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UNIT III

QUALITY CONTROL

TQM involves a never ending process of continuous improvement with the objective of achieving perfection.

TWO APPROACHES

1. Acceptance sampling

2. Statistical Process Control.

STATISTICAL PROCESS CONTROL

It is the application of statistical methods to the measurement and analysis of variation in any process. It is used to measure the performance of a process and thereby ensure that the process is meeting the specified standards. It is a methodology for monitoring a process to identify special causes of variation and signalising the need to take corrective action when appropriate.

DEFINITION

JURAN & GRYNA – “The application of statistical methods to the measurement and analysis of variation in any process”.

A process is a unique combination of machine methods, materials and people that attains an output in goods or services.

TYPES OF VARIATION

1. **Natural - Common causes**
2. **Assignable – special causes**

QUALITY CONTROL MEASUREMENTS

TWO CATEGORIES

1. **Attribute**
2. **Variable**

ATTRIBUTE – MEANING

It is performance characteristics that is either present or absent in the product or service consideration. Ex. surface finish of furniture

VARIABLE – MEANING

Variable measurements are concerned with the degree of conformance to specifications.

Ex. Temperature in degree centigrade

CONTROL CHARTS FOR VARIABLES & ATTRIBUTES

SOURCES OF ASSIGNABLE CAUSES

i. **Equipment**
ii. **Material**
iii. **Environment**
iv. **Operator**

CATEGORIES OF VARIATION

i. **Within piece variation**
ii. **Piece to piece variation**
iii. **Time to time variation.**

CONTROL CHARTS

The control chart is a line chart with control limits. It is based on the work of Shewhart and Deming

3 BASIC COMPONENTS

1. **A control line, usually the mathematical average of all the samples plotted**
2. **Upper and lower control limits that define the constraints of common cause variations**
3. **Performance data plotted over time.**

   If the process is in control, nearly all the sample points will fall between UCL and LCL.

STEPS

1. **PREPARATION**
   - **1.1. Choose the variable or attribute**
   - **1.2. Determine the basis, size & frequency of sampling**
   - **1.3. Set up the control chart.**
2. **DATA COLLECTION**
   - **2.1. Record the data**
   - **2.2. Calculate relevant statistics, averages, proportions and so on.**
   - **2.3. Plot the statistics on the chart.**

3. DETERMINATION OF TRIAL CENTRAL LINES AND CONTROL LIMITS.

3.1. Draw the central line(Process average)on the chart

3.2. Compute the upper and lower control limits

4. ANALYSIS AND INTREPERTATION

4.1. Investigate and identify the points of lack of control.

4.2. Eliminate ‘Out of Control’ points.

4.3. Recompute control points, if necessary.

5. USE AS A PROBLEM SOLVING TOOL

5.1. Consider data collection and plotting

5.2. Identify out of control situations and take corrective action.

5.2. Identify out-of-control situations and take corrective action.

Types of Control charts.

- for variables
  - (i) $\bar{x}$ chart – Mean chart.
  - (ii) R chart – Range "
  - (iii) S chart for sample S.deviation
- attributes.
  - (i) p chart
  - (ii) np "
  - (iii) C "
  - (iv) U "

X chart.

$$UCL_{\bar{x}} = \bar{\bar{X}} + A_2\bar{R}$$

$$LCL_{\bar{x}} = \bar{\bar{X}} - A_2\bar{R}$$

A_2 = Constants.

$\bar{\bar{X}}$ = Average of the subgroup averages.

$\bar{R}$ = Average of the subgroup ranges.

R chart.

$$UCL_R = D_4\bar{R}$$

$$LCL_R = D_3\bar{R}$$

D_3 & D_4 = Constants.

$\bar{R}$ = Average of the subgroup ranges.

S chart for sample Std deviation

$$UCL_x = X + 3\sigma_{\bar{x}}$$

$$LCL_x = X - 3\sigma_{\bar{x}}$$

$$UCL_R = R + 3\sigma_R$$

$$LCL_R = R - 3\sigma_R$$

Control charts for attributes

1. P chart. chart for fraction rejected

$$UCL = \bar{p} + 3\sqrt{\frac{\bar{p}(1-\bar{p})}{n}} \qquad \bar{p} = \frac{\text{No. of defectives}}{\text{Total No. inspected}}$$

$$LCL = \bar{p} - 3\sqrt{\frac{\bar{p}(1-\bar{p})}{n}}$$

2. np-chart chart for number of defectives.

$$UCL = \overline{np} + 3\sqrt{\overline{np}(1-\bar{p})} \qquad \overline{np} = \frac{\text{Total No. of defectives}}{\text{No. of samples.}}$$

$$LCL = \overline{np} - 3\sqrt{\overline{np}(1-\bar{p})}$$

3. C chart - chart for non-conformities

$$UCL = \bar{c} + 3\sqrt{\bar{c}}$$

$$LCL = \bar{c} - 3\sqrt{\bar{c}}$$

4. U chart- chart for non-conformities per unit.

$$UCL = \bar{u} + 3\sqrt{\frac{\bar{u}}{n}}$$

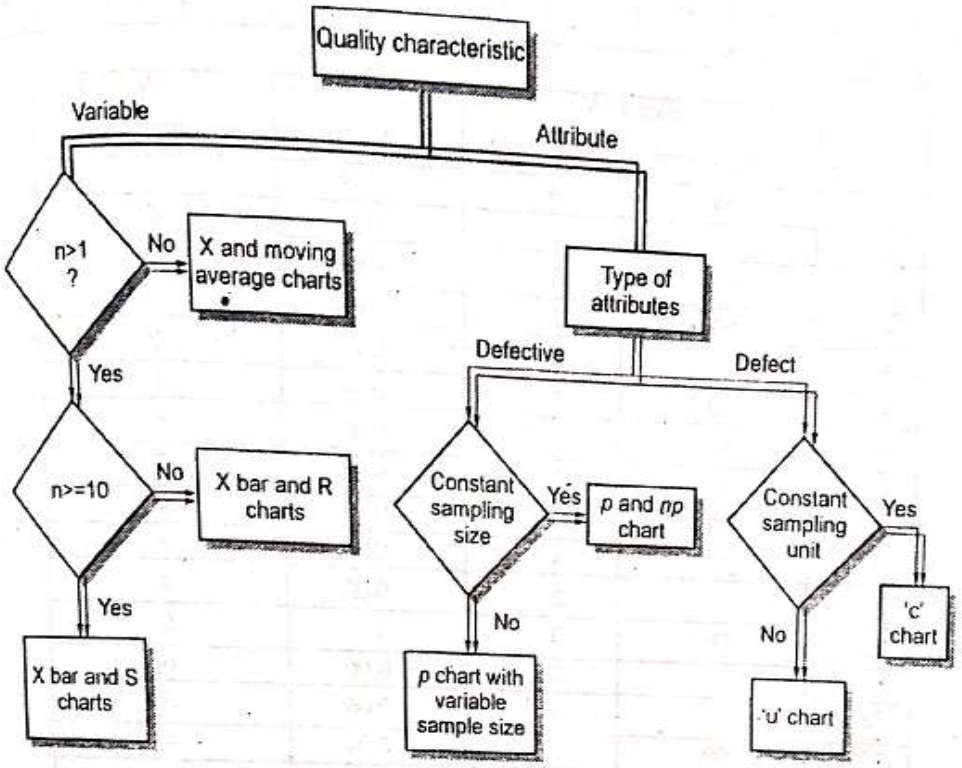
$$LCL = \bar{u} - 3\sqrt{\frac{\bar{u}}{n}}$$

