

Quality Management

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Quality :

Quality refers to how good something is compared to others similar things. In other words, its degree of excellence.

Quality is a judgment of how excellent something or someone is.

Example of quality is a product that won't break easily.
An example of quality is a well-made product.

Quality Management :

Management is the process of designing and maintaining an environment in which individuals, working together in groups, efficiently accomplish selected aims.

Quality Management :

It is a process that the product throughout its life cycle.

It is a process that ensures the quality of the product throughout its life cycle.

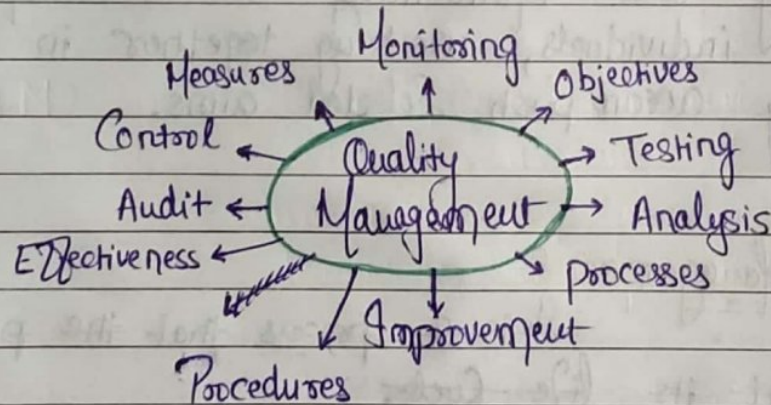
Quality Management is the act of overseeing all activities and tasks that must be

accomplished to Maintain a desired level of excellence.

This includes the determination of a quality policy, Creating and implementing quality planning and assurance, and quality control and quality improvement. It is also referred to as total quality management.

In general, quality Management focuses on long-term goals through the implementation of short-term initiatives.

Quality Management Processes:



- | | |
|---------------|-----------------|
| ① Objectives | ⑦ Effectiveness |
| ② Testing | ⑧ Audit |
| ③ Analysis | ⑨ Control |
| ④ Processes | ⑩ Measures |
| ⑤ Improvement | ⑪ Monitoring |
| ⑥ Procedures | |

Q:- Discuss Quality Management Process.

Ans:- A Quality Management process is a set of procedures that are followed to ensure that the deliverables produced by a team are "Fit for purpose". The start of the quality management process involves setting quality targets, which are agreed with the customers.

