specified in Appendix A – Quality Records Retention is satisfied.

- Quality Records may be disposed of after the minimum retention period is satisfied or as directed by Customer order.

Storage

Quality Records are stored in manner so that the records will not be damaged (i.e. rain, fire, direct sun light, high humidity, etc.) or lost.

Protection

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

Retrieval

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

8. QUALITY ASSURANCE

General

Quality Assurance shall audit this process as scheduled per ***ATS-QAP***-1008, Internal Audits.

Table 1: Quality Records Retention

Item No.	Quality Record type	Minimum Retention Period	Responsible Function and Retention
1	ISO 9001 Management Report(s) and Quality Objective Data	3 Years minimum	Quality Assurance
2	Internal Audits; Schedule and Audit Results	3 Years minimum	Quality Assurance
3	Receiving Inspection Records; Vendor Supplied Packing Slips, C of C's, Vendor Data, etc.	3 Years minimum	Purchasing
4	Inspection and Test Documentation; Final Inspection Records	3 Years minimum	Business Operations/Human Resources
5	Purchasing Records; Supplier Purchase Orders	3 Years minimum	Purchasing
6	Customer orders, correspondence change documentation	3 Years minimum	Business Operations
7	Corrective Action(s); Internal, Supplier and Customer	3 Years minimum	Quality Assurance
8	Calibration Records (When Applicable)	3 Years minimum	Quality Assurance
9	Training Records	3 Years minimum	Training
10	Document Control Documentation/ERs/ECNs; ISO 9001 QMS (Manual, Procedures, Instructions, Forms)	3 Years and as defined by Customer Order	Quality Assurance
11	Proposals	3 Years for Customer orders and As Required for Non- Customer orders	Bid/Proposals or Corporate Secretary/General Admin.
12	Business Operations – Outsourcing and Business Solutions and Training Support Documentation & Software	3 Years minimum	Business Operations/Quality Assurance
13	Human Resource Documentation and Performance Reviews	3 Years minimum	Human Resources

Information Sheet 2	Maintaining records of work quality

3.2. Maintaining records of work quality/Control of Quality Records

Purpose- The purpose of this procedure is to ensure that all EBME Quality Records are correctly managed, and that the associated responsibilities are defined.

Scope: This procedure applies to all quality-relayed records

Quality Record: All quality management system documentation as described in the list (spreadsheet) of quality records. Computer/cloud storage: All data produced on any section databases and associated software that is quality related.

Responsibilities: It is the responsibility of the Quality Assurance Manager to ensure that all aspects of this procedure are adhered to and the responsibility of their senior manager to ensure that adequate facilities exist for the safe keeping of Quality Records.

Procedure: The Document Control procedure includes a list of approved documents and describes the arrangements for approval, issues and changes/modifications to documents.

These documents become quality records following completion of the quality related information for which each document has been designed. These records are then maintained for reference purposes to demonstrate achievement of the required quality and also the effective operation of the quality system.

Records are also maintained for relevant information not included in the quality system, e.g. pertinent subcontractor quality records, hazard warnings, NHS directives, manufacturers handbooks and records of management review meetings

etc.

Each type of record is maintained in a suitable electronic folder or hard-backed file and stored in a recognised location, such as a secure server, or in the case of paper based records, in a cupboard or filing cabinet.

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

Purchasing documents are held separately, while all audit related documents are held in a specific audit file held by the section manager. The remainder of the quality literature, records and documents are held by the quality assurance manager in a quality records file or in marked locations, while master documents are also held in a secure electronic location, or in a hard back folder. All locations must be logged and accessible to authorized staff. This ensures that retrieval of records can be performed when required and that deterioration and damage is reduced to a minimum.

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

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

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

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

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

The database records must be backed up daily (automatically using its own backup facility). Once a week a copy of the backup is to be retained off-site by the authorized officer. In the event of theft/fire the worst case scenario would be less than 5 working days of lost data.

A 10-Step Records Management Plan for Your Office

This document outlines the primary steps to follow to establish and maintain a records management program for your office;

First, as a Federal employee, at the FAA, you will be creating and using Federal government records. There are rules governing the use and destruction of all Federal records. For example, it is your responsibility to protect Federal records in your custody, and there are legal implications for destroying records without the proper authority.