Need for Control charts for attributes

(i) Used for quality characteristics

(ii) Q There are many variables in mfg unit. - Confusion / expensive

P Chart – Varying sample size
(average sample method)



Control chart selection

P - chart - Chart for fraction rejected

np - chart - Chart for number of defectives

c - chart - Chart for non-conformities

u - chart - Chart for non conformities per unit.

Illustration 2

SIGNIFICANCE OF SPC

i. **Detecting error at inspection**
ii. **More uniform quality of production**
iii. **Reduces inspection costs**
iv. **Reduces no of rejects and saves the cost of material**
v. **Determining the capability of the manufacturing process**
vi. **Provides process capability analysis with comparison to product tolerance**

manu... associated with the ...
together with the life cycle cost curves exhibited by many manufactured products

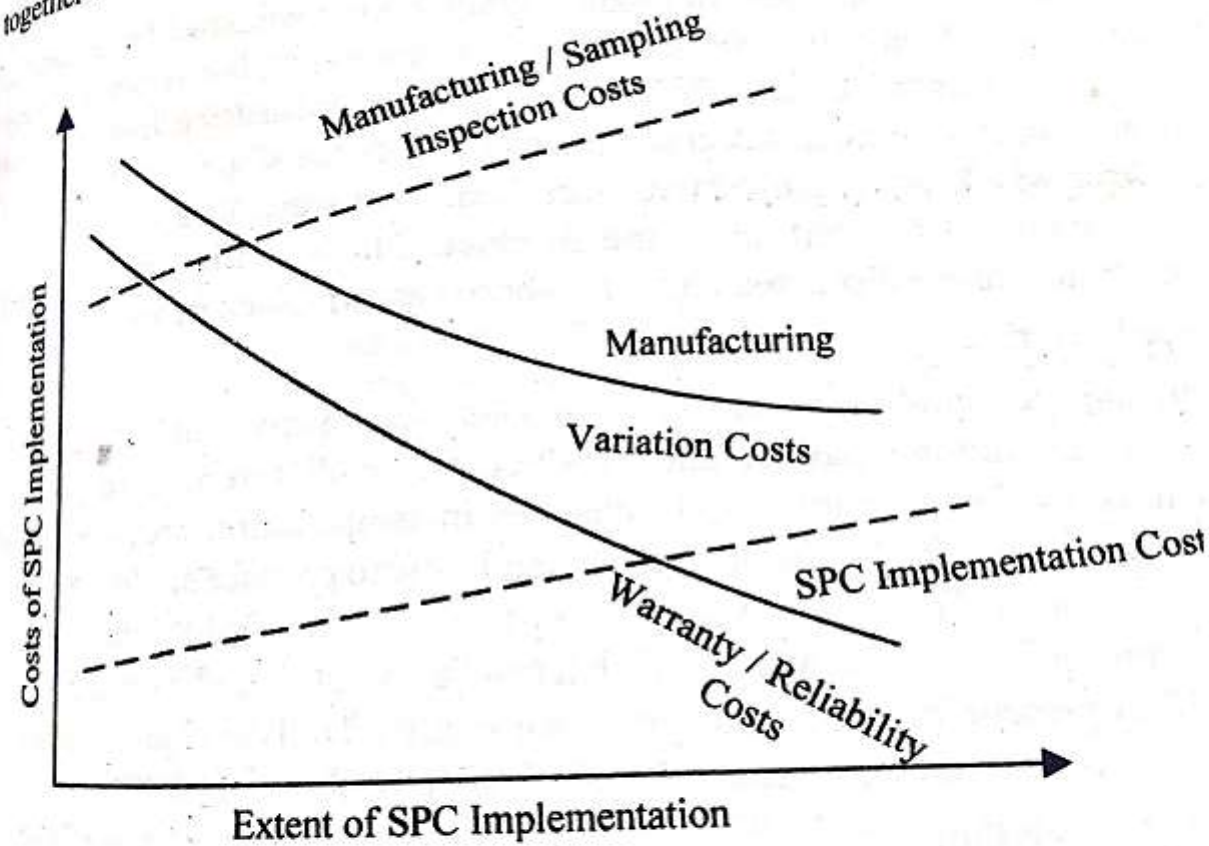


Figure 15.1 - SPC Implementation and Life Cycle Cost

PROCESS CAPABILITY

Process capability may be defined as the minimum spread of a specific measurement variation which will include 99.74% of the measurements (area under the normal curve between -3σ to 3σ) from the given process.

Refers to the ability of a process to produce uniform products with very low variations.

even process.

Refers to the ability of a process to produce uniform products with very low variations.

$$\text{Process Capability } (C_p) = \frac{\text{Total specification tolerance}}{\text{Total effective range.}}$$

$$C_p = \frac{T_u - T_L}{6\sigma}$$

T_u & T_L = Upper and Lower specification limits

$C_p = 1$ means process is capable.