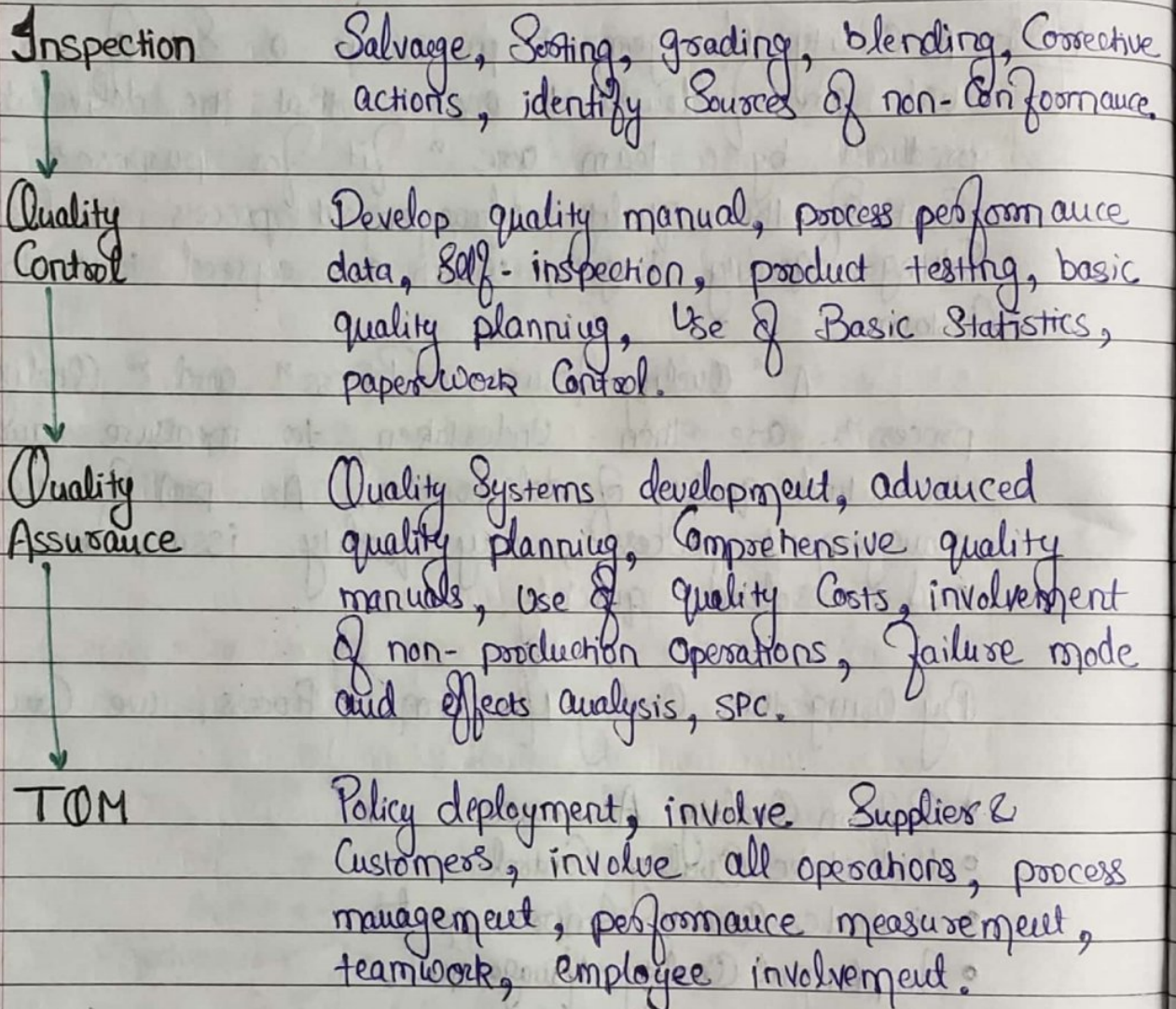
A "Quality Assurance Process" and "Quality Control process" are then undertaken, to measure and report the actual quality of deliverables. As part of the quality management process, any quality issues are identified and resolved quickly.

By Using this Quality Management Process, we can:

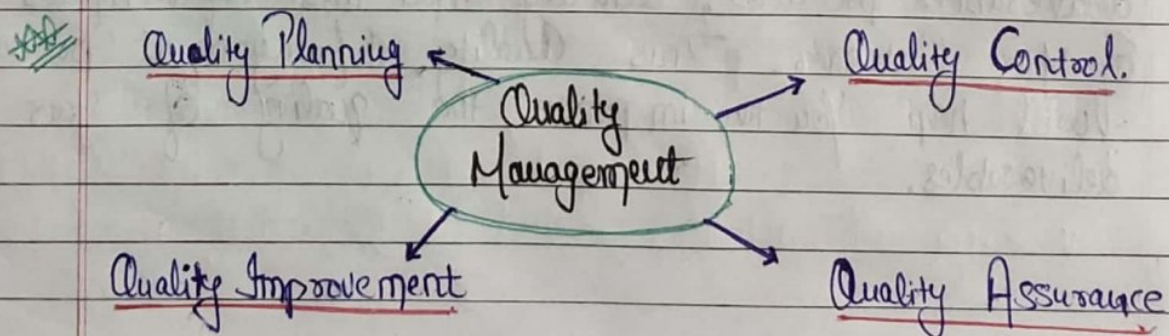
- Perform Quality Assurance
- Undertake Quality Control
- initiate Quality Improvement
- Implement Quality Management.