Second, following good records management practices will not only help you meet legal requirements, they will benefit you and the Agency in many ways such as:

- Improving access to information;
- Controlling the growth of materials taking up valuable office space;
- Reducing operating costs;
- Minimizing litigation risks;
- Safeguarding vital information;
- Supporting better management decision making;

The ten (10) steps are:

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

Establish a project team with representatives from all sub units and job series (not just support and clerical staff) to oversee the project. The project team should:

- Set up a network of "records liaisons" with a lead person and liaisons for each office.
- Decide if everything will be done "in house" or if outside help (e.g., contractors) will be needed.

- Select one office or sub unit in which to initiate the project. Based on the experience obtained in this one office, you can estimate the resources needed to do other offices.

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

Conduct an inventory of the materials in your office. Don't forget to include empty offices, closets, and other areas where things may have been "stashed."

Document, at a minimum, where materials are located, how much there is, and the format (e.g., paper, electronic, maps, etc.). (When you have a "snapshot" of the scope of materials in your office, you may need to go back to Step 1 and review the resources available to complete the project.)

An inventory will help you identify which materials are:

- Records,
- Reference materials (nonrecords),
- Personal papers (nonrecords),
- Extra copies of documents, publications, and forms (nonrecords).

The inventory will also help you identify which records would need to be immediately available in the event of an emergency (vital records).

Step 2 resources

- Interactive Q & A: What is a Record?
- E-Mail Quick Reference Guide
- Frequent Questions about Working Files
- Frequent Questions about Personal Papers

Frequently Asked Questions About Records Inventories

Step 3. Establish your procedures (recordkeeping requirements).

Now that you know what you have in your office, the project team needs to determine:

- If records will be kept in a "centralized" area, or "decentralized" at individual work stations;
- The type of documents that are included in the record files;
- How draft documents, working papers, and concurrence copies will be handled.
- Who will be responsible for maintaining the record copy (records custodian).

Remember - Nonrecord materials such as convenience copies and personal papers need to be maintained separate from records.

Step 3 resources

- Centralized vs. Decentralized Filing

Step 4. Match your records to the records schedules.

The next step in the project is to match the records identified in your inventory with the *records schedules*. Records schedules provide information on how long records are to be kept in the office and what happens when they are no longer needed in the office. Retention periods as stated in the schedules are **mandatory**.

Step 4 resources

- Approved records schedules

If a records schedule is still in draft, you can not destroy records covered by that schedule until it has been moved to the approved portion of the website.

Contact your Program Office, Region, or Center Records Officer if:

- You can not find an appropriate records schedule;
- Your existing schedule is out of date or you need a new one.

Step 5. Prepare a "file plan."

Now that you know what records you have and what the appropriate records schedules are, you can begin to organize them. **Step 5 resources**

File Plan Guide

Step 6. Document your recordkeeping requirements and procedures.

Prepare a document, a *file plan*, which gives details on:

- How your records are organized and maintained,
- Who is responsible for doing what,
- When it should be done (e.g., annual file retirement),
- What happens to the records when they are no longer needed in the office.

Include all the decisions you made in steps 1 through 5 (e.g., what happens to draft documents).

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

Once you have documented your file plan you can begin to organize your records. First, however, it is a good idea to get rid of those materials in your office which are not needed. If authorized by the records schedule, you can:

- Retire records which are no longer needed in the office to offsite storage (e.g., the Federal Records Center (FRC)).
- Transfer permanent records to the National Archives, if appropriate. Contact your Program Office, Region, or Center Records Officer for assistance.
- Recycle materials which have passed their approved retention period. Remember to shred materials containing confidential or personal information.

Step 7 resources

- Using the Federal Records Center Tool Kit
    - **Step 8. Organize your records.**
    - Now you can begin to implement your file plan.
    - First, prepare folders and organize documents within the folders. Follow the procedures established in your file plan.
    - Place reference sheets in folders, when necessary, to refer users to the location of related non-paper materials such as maps, drawings, videotapes, etc.
    - Organize electronic documents (e.g., WordPerfect documents, e-mail messages) residing on individual computer or local network directories using the Agency file codes.
    - Remember to spend the majority of your time on the "mission-related" records and less on administrative or "housekeeping" records such as routine correspondence.