$C_p < 1$ " " is not "

$C_p > 1$ " " is very "

Process Capability Index

$$\text{Process Cap Index } (C_{pk}) = \frac{\text{Average value} - \text{Nearest tolerance}}{\text{Half the effective range}}$$

$$= \frac{\bar{X} - T_L}{3\sigma} = \frac{T_u - \bar{X}}{3\sigma} = \text{Whichever is less.}$$

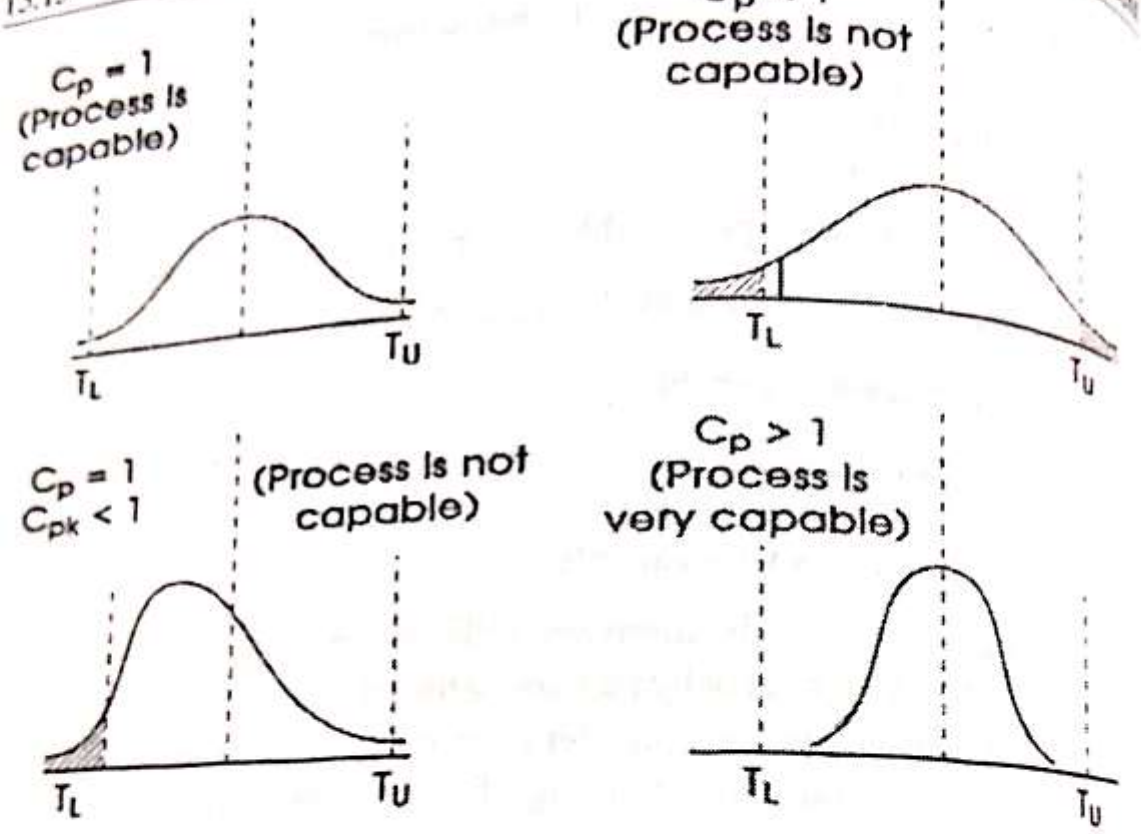


Figure 15.9 – Process Capability and Process Capability Index

Interpreting Process Capability Indices

SIX SIGMA QUALITY

Variability is measured statistically in standard deviation /σ

DEFINITION – HARRY MIKEL & SCHREDER RICHARD

A business process that allows organisations to drastically improve their bottom line by designing and monitoring everyday business activities in ways that minimise waste and resources while increasing customer satisfaction.

It is related to the normal distribution with sigma denoting standard deviation of the process

Six sigma criterion is equivalent to a process capability of Cpk = 1.5

PHILOSOPHY OF SIX SIGMA PROGRAMME

i. **Thinking in terms of key business processes and customer requirements**
ii. **Focus on corporate sponsors**
iii. **Emphasize on quantifiable measures for defects**
iv. **Emphasis on appropriate metrics in the process**
v. **Provide extensive training**
vi. **Create highly qualified process improvement experts**
vii. **Objectives for improvement**

INGREDIENTS

i. **A superordinate goal of ‘total customer satisfaction’**
ii. **Common and uniform quality metrics for all areas**
iii. **Goal directed incentives for both management and employees**
iv. **Coordinated training in ‘why’ and ‘how’ to achieve the goal.**

quality-cost relationships is given below:

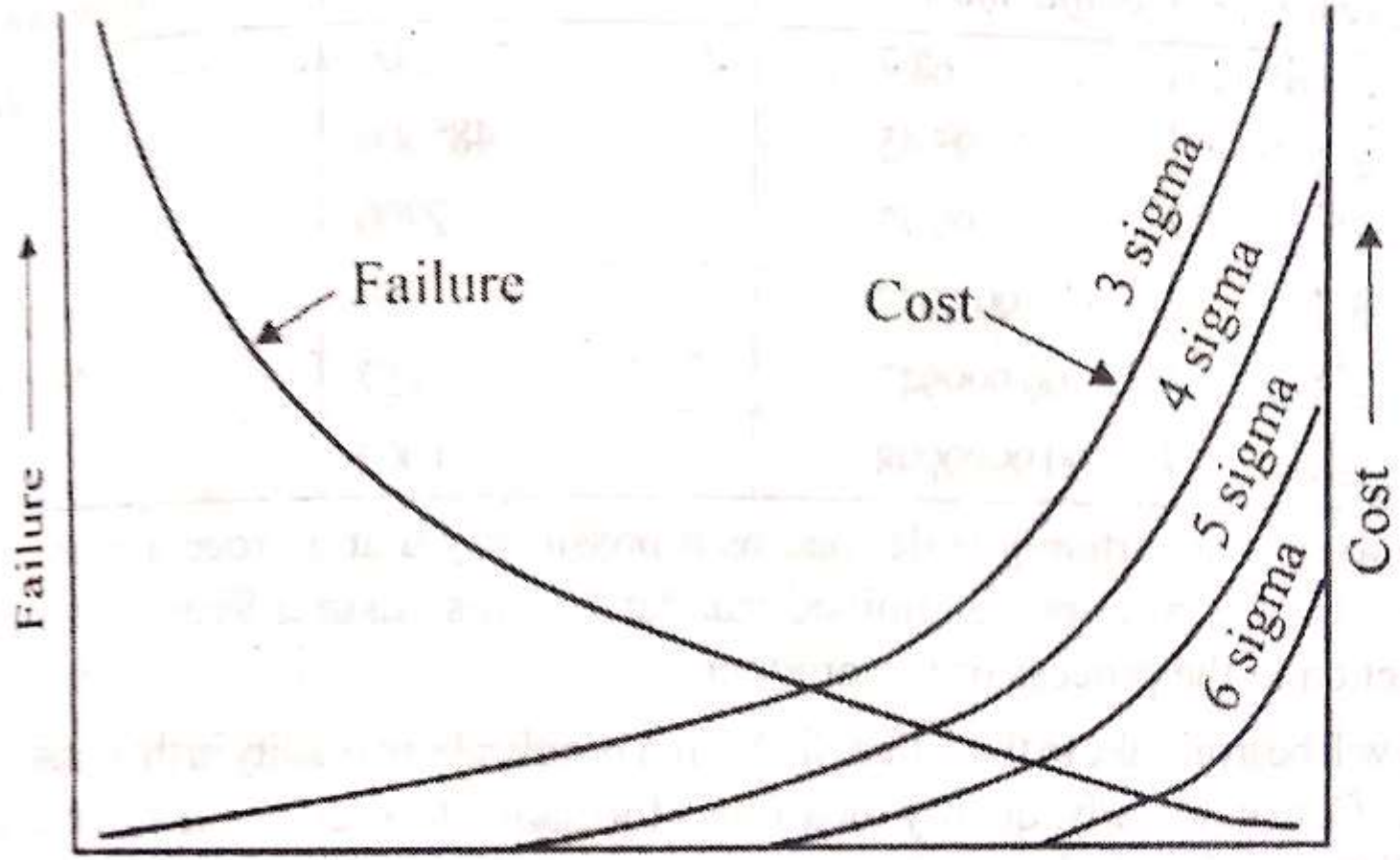


Figure 19.1 – Actual quality-cost relationships

Motorola's Six Sigma process changed the relationship between quality and

BENEFITS OF SIX SIGMA

i. **Reduces operational costs**
   - **1.1 Inspection costs**
   - **1.2 Rework costs**
   - **1.3 Customer complaints**

ii. **Improves efficiency or timeliness**

iii. **Improves accuracy, controls and policy compliance**

iv. **Improves customer services**

v. **Improves cash flow**

vi. **Improves regulatory compliance**

vii. **Reduced cycle time**

KEY PLAYERS IN SIX SIGMA APPROACH

i. **Leader / champion – Top management**
ii. **Master black belt – Six sigma or quality experts**
iii. **Black belt – Managerial level or technical specialist**
iv. **Green belt – six sigma project leaders**
v. **Project team members – Manager**
vi. **Process owner**

SIX SIGMA IMPLEMENTATION

i. **Recognise**
ii. **Define**
iii. **Measure**
iv. **Analyse**
v. **Improve**
vi. **Control**
vii. **Standardise**
viii. **Integrate**

SEVEN BASIC STATISTICCAL TOOLS

i. **CHECK SHEETS**
ii. **PROCESS FLOW DIAGRAM**
iii. **PARETO CHARTS**
iv. **CAUSE AND EFFECT DIAGRAM**
v. **SCATTER DIAGRAM**
vi. **HISTOGRAM**
vii. **CONTROL CHARTS**

CHECK SHEETS

It is also termed as DEFECT CONCENTRATION DIAGRAMS. A check sheet is a structured, prepared form for collecting and analysing data. The function of a check sheet is to present information in an efficient graphical format

STEPS

- **Clarify the measurement objectives**
- **Prepare a form for collecting data**
- **Collect the data for the items being measured**
- **Tally the data by totalling the number of occurrences for each category being measured**

TYPES

i. **Defect location check sheet**
ii. **Tally check sheet**
iii. **Defect cause check sheet**

PROCESS FLOW CHART

A process flow chart is a diagrammatic view of the various steps in sequential order which forms an overall process of an organisation. It indicates the various steps in a process which means, all the sub processes and their inputs and outputs are documented in one diagram.

STEPS

i. **Define the process**
ii. **List the steps involved**
iii. **Draw the diagram, placing the process steps in boxes in the order of their sequence and link each other by arrows**
iv. **Analyse the flow charts**

PARETO CHART

A Pareto Chart is a special bar graph, the lengths of which represents frequency or cost and are arranged with the longest bars on the left and the shortest to the right, these are often referred to as the 80-20 rule.

Pareto analysis is a statistical technique in decision making that is used for the selection of a limited number of tasks that produce a significant overall effect.

According to the Pareto effect, 80% of the problems usually stem from 20% of the causes. This is also termed as the theory of the *VITAL FEW AND THE TRIVIAL MANY.*

STEPS

1. **List the activities or causes in a table and their frequency of occurrences.**
2. **Place these in descending order of magnitude in the table.**
3. **Calculate the total for the whole list.**

CAUSE AND EFFECT DIAGRAM

ISHIKAWA DIAGRAM/FISHBONE DIAGRAM

To associate multiple causes with a single effect.

The diagram is constructed to identify and organise the possible causes for it.

Causes in a cause and effect diagram are frequently arranged in four major categories.

- **Manpower, methods, materials and machinery (manufacturing)**
- **Equipment, policies, procedures and people (Administration and services).**

REQUIREMENTS

1. **Be sure everyone agrees on the effect or problem statement before beginning**
2. **Be succinct**
3. **For each node think what could be its causes. Add them to the tree.**
4. **Pursue each line of causality back to its root cause.**
5. **Consider grafting relatively empty branches on to others.**
6. **Consider splitting up overcrowded branches**
7. **Consider which root causes are most likely to merit further investigation.**

STEPS IN CONSTRUCTING A CAUSE AND EFFECT DIAGRAM

i. **Write the issue on the right side of the cause and effect diagram**
ii. **Identify the major causes**
iii. **Brainstorm the potential causes of the problem**
iv. **Review each major cause category.**
v. **Review the causes that are circled**
vi. **Reach an agreement on the most probable cause.**

SCATTER DIAGRAM

Is a graphical tool showing the influence of one variable over the other. It shows the pattern of relationship between two variables.

HISTOGRAM

- **Histogram is a powerful tool for elementary analysis of data that contain variation. In a bar graph the range of resistance values measured have to be plotted in the x-axis and the frequency of occurrence of the range of values in the y-axis. The frequency of occurrence is the number of times the values falling in the range was measured.**
- **A.M. GURREY – French statistician – 1833**
- **It is a bar graph**

STEPS

i. **Measure and record data pertaining to a process**
ii. **Arrange values in an ascending order**
iii. **Note the range**
iv. **Divide the range into number of groups called class intervals.**
v. **Now divide the X-axis as per class intervals**

STEPS

vi. Choose a proper scale for Y-axis

vii. Count the number of occurrences of the data in each class interval. This is called frequency of occurrence in each interval.

viii. Plot the frequency or count of number of occurences corresponding to each interval in the form of bars. It is essentially a column graph

ix. Give a suitable title for the histogram. Here, we call it “resistance value”

UNIT – IV

Continuous Quality Improvement Techniques

Standard Work

Standard work is simply the documentation of the current best practice for any given task or process. It should be detailed and include any necessary supporting assets like diagrams or images. It needs to be accessible to everyone performing the work and is ideally designed by those involved.