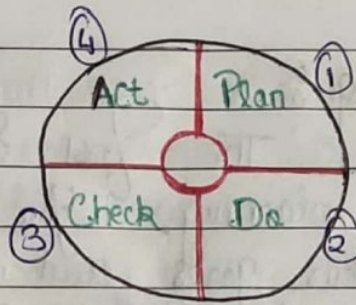
A Quality Management process is critical process within any business, as it help you to ensure that the deliverables produced, actually meet the requirements of your customers. This Quality Management process will help you to improve the quality of your deliverables.

Evolution of Quality Management :



Components of Quality Management :





Plan :

- ① Identify Your goals and baseline.
- ② Assemble internal resources.
- ③ Determine quality standards and the requirements to meet those standards.
- ④ Determine what procedure will be used to ensure criteria is being met.

Do :

- ① Organize Supporting documentation (ISO documentation, policies, procedures, training materials, work instructions, etc) in a document management.
- ② Train employees on new process.
- ③ Deploy the quality management system.

Check :

- ① Control, measure and monitor your outputs to ensure they meet expected criteria.
- ② Identify areas where there is opportunity for improvement.

Act :

- ① Review the findings of your quality management system.
- ② Re-evaluate both the processes and the product.
- ③ Begin the quality management process again.

- Quality Control: Quality Control is needed to review the quality of the product and service. Inspection and testing is necessary to identify problems and defects that need correction.

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① Quality Planning:

The first step of quality management is planning. You need to take the time to identify your goals and what you want your base line to be. You should determine what your quality standards are, the requirements necessary to meet these standards, and what procedures will be used to check that these criteria are being met.

② Quality Control:

Once you have a plan in place, quality control comes into play. This is the process of physically inspecting and testing what you laid out in the planning stage to make sure it is obtainable. You need to confirm that all the standards you have put into place are met, and you need to identify any mishaps or errors that need to be corrected. The sooner you can catch these errors, the better. As such, you should be paying attention to all aspects of the product, including both the materials used and the process of putting them together.

③ Quality Assurance:

While quality control involves inspecting the actual products or services in the field, quality

assurance is reviewing the delivery process of services or the quality management manufacturing of goods. By inspecting your goods or services at the source, you can catch mistakes before they reach the customers. You can also fine tune your processes to prevent errors in the future. When reviewing your product or service during this stage of quality control management, you will want to follow these steps:

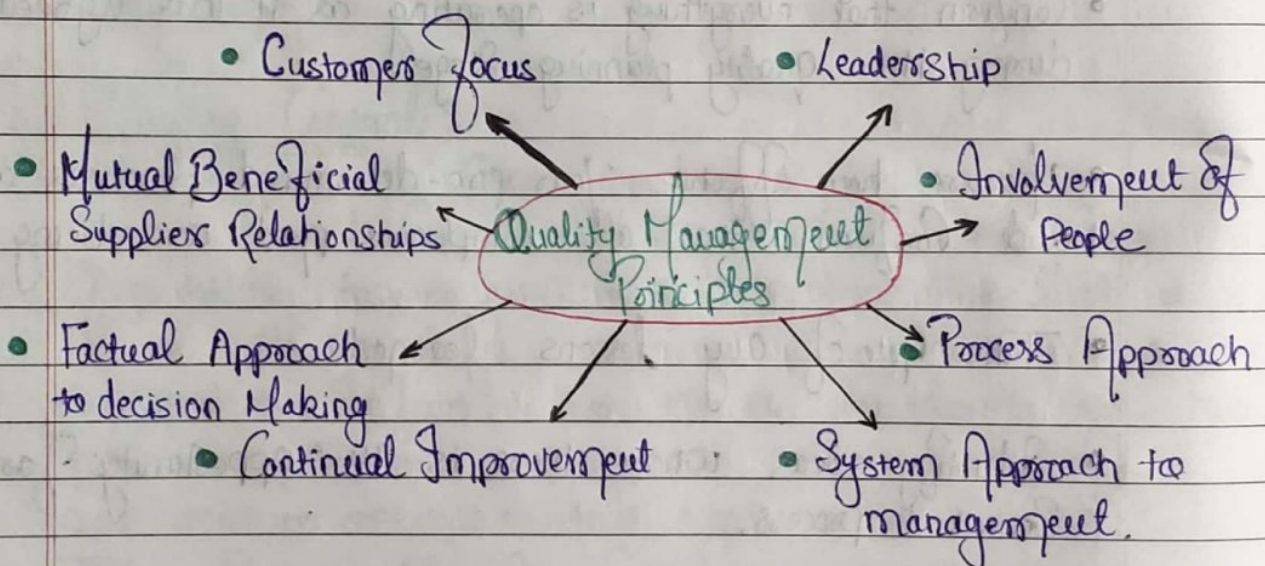
- Confirm that everything is operating as it was agreed upon during the quality planning stage.
- Measure how effective your pre-determined processes are and confirm that all compliance needs are being met.
- Take note of any lessons learned.
- Identify areas where there is an opportunity for a smoother process.