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

Once everything is organized, it is important to keep it current and up to date. Be sure to:

- File new materials on a regular basis (e.g., weekly).
- Protect records containing confidential information such as confidential business information (CBI) or personal information.

- Establish a check-out system (e.g., "out" cards) to track the location of your records so you always know where they are.
- Clean out inactive materials on a regular basis, usually at the end of the year (as per your written procedures).
- Retire eligible records to the FRC.

  Clean out superseded or obsolete reference materials.

  Step 10. Train, train, train.

  Congratulations! Now you have a file plan. You've cleaned out all the unnecessary materials and organized the necessary materials. Your job isn't over yet! You need to be sure all staff members (and contractors) know about their recordkeeping responsibilities. Records liaisons need to brief senior management on the importance of your records management program and train office staff on how it works.

  Your RO can help you with:
- Training sessions, including basic records management and records retirement;
- Tool kits giving more details on how to complete each of these steps; and,
- Presentations and handouts you can tailor for your particular office.

Mechanics

Level-III

Learning Guide-50

Unit of Competence: Apply Quality Control

Module Title: Applying Quality Control

Module Code: XXXXX

LG Code: XXXXX

TTLM Code: XXXXX

LO4: Study causes of quality deviations

Instruction Sheet	Learning Guide #50

This learning guide is developed to provide trainees 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 trainees to attain the learning outcome stated in the cover page. Specifically, **upon completion of this Learning Guide, trainees will be able to**:

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

Learning Instructions:

1. Read the specific objectives of this Learning Guide
2. Follow the instructions described from 1 to 3
3. Read the information written in the information “Sheet 1and Sheet 2,

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

4.1. Study causes of quality deviations

Causes of deviations from final outputs or services are investigated and reported in accordance with organization procedures.

What is a deviation? A departure from standard practices or specifications resulting in non-conforming material / or processes, with potential to impact on product quality, safety, efficacy or data integrity.

Deviation in manufacturing

In manufacturing, a deviation is a notable statistical different in the units being produced. It typically means that there is an increase in product defects or a notable change in product quality that is the same throughout several batches but not in accordance with product designs.

Deviations management

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
- Operation
- 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. While identifying ways to effectively implement **business** process improvement companies often search for causes of nonconformance in business operations to obtain deviations.

Deviations are trends investigated for corrective action and preventive action. Quality impact of deviations is usually identified upon reviewing the scope of nonconformance and trends of nonconformance in: - processes, material, suppliers, events etc.

A full closed loop process would be necessary to minimize deviations. The following are sources for identifying deviations:

1. Internal and external supplier audits
2. Customer complaint
3. Process controls e.g. statistical analysis
4. Root cause analysis
5. Product or materials deviation
6. Deviation of manufacturing facility, equipment, operations, distribution.

Process Variability

- Variations due to: Natural Causes:
    - Temperature variation
    - Material variation
    - Customer differences
    - Operator performance
- Variations due to Special Causes: Must be monitored
    - Machine is breaking and untrained operative

4.2. Recommending suitable preventive action

Preventive action: **Action** taken to prevent the occurrence of such non-conformities, generally as a result of a risk analysis. In certain markets and industries, CAPA may be required as part of the **quality** management system, such as the Medical Devices and Pharmaceutical industries in the United States.

A **preventive action:** is a change implemented to address a weakness in a management system that is not yet responsible for causing nonconforming product or service. ... The focus for **preventive** actions is to avoid creating nonconformance's, but also commonly includes improvements in efficiency.

Corrective and preventive action (**CAPA** or simply **corrective action**) consists of improvements to an organization's processes taken to eliminate causes of non-conformities or other undesirable situations. It is usually a set of actions that laws or regulations require an organization to take in manufacturing, documentation, procedures, or systems to rectify and eliminate recurring non-conformance. Non-conformance is identified after systematic evaluation and analysis of the root cause of the non-conformance. Non-conformance may be a market complaint or customer complaint or failure of machinery or a quality management system, or misinterpretation of written instructions to carry out work. The corrective and preventive action is designed by a team that includes quality assurance personnel and personnel involved in the actual observation point of nonconformance. It must be systematically implemented and observed for its ability to eliminate further recurrence of such non-conformation.