Catchball

The idea of Catchball comes from the Lean business management methodology. The idea is that no matter who starts a project, that person (often, but not always a manager) states the purpose, objectives and other ideas and concerns and then 'throws' them to others for feedback, ideas, support, and action. This creates a bi-directional loop, which clear ownership and accountability. Everyone knows who has the “ball” so to speak.

The 5 Whys

The 5 Whys is a process for getting to the root cause of any problem. When something goes wrong, you ask “why.” That answer leads to another “why” and so forth. It turns out that the underlying cause of most process breakdowns can be uncovered by asking why about 5 times.

Digital Huddle Boards

Huddle boards (also called Kaizen boards) are used to create a visual representation of improvement work. This helps people easily understand the health of continuous quality improvement within the organization and immediately detect when progress on any given project is stalled. In modern practice, they are electronic so they can be accessed from anywhere by any member of the team.

5S

5S is a workplace organization method that uses a list of five Japanese words: seiri (sort), seiton (set), seiso (shine), seiketsu standardize), and shitsuke (sustain). .

Gemba Walks

During a Gemba Walk, a supervisor or other leader goes to the place where the work is done to observe and ask questions of the people doing the work. The goal is not to evaluate people's performance, but rather to seek opportunities for improvement and get a clear understanding of how the standard work is being executed in the real world.

Value Stream Mapping

Is a way of documenting and assessing everything that happens to bring value to the customer. It is an end-to-end analysis of how a service or product goes from the initial requirement into the hands of the customer.

PDSA

PDSA stands for Plan, Do, Study, Act. It is a basic improvement cycle that helps teams act on opportunities for improvement. The planning phase involves understanding the current state of affairs and describing the desired state. During the “Do” step, potential improvements are introduced. This is followed by a period in which the results are studied. Finally, if the changes are positive, the standard work is updated, and the new process is enacted.

Mind Mapping

A mind map is a diagram used to visually organize information. It is a technique for visualizing connections between many related ideas or pieces of information. It can be extremely useful in brainstorming, problem-solving, project planning, and note-taking. Mind maps are like a tree, starting with a core thought (the trunk) and connecting it to related ideas, big (branches), and small (twigs). The visual structure makes gaps in knowledge readily apparent and relationships between ideas clear. It is useful anytime fresh thinking is needed and is effective for process development, product improvement, quality control, or any other opportunity for improvement.

The Concept of Zero Defects in Quality Management

Zero Defects, a term coined by Mr. Philip Crosby in his book "Absolutes of Quality Management" has emerged as a popular and highly-regarded concept in quality management – so much so that Six Sigma is adopting it as one of its major theories. Unfortunately, the concept has also faced a fair degree of criticism, with some arguing that a state of zero defects simply cannot exist. Others have worked hard to prove the naysayers wrong, pointing out that "zero defects" in quality management doesn't literally mean perfection, but rather refers to a state where waste is eliminated and defects are reduced. It means ensuring the highest quality standards in projects.

Meaning of Zero defects

From a literal standpoint, it's pretty obvious that attaining zero defects is technically not possible in any sizable or complex manufacturing project. According to the Six Sigma standard, the definition of zero defects is defined as 3.4 defects per million opportunities (DPMO), allowing for a 1.5-sigma process shift. The zero defects concept should pragmatically be viewed as a quest for perfection in order to improve quality in the development or manufacturing process. True perfection might not be achievable but at least the quest will push quality and improvements to a point that is acceptable under even the most stringent metrics.

Zero Defects – The Theory and Implementation

Theory ensures that there is no waste existing in a project. Waste refers to all unproductive processes, tools, employees and so on. Anything that is unproductive and does not add value to a project should be eliminated, called the process of elimination of waste. Eliminating waste creates a process of improvement and correspondingly lowers costs. Common with the zero defects theory is the concept of “doing it right the first time” to avoid costly and time-consuming fixes later in the project management process

Zero defects theory is based on **four elements** for implementation in real projects.

(I) Quality is a state of assurance to requirements. Therefore, zero defects in a project means fulfilling requirements at that point in time.

(II) Right the first time. Quality should be integrated into the process from the beginning, rather than solving problems at a later stage.

(III) Quality is measured in financial terms. One needs to judge waste, production and revenue in terms of budgetary impact.

(IV) Performance should be judged by the accepted standards, as close to perfection as possible.

Zero Defects – advantages and disadvantages

Advantages

The clear advantage of achieving a zero defect level is waste and cost reduction when building products to customer specifications. Zero defects means higher customer satisfaction and improved customer loyalty, which invariably leads to better sales and profits.

Disadvantages

(I)A zero defects goal could lead to a scenario where a team is striving for a perfect process that cannot realistically be met.

(II)The time and resources dedicated to reaching zero defects may negatively impact performance and put a strain on employee morale and satisfaction.

(III)There can also be negative implications when you consider the full supply chain with other manufacturers that might have a different definition of zero defects.

The Principles of Zero Defects are:

Quality is defined as conformance to the requirements

Every product or service should have a requirement (a description of what the customer expects to see). A product achieves quality when it meets those requirements.

Defects prevention is better than quality inspection and correction

In other words, it's better to find a defect in the process and fix it, rather than find the defect in the finished products

Quality standard means zero defects

If a product does satisfy the customer need even if it doesn't meet all of the requirements, then the requirements need to be reviewed and changed to reflect reality.

Quality is measured in terms of money (i.e. the price of non-conformance: PONC)

This philosophy assumes that every defect represents a hidden cost: inspection time, rework, revenue, wasted material, labour, and customer dissatisfaction.

DEFECT DIAGONSIS AND PREVENTION

Defect analysis is part of the continuous quality improvement planning in which defects are classified into different categories and are also used to identify the possible causes in order to prevent the problems from occurring. It helps projects to identify how issues can be prevented and in reducing or eliminating significant numbers of defects from being injected into the system.

1.What is DA

- Examination of information about problems
- Intent to identify causes of defects so that they can be prevented or detected earlier
- Many different approaches called defect analysis or root cause analysis – employ many different techniques

Software

ABC Analysis

Using ABC to implement TQM

The advantages of using ABC

Method Activity-Based Costing (ABC) originally appeared in the United States of America in the late '80s as a result of work by the group CAMI. Traditional cost calculation models used for allocating indirect costs based on a uniform allocation, on a rough average in terms of resource consumption of a product (or the subject of cost), while actually, the consumption of resources is done in a uniform manner.