Corrective action: Action taken to eliminate the causes of non-conformities or other undesirable situations, so as to prevent recurrence. Preventive action: Action taken to prevent the occurrence of such non-conformities, generally as a result of a risk analysis.

CAPA is used to bring about improvements to an organization's processes, and is often undertaken to eliminate causes of non-conformities or other undesirable situations.[3] CAPA is a concept within good manufacturing practice (GMP), Hazard Analysis and Critical Control Points/Hazard Analysis and Risk-based Preventive Controls (HACCP/HARPC) and numerous ISO business standards. It focuses on the systematic investigation of the root causes of identified problems or identified risks in an attempt to prevent their recurrence (for corrective action) or to prevent occurrence (for preventive action).

Corrective actions are implemented in response to customer complaints, unacceptable levels of product non-conformance, issues identified during an internal audit, as well as adverse or unstable trends in product and process monitoring such as would be identified by statistical process control (SPC). Preventive actions are implemented in response to the identification of potential sources of non-conformity.

To ensure that corrective and preventive actions are effective, the systematic investigation of the root causes of failure is pivotal. CAPA is part of the overall quality management system (QMS).

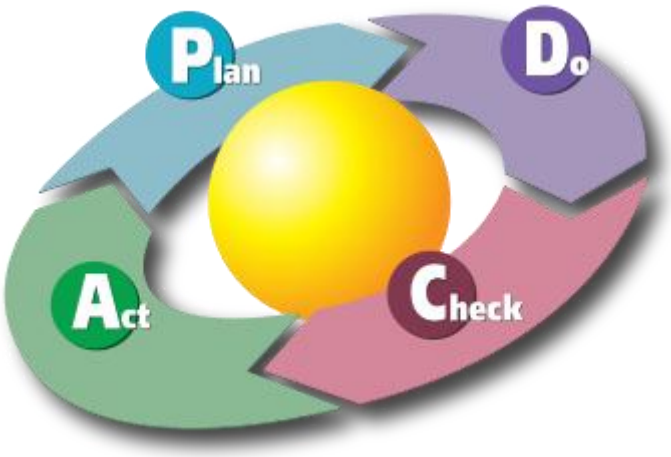


Figure 2: Preventive action of quality deviation

Summary: study causes of deviation

Investigate and report Causes of deviations from final outputs or services

Corrective and Preventative Action

- Internal and external data is reviewed to identify problems and appropriate corrective and preventative actions (user satisfaction and complaints, internal system and process audits, external quality assurance data, quality improvements…)
- Procedures for corrective and preventative actions must include an investigation to determine root causes.
- Effectiveness of corrective and preventative actions must be monitored and evaluated at management review

Continuous Improvement

- Action plans for improvement shall be developed, documented and implemented as appropriate.
- Prepare training plan.
- Management shall monitor effectiveness of the improvement action plan at management review.
- Results of the improvement program must be communicated to all staff.

☞ Among the essential elements of a well established Quality Management System (QMS), **deviation handling plays a key role** in assuring quality in products and by contributing to continuous improvement.

☞ Manufacturers are expected to "establish processes and define appropriate controls for measurement and analysis to identify nonconformities and potential non-conformities;

- Defining when and how corrections, corrective actions, or preventive actions should be undertaken.
- These actions should be appropriate with the significance or risk of the nonconformity or potential nonconformity"

☞A sequence of steps may be identified when handling events and possible deviations:

- Event (occurrence) Detection
- Decision Making Process / Deviation Categorization
- Deviation Treatment
- Root cause investigation

Event detection:

- The manner on how personnel react when in presence of an event is the first challenge to the system, and it largely depends on their level of training, qualification, commitment, and support form upper management.

Deviation Categorization

The decision tree describeis a simplified risk assessment that answers the following questions when an event is encountered:

A. Can the event affect a product attribute, manufacturing operational parameter or the product's quality?

B. Does the event contradict or omit a requirement or instruction contemplated in any kind of approved written procedure or specification?

Minor Deviations

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

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

Major Deviations

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

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

Deviation Treatment

☞A pre-existent QRM (Quality Risk Management) will contribute to determine the categorization of the deviation. If QRM has not been performed, it may be carried out at this time as part of the impact assessment in order to determine the criticality of the process parameters involved, and the risk to the patient.

Corrective and Preventive Actions (CAPA)

☞The root cause investigation process is a key step in handling major and critical deviations as it will provide objective evidence to implement corrective and possibly preventive actions as part of the CAPA system.

☞ Corrective Actions are taken to eliminate the root causes of deviations, and should be based on good quality investigations. Corrective actions should be QA approved before implemented and their efficacy verified in a documented manner, activity that could require a significant period of time. Corrective actions could be transferred to an independent CAPA system to avoid unnecessary delay for deviation closure. This independent CAPA system should include tracking of all actions required by a pre-approved CAPA plan and effectiveness check.

- Not all corrective actions will have associated preventive actions. Corrective actions are "reactive" in nature and are triggered in response to detected deviations and could generate preventive actions as well.
- These preventive actions (linked originally to nonconformities) will act on similar processes, manufacturing lines or different sites, where there has not been yet a deviation

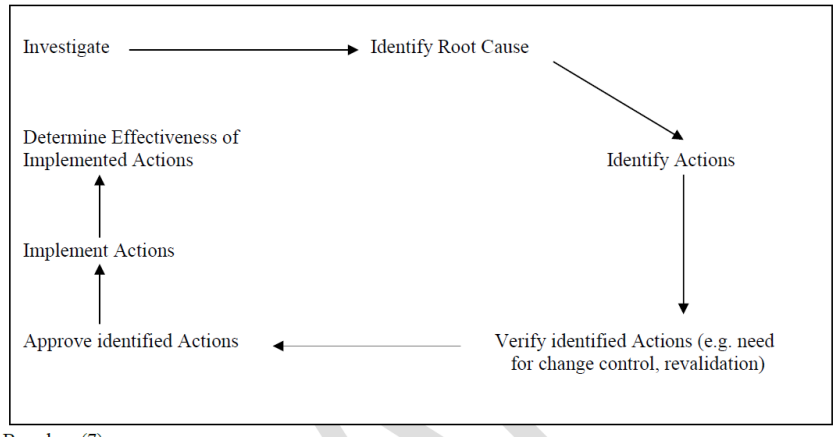


Figure 3: **Improvement Process**

- In addition, manufacturers are strongly recommended to identify preventive actions which are proactive (positive) in nature and are defined and implemented independently from the occurrence of deviations (i.e. preventive actions act on potential deviations).

- In other words, “The manufacturer may encounter situations that have not actually caused nonconformity, but may do so in the future. Such situations may call for preventive action.
- In order to achieve this, the QMS (Quality Management System) has to establish the different sources of information to be followed and trended as part of a systematic, periodic and documented evaluation, usually steered by QA.
- As part of the CAPA and improvement process, activities like product and QMS review (e.g. Annual Product Review) give the opportunity to summarize the accumulated information, findings and trends on an annual basis in order to identify systemic actions to improve the QMS.

☞ Examples of information sources to identify preventive actions regarding production process, equipment or facilities would include:

  - Manufacturing in-process control or Quality Control analytical trend data indicating that control or alert limits are being approached. Preventive actions could include actions planned to return process performance to nominal values from the edges of the process control range.

Risk assessment

Risk assessment includes the following sequential activities:

☞ **Identification of Hazards**, based on well-defined process description, and adequate sources of information (e.g. historical data; description of the possible consequences). It addresses the question “What might go wrong?”.

☞ **Risk Analysis** estimates the risk associated with the identified hazard/s. “It is the qualitative or quantitative process of linking the likelihood (probability) of occurrence and severity of harms; in some risk management tools, the ability to detect the harm (i.e. detectability) also factors in the estimation of risk”.

☞ **Risk Evaluation** “compares the identified and analyzed risk against given risk criteria and the strength of evidence for all three of the fundamental questions”.

Risk Control.