Traditional methods lead to the emergence of such phenomena underestimate, overestimate or subsidy costs. To avoid these errors, companies looking to refine their cost system. With this refinement should ensure a better appreciation of the uneven consumption of resources. ABC method is one way of refining the system cost.

Basics of implementing ABC method are: -

(I) Cost objects consume activities; -

(II) Activities consume resources; -

(III) Consumption of resources is generating costs; -

(IV) Understanding the causal relationship is the basis of successful management.

Context of the emergence and the need for ABC method can be explained by the following elements:

(I) Increased indirect costs in most sectors of the economy, both as absolute value and relative value; -

(II) Change in the nature of indirect costs. Share of indirect costs in total costs increased at the expense of variable costs related to production volume, this being due to the complexity, diversity of product mix and product quality; -

(III) Development of direct labour. The proportion of Direct labour costs in the total cost has been reduced steadily.

Definition

CAMI defined the ABC method as the method used to identify connections between cost drivers; causes of cost and cost of activities by measuring process costs covered activities and cost objects.

ABC method in the TQM implementation is done in accordance with certain requirements and involves:

(I) Establishing processes, activities and operations according to specific cross organization of the enterprise; -

(II) The establishment of units or cost drivers related articles cost calculation specific TQM;

(III)The adoption and improvement of the specific documents the ABC method. Therein will include registration of documents aimed at production, the cost of deviations from cost ante calculate respectively piloting indicators analysis and scoreboards.

Stages of implementation of ABC method

1. Identifying activities and costs. Number of activities depends on the fineness of the expected information system;
2. Setting cost driver cost for each activity (cost driver);
3. Formation of homogeneous cost pools, by grouping activities with the same (determined as the causal structure of costs);
4. Calculate cost of parts, subassemblies, by adding direct costs to the cost of necessary cost drivers;
5. Calculate cost of products, works, and services;
6. Calculate total cost.

TQM implementation model using ABC

- To implement TQM must meet the following conditions: -
- Company should benefit from TQM gradually, increasing continuously product quality, customer satisfaction and market share (TQM implementation should be applied at least 5 years)
- Management accounting organizes the specific application of ABC method;
- Responsibilities for quality data collection costs are made by the Department of Quality Assurance but with sales and supply department and the production department;
- should be used "method of analysis of processes" to determine key quality activities, are identified to work on quality and cost are identified cost drivers;
- being drawn up "The cost of quality" during the years of study;
- Management company should focus on cost control nonconformities, internal failure costs and external failure costs;
- To examine "The cost of quality" at the end of each year to determine whether the cost of internal failure had a greater or less than the cost of external failures and to be able to act (i.e.: external failure had a percentage higher than external failure);
- Pareto chart is drawn up and cause-effect diagram to analyze the costs of failure in internal / external (if internal damage is higher than external failure).

UNIT-V
QUALITY SYSTEM

Introduction to ISO and ISO 9000

The International Standards Organization is dedicated to creating and developing standards to help facilitate the international exchange of goods and services. It consists of members from national standard bodies of 100 different countries.

Standardization has become required as a result of free market economies that encourage diverse sources of supply. Fair competition is created by creating identifiable, clearly defined common references that are recognized worldwide.

"An industy-wide standard, internationally recognized, developed by a consensus among trading partners, serves to facilitate the language of trade." ISO Easy

ISO 9000 is the family of standards that describe the framework, models, specification and guidance for quality management systems. It represents the best practice in management and control when applied to production. The primary concern of this standard is the quality assurance of functional organizational capabilities. It affects any member within an organization associated with planning, design, sales, training, supply, manufacturing, inspection, testing, customer services, engineering, or field services.

There are twenty requirements under ISO 9001 that a company must meet. Documenting and standardizing processes used to develop the end product under each of these criteria will result in a quality product. ISO 9001 is not intended to standardize the end product, but rather the process used in the various stages from creating, implementation, and support of that product.

Selection of ISO Model and Implementation of ISO 9000

1 Identify what goals you want to achieve

Typical goals may be:

- Be more efficient and profitable
- Produce better products and services
- Achieve customer satisfaction
- Increase market share
- Improve communication and morale in the organization
- Reduce costs and liabilities

2 Identify what others expect of you

These are the expectations of interested parties (stakeholders) such as:

- Customers and end users
- Suppliers
- Shareholders
- Society
- Employees

3 Establish your current status

You may use one or more of the following:

- self assessment
- assessment by an external organization
- customer feedback

4 Obtain information about the ISO 9000 family

- For general information, look to this brochure
- For more detailed information, see ISO 9000-1
- For terminology, see ISO 8402

In some cases you may wish to use only one or two specific standards in the ISO 9000 family to meet your needs

5 Apply the ISO 9000 standards in your management system

- Use ISO 9004-1 as a basis
- For small and medium sized organizations refer to the handbook *ISO 9000 for Small Businesses*

Where appropriate, consider the requirements in:

- ISO 9001 if you are involved with any kind of product development, or
- ISO 9002 if you are producing products or services (but not involved with any kind of product development), or
- ISO 9003 if you are only relying on final inspection or testing

6 Use sector-specific and general guidance

For general guidance use:

- ISO 9000-2

For specific guidance use:

- ISO 9000-3 for computer software
- ISO 9004-2 for services
- ISO 9004-3 for process industry
- *ISO 9000 for Small Businesses*
- Relevant national standards and industry sector guidelines

For dependability guidance use:

- ISO 9000-4 for dependability programme management

7 Obtain guidance on specific topics within the quality management system

These topic-specific standards are:

- ISO 10005 for quality plans
- ISO 10007 for configuration management
- ISO 10011 for auditing
- ISO 10012 for measurement systems
- ISO 10013 for quality manuals

8 Do you need to demonstrate conformance?

You may need to show conformance (certification/registration) for various purposes, for example:

- Contractual requirements
- Market reasons
- Regulatory requirements
- Risk management
- To set a clear goal for your internal quality development (motivation)

YES

NO

9 Undergo independent audit

- Use all parts of ISO 10011 for guidance in auditing, auditor qualification and managing audit programmes
- Use ISO 9001, ISO 9002 or ISO 9003 as the specification for quality assurance

(*ISO 9000 for Small Businesses* may be used since it includes ISO 9001)

10 Continue to improve your business

Review the effectiveness and suitability of your management system.

ISO 9004-4 provides guidance for quality improvement

GO TO STEP 1

Need for ISO

1. Improved Processes

ISO 9001 is a comprehensive framework that addresses all key processes throughout the company - not just quality control. By taking such a broad view, ISO 9001 leads not only to quality products and services, but also to improved production and service provision with less rework and lower cost. In fact, the current year 2015 revision of ISO 9001 focuses on the "process approach " as a central pillar of ISO 9001.

2. Better Decision-Making

Good decision-making is key to business success. ISO 9001's structured framework for quality management provides management with both information and processes for fact-based decisions that rely on evidence, not merely on gut feelings.

3. More Revenue and Profit

Customers want quality and they will reward companies that provide it. For this reason, ISO 9001-certified organizations are not only perceived as being more competent, they are paid 7% more on average than non-ISO 9001 companies.

4. Support for Other Industry-Specific Standards

ISO 9001 has the additional benefit in that it sets the foundation for other industry-specific standards, such as ISO 14001 (environmental management), ISO 20000 (IT service management), ISO 13485 (medical devices), and ISO/TS 16949 (automotive industry). Implementing ISO 9001 first makes the addition of other management standards rather quick and easy.

5. Better Credibility and Improved Perception

ISO 9001 certification is a clear indicator that a company is committed to quality. As ISO 9001 is the world's most well-known quality standard, your potential customers will automatically have a better perception of your company if you can advertise your ISO 9001 certification. An ISO 9001 certification mark adds credibility to advertising and marketing.

6. Meets Requirements for Government Contracts

For certain types of companies, government contracts can be a lucrative business. Unfortunately, obtaining government contracts can require a lot of hoops to jump through, starting with an involved RFP or tender process. ISO 9001 helps set your organization up for success with public sector work. And, in fact, for some municipalities and government agencies, ISO 9001 certification will be a requirement.

Amazon, for example, advertises their ISO 9001 compliance for their AWS business cloud services noting that "using an ISO 9001 certified provider like AWS can make your certification process easier".

7. Reduced Costs

With improved operational processes, production and service provision will become efficient and error-free, resulting in reduced cost and an improved bottom line.

8. Smoother Ordering and Customer Interaction

ISO 9001 certified companies have an improved order process in place. The communication of customer orders will become smoother, misunderstandings will be avoided, and there won't be a need to ask the customer the same questions again. These improvements not only increase operational efficiency, they also reduce friction with customers.

9. Greater Customer Satisfaction

If your operational processes are running more smoothly and more efficiently, and your product or service quality has improved as a result, your customers will be happier. In fact, companies who have gone through the ISO 9001 certification process have reported that their customers are more satisfied. Increased customer satisfaction not only leads to increased customer loyalty, but satisfied customers are also willing to pay more: on average 7% more, as we've noted earlier.

10. No Need to Reinvent the Wheel

There are many frameworks for quality management systems, ranging from the general experience and gut feelings of the CEO to detailed requirements. The ISO 9001 standard is a set of detailed

requirements that are proven to work. By using ISO 9001 as the framework for your quality management system, you don't need to start from scratch and you can avoid mistakes.

Benefits :

1. **Increased Efficiency:**
   The companies have done extensive researches on the processes they are following, how to maximize quality and efficiency before going through the ISO 9000 series Quality Management Standards certification process. Once they achieve certification, the processes are established
2. **Increased Revenue:**
   It has been observed that ISO QMS certified companies have shown improvements in the field of productivity, financial performance as compared to the uncertified ones.
3. **Employee Morale:**
   The staff is more satisfied and motivated once there are defined roles and responsibilities, accountability of management, established training procedure and a well-defined picture of how the roles of the employees affect quality and overall success of the company.
4. **International Recognition:**
   The International Organization for Standardization (ISO) is recognized worldwide as the authority on quality management.
5. **Factual Approach to Decision Making:**
   The ISO9000 QMS standard sets out clear instructions regarding audits and process reviews. This helps in information gathering and decision making based on data.
6. **Supplier Relationships:**

ISO certification has been found beneficial regarding supplier relationships. The documentation and testing procedures help to ensure the quality of the raw materials used for production purpose.

Documentation:

Since the ISO QMS standard requires proper documentation of all processes, and changes made, errors or discrepancies, it helps mitigate problems, and provides stability. The staff is also more accountable. Documentation also guarantees that traceable records are available in case of non-compliant products or raw materials.

7. **Consistency:**

Since all processes are documented, there is a minimum scope of errors. Processes starting right from research and development, covering production, shipping is well documented. Even any small change in the process has to be documented ensuring that the changes are well planned and implemented in the best possible way to ensure maximum efficiency.

8. **Customer Satisfaction:**

Companies can gain the confidence of clients easily because the ISO is a universally accepted standard. ISO9001 QMS certification ensures efficiency, consistency and dedicated quality service by the companies thereby ensuring the satisfaction of the customers.

9. **Improvement Processes:**

The ISO 9000 QMS emphasizes on audit processes, management review and improved processes based on collected data. Based on facts and using a system of documentation and analysis, improvements are carefully planned and implemented. This ensures that the best decisions are made for your company.

STEPS TO ACHIEVE ISO:

1: Choose a Management Standard

With over 22,000 international standards available, finding the right one for your business might seem a little daunting.

The **ISO 9001 Quality** Management System is the most popular place to start. This standard helps ensure you deliver a consistent level of quality and satisfaction.

2: Contact Us

If you haven't done so already, please contact our account management team to discuss your requirements. We will then book a visit with one of our consultants to come and run through your needs in more detail.

3: The Initial Assessment

If you accept our proposal, we will book an initial assessment with one of our experienced Lead Auditors. They will conduct a gap analysis to identify what works need to be done in order to become compliant. We will make a series of recommendations.

4: Documentation Preparation

We prepare documentation to include compulsory procedures (as required by the Standard), in line with your current company procedures.

5: Certification

Provided all requirements are met, we will present you with your ISO certification.

The systems are focused on continual improvement and we will continue to support you through the term of your contract by carrying out a six monthly review, ensuring you stay on track and are ready for re-certification each year.

6: Maintaining Compliance

Management systems focus on continual improvement of your products, services or processes so you will be required to continually maintain your management system.

Quality management system(QMS):

A quality management system (QMS) is defined as a formalized system that documents processes, procedures, and responsibilities for achieving quality policies and objectives. A QMS helps coordinate and direct an organization's activities to meet

customer and regulatory requirements and improve its effectiveness and efficiency on a continuous basis.