Risk Control is a decision making process to reduce the risk to an acceptable level. It includes:

- **Risk reduction:** mitigation or elimination of the risk when it exceeds a specified level (not acceptable), in terms of severity and probability of harm. “Processes that improve the detectability of hazards and quality risks might also be used as part of a risk control strategy. The implementation of risk reduction measures can introduce new risks into the system or increase the significance of other existing risks. Hence, it might be appropriate to revisit the risk assessment to identify and evaluate any possible change in risk after implementing a risk reduction process”. Any implementation of risk reduction measures should follow the established change control system.
- **Risk acceptance** is a formal decision to accept the residual risk or it can be a passive decision in which residual risks are not specified.

Purpose of Quality Risk Management

- Improve the understanding of processes through identification of hazards in the manufacturing process
- Identification of critical points associated to those hazards
- Identification of risk reduction actions at critical steps
- Evaluation of effectiveness of actions

Information sources for Quality Risk Management

- Product Development Reports
- Process and analytical technology transfer documentation
- Specifications and control methods of finished product, intermediates and raw materials
- Specifications and methods of in-process controls (IPC)
- Process flow diagram of each operation in each process stage, including operational parameters and established ranges

☞ Defined critical parameters with their appropriate justification

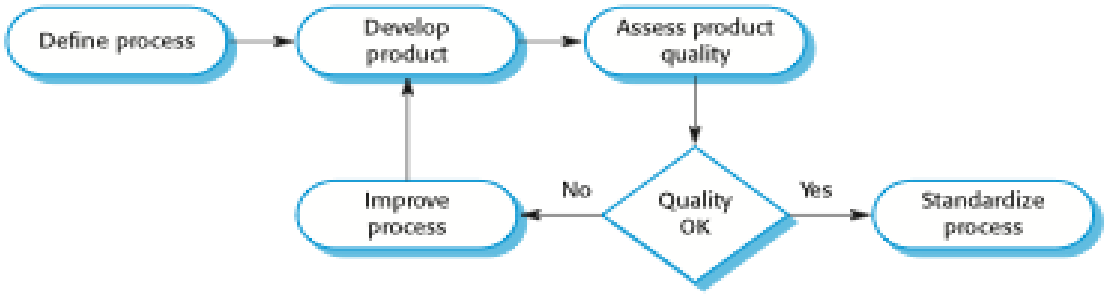
☞ Lists of equipment and measuring instruments to be used in the process, with their qualification, maintenance and calibration status

Figure 4: Quality Management system

Recommend Suitable preventive action based on organization quality standards

Internal Audits

- Documented internal audit program.
- Prepare annual internal audit program.
- This program must evaluate both the Quality Management System and every process in the loop.
- Review audits**.**



Management Review

- Goals and objectives versus progress
- Close out of complains and non conformances
- Monthly quality meetings
- Quality monitors
- External audits
- Third party assessments

Identifying causes of deviation from specific quality standards

- Communication skills needed to interpret and apply defined work procedures
- Fault Identification and Reporting
- Quality Standards

Mechanics

Level-III

Learning Guide-51

Unit of Competence: Apply Quality Control

Module Title: Applying Quality Control

Module Code: XXXXX

LG Code: XXXXX

TTLM Code: XXXXX

LO5: Complete documentation

Instruction Sheet	Learning Guide #51

This learning guide is developed to provide trainees 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 trainees to attain the learning outcome stated in the cover page. Specifically, **upon completion of this Learning Guide, trainees will be able to**:

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

Learning Instructions:

1. Read the specific objectives of this Learning Guide
2. Follow the instructions described from 1 to 3
3. Read the information written in the information “Sheet 1

Instruction Sheet-1	Record information and complete documentation

Record information and complete documentation

Record Basic information on the quality performance

Identify Records

- In every workplace you are required to identify and keep records.
- The records that you are required to keep will be determined by your job tasks. This workbook will discuss and provide examples and formative assessments for a range of commonly used records such as physical records, preparing and processing basic financial transactions, establishing and maintaining a cashbook and reconciling and preparing invoices.
- However the record keeping and administration requirements have many common factors related to the:
  - Types of records
  - Legislative requirements
  - Ethical standards
  - Technology and equipment used
- Both the physical and financial records of the business are vital for planning purposes, meeting legislative (law-making) requirements and the efficient operation of the business on a daily basis.

The four basic rules for record keeping are:

- **Useful** — don't waste your time keeping records you will never use.
- **Easy to use** — Simple and neat to encourage you to use the system.
- **Accurate** — Bad records can lead to poor decisions.
- **Compulsory** – These are the records you are required to keep by law e.g. financial records for tax returns.

- By having a better understanding of what records to keep and how to keep records, you will gain the skills and knowledge to participate in your workplace more efficiently and effectively.
- You cannot rely on your memory, so you need to record your physical and financial transactions. Through this process we are able to:

- satisfy various legal requirements
- assist in preparation of tax returns
- to help management identify areas where efficiencies can be introduced
- enable management to monitor business, exercise control and make informed decisions
- Use information from the past to plan for the future It is important when considering implementing recording systems that they are simple, easy to use, effective and suit the business.

❖ For your workplace, list all of the records that you keep specifically related to your job as well as a summary of others that you know are kept in the business.

❖ You are also required to comment as to why the records are kept. As a hint, consider the records listed previously as well as records like work diaries, materials received or dispatched incidents which may be subject to investigation or query at a later date, inventory control records, drawings, plans and specifications, work schedules, standard procedures and practices, permits.

WHAT SORT OF THINGS SHOULD BE RECORDED IN PHYSICAL RECORDS?

❖ As previously stated both the physical and financial records of the business are vital for

- planning purposes,
- meeting legislative requirements, and
- The efficient operation of the business on a daily basis.

❖ Physical records vary according to the particular business needs as well as legislative, compliance and standards requirements. The physical records are relevant to the efficient and productive management of the workplace so could be termed “Records for Management”.

☞ Information is only useful if the right information is collected in the right format.

☞ **The good news** is there is a great quantity of information available from every workplace, associated industries and organisations.

☞ **The bad news** is that a lot of that information is of limited value to us. Increasingly every business receives more and more information and data.

☞ As workers or managers in a business, it is often difficult to know what information to absorb and what to screen out.

As a basic criteria information must be:

- **Accurate**: Information is true and verifiable.**Current**: Information is applicable to the present time and/or needs of the business.
- **Relevant**: Information applies to the interests of the individuals who use it for the decisions they are facing.
- **Specific**: Information must contain concrete facts or answer specific questions.
- **Understandable**: People using the information must be able to understand it.
- **Comprehensive**: The information should include all the important categories within its scope of coverage.
- **Comparable**: The information presented should be of uniform collection, analysis, content, and format so that a user of the information can compare and contrast the various files.

Methods for collecting information may include:

- ☞ Observation and listening
- ☞ file records
- ☞ Individual research
- ☞ Statistics and reports from other organisations
- ☞ producing reports from data collected in the business
- ☞ translating data from diaries and note-books
- ☞ Professional data collection agency
- ☞ Interviews with colleagues/customers
- ☞ questioning (in person or indirect) via questionnaires or face to face interview
- ☞ Recruitment applications and other forms

Maintain (Keep up) Records according to work quality (Documentation)

Filing System

- Every business has filing to do and invariably multiple staff within the business need to be able to easily access information that is being filed.
- It is important to everyone in your workplace that you are diligent (attentive) about your filing responsibilities and properly follow the designated systems.
- There are three main areas applicable to the majority of workplace filing systems:
  - business records for financial management
  - technical information for physical management
  - personal information for OHS, employment, human resource management
- There are many different filing systems that can be adopted including:
  - Alphabetic
  - numeric
  - subject
  - geographic
  - technical systems
  - chronological (sequential)
- If business information is not easy to find, simple work can become a laborious chore (difficult task).
- It is therefore important that the system used is:
  - Simple
  - Easy to set up new files
  - Easy to retrieve files
  - Easy for someone else to use
- Have a look at the filing systems used in your workplace and remember that different filing systems may be used for different reasons. For example financial records are usually electronic yet the actual original invoices are held in paper files.
- When looking at our recording systems we need to ask ourselves the following question:
  - Why do I keep the records and how do I need to use the records in future?
  - How long do I need to retain records?
  - Who needs to access the records?

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