ISO 9001:2015, the international standard specifying requirements for quality management systems, is the most prominent approach to quality management systems. While some use the term "QMS" to describe the ISO 9001 standard or the group of documents detailing the QMS, it actually refers to the entirety of the system.

- Meeting the customer's requirements, which helps to instill confidence in the organization, in turn leading to more customers, more sales, and more repeat business
- Meeting the organization's requirements, which ensures compliance with regulations and provision of products and services in the most cost- and resource-efficient manner, creating room for expansion, growth, and profit.

ELEMENTS OF A QMS

Each element of a quality management system helps achieve the overall goals of meeting the customers' and organization's requirements. Quality management systems should address an organization's unique needs; however, the elements all systems have in common include:

The organization's quality policy and quality objectives

- Quality manual
- Procedures, instructions, and records
- Data management
- Internal processes
- Customer satisfaction from product quality
- Improvement opportunities
- Quality analysis

IMPLEMENTYATION OF QUALITY SYSTEM

STEP 1: COMMITMENT FROM TOP MANAGEMENT

The top management of an organization should be determined and committed to implement a quality management system. No quality initiative within an organization can succeed without commitment from top management. Top management can demonstrate to their clients that the organization is committed to quality through the certification and registration of the ISO 9000 standard. Top management should thus come to the realization that overall business efficiency would be improved by means of a quality management system

Step 2: Establishing an implementation

People are responsible for the implementation of ISO 9000. An implementation team, headed by a service provider and a management representative (MR), is to be established. The service provider and MR is the coordinator and is responsible for planning and overseeing the implementation of the quality management system. He is thus the link between top management and the ISO 9000 registrar. All departments within the organization should be represented on the implementation team.

Step 3: conducting ISO 9000 awareness programs

Conducting ISO 9000 awareness programs will inform all employees about the aim of a quality management system. These include the advantages offered to customers and employees, their respective responsibilities and roles within the system, and how the quality management system operates. The benefits that an organization hopes to realize through a quality management system implementation should be emphasized through ISO 9000 awareness programs.

STEP 4: PROVIDING TRAINING

All personnel and all areas in an organisation are affected by a quality management system. Training regarding the quality management system should thus be provided for all employees.

The quality management system implementation plan should make provision for this training. All basic concepts of quality management systems and its impact on the organization should be covered.

STEP 5: CONDUCTING AN INITIAL STATUS SURVEY

A quality management system conforming to the **ISO 9000** standard should be created. However, this does not preclude incorporating, adapting, or adding onto quality programs that already exists. Thus, this step basically involves comparing an organization's existing quality management system (if there is one) with the requirements of ISO 9001:2015.

STEP 6: CREATING A DOCUMENTED IMPLEMENTATION PLAN

Once an organization's **quality management** system has been compared with the ISO 9001:2015 standard, a documented implementation plan is used to address any non-conformances. The documented implementation plan identifies and describes processes in order to make the organization's current quality management system in full compliance with the ISO 9000 standard.

STEP 7: DEVELOPING A QUALITY MANAGEMENT SYSTEM DOCUMENTATION

Documentation is an area where non-conformance regarding quality management systems are very common. In order to avoid these non-conformities, documentation of a quality management system should include the following:

- Documented statements of a quality policy and quality objectives;
- A quality manual;
- Documented procedures and records required by the standard of ISO 9001:2015; and
- Documents needed to ensure effective planning, operation and control of its processes.

STEP 8: CONTROL OF DOCUMENTS

In order to control quality management system documentation, a documented system should be created. The creation, approval, distribution, revision, storage, and disposal of various types of documentation are thus managed. Document control systems should be as easy and simple to operate as possible. However, it should still be sufficient enough to meet the requirements of ISO 9001:2015.

STEP 9: IMPLEMENTATION

In large organizations, it is best to implement the quality management system being documented as the documentation is developed. This is in stark contrast to smaller organizations, where the quality management system is implemented throughout the organisation all at once. During phased implementation, however, an evaluation can take place regarding the effectiveness of the system in different areas.
Through management review and an internal quality audit, the implementation progress is monitored to ensure that the quality management system is effective and thus conforms to the IS0 9000 standard.

STEP 10: INTERNAL QUALITY AUDITS

The effectiveness of the installed system should be checked regularly by means of an internal quality audit.

- To ensure that the quality management system conforms to the quality management system requirements established by your organization, as well as to the requirements of the ISO 9001:2015 standard; and
- To ensure that the quality management system is implemented and maintained in an effective manner.

Quality audits

Auditing is defined as the on-site verification activity, such as inspection or examination, of a process or quality system, to ensure compliance to requirements. An audit can apply to an entire organization or might be specific to a function, process, or production step. Some audits have special administrative purposes, such as auditing documents, risk, or performance, or following up on completed corrective actions.

Three types of Audits:

Audit as a "systematic, independent and documented process for obtaining audit evidence [records, statements of fact or other information which are relevant and verifiable] and evaluating it objectively to determine the extent to which the audit criteria [a set of policies, procedures or requirements] are fulfilled." There are three main types of audits:

Process audit:

This type of audit verifies that processes are working within established limits. It evaluates an operation or method against predetermined instructions or standards to measure conformance to these standards and the effectiveness of the instructions. A process audit may:

- Check conformance to defined requirements such as time, accuracy, temperature, pressure, composition, responsiveness, amperage, and component mixture.
- Examine the resources (equipment, materials, people) applied to transform the inputs into outputs, the environment, the methods (procedures, instructions) followed, and the measures collected to determine process performance.
- Check the adequacy and effectiveness of the process controls established by procedures, work instructions, flowcharts, and training and process specifications.

Product audit:

This type of audit is an examination of a particular product or service, such as hardware, processed material, or software, to evaluate whether it conforms to requirements (i.e., specifications, performance standards, and customer requirements).

- **System audit:**

An audit conducted on a management system. It can be described as a documented activity performed to verify, by examination and evaluation of objective evidence, that applicable elements of the system are appropriate and effective and have been developed, documented, and implemented in accordance and in conjunction with specified requirements.

- A ***quality management system audit*** evaluates an existing quality management program to determine its conformance to company policies, contract commitments, and regulatory requirements.
- Similarly, an ***environmental system audit*** examines an environmental management system, a ***food safety system audit*** examines a food safety management system, and ***safety system audits*** examine the safety management system.

REFERENCE MATERIALS:

1. *Total Quality Management: R.Saravanavel & S.Balakumar(Margham publications)*
2. *Total Quality Management: prof.K.Shridhara Bhat(Himalaya publications)*