④ Quality Improvement:

Finally, after completing the quality control process, you need to thoroughly review your findings and come up with a way to improve your methods going forward. (Quality control management is fruitless if you are not willing to make changes when they are necessary. The desire for every successful company. Continual improvement is the goal for every successful company. So gather all your data, re-evaluate both the processes and the product - always keeping

Compliance in mind - and then begin the quality Control Management process again. With each cycle, you will end up with a better product, happier customers, and more profit in your pocket.)

Principles Of Quality Management :



① Customer Focus :

Organizations depend on their Customers and therefore should understand current and future Customer needs, should meet Customer requirements and strive to exceed Customer expectations.

② Leadership :

Leaders establish unity of purpose and direction of the organization. They should create and maintain the internal environment in which people can become fully involved in achieving the organization's objectives.

③ Involvement of People :

People at all levels are the essence of an organization and their full involvement enables their abilities to be used for the organization's benefit.

④ Process approach :

A desired result is achieved more efficiently when activities and related resources are managed as a process.

⑤ System Approach to Management :

Identify, Understanding and Managing interrelated processes as a System contributes to the organization's effectiveness and efficiency in achieving its objectives.

⑥ Continual Improvement :

Continual improvement of the organization's overall performance should be a permanent objective of the organization.

⑦ Factual approach to decision making :

Effective decisions are based on the analysis of data and information.

⑧ Mutually Beneficial Supplier relationships :

An organization and its suppliers are ~~inde~~ interdependent and a mutually beneficial relationship enhances the ability of both to create value.

Dimensions of Quality Management :

There are 8 dimensions of quality management :

- ① Performance
- ② Features
- ③ Reliability
- ④ Conformance
- ⑤ Durability
- ⑥ Serviceability
- ⑦ Aesthetics
- ⑧ Perceived quality.

① Performance :

How well the product performs in comparison to how it was designed to perform.

Performance refers to a product's primary operating characteristics. This dimension of quality involves measurable attributes; brands can usually be ranked objectively on individual aspects of performance.

② Features :

What different functions or tasks can the product perform.

Features are the additional characteristics that enhance the appeal of the product or service to the users.

③ Reliability :

Likelihood that the product will perform throughout its expected life.

Reliability is the likelihood that a product will not fail within a specific time period. This is a key element for users who need the product to work without fail.

④ Conformance :

Does the product meet its Specifications as designed.

Conformance is the precision with which the product or service meets the specified standards.

⑤ Durability :

The actual life expectancy of the product.

Durability measures the length of a product's life. When the product can be repaired, estimating durability is more complicated. The item will be used until it is no longer economical to operate it. This happens when the repair rate and the associated costs increase significantly.

⑥ Serviceability :

What is the ease of fixing or repairing the product if it fails.

Serviceability is the speed with which the product can be put into service when it breaks down, as well as the competence and the behaviour of the service person.

⑦ Aesthetics :

The Style, materials and visual appeal of the product.

Aesthetics is the Subjective dimension indicating the kind of response a User has to a product. It represents the individual's personal preference.

⑧ Perceived Quality :

~~Perceived~~ Based on Customer's experience before, during and after they purchase a product.

Perceived Quality is the quality attributed to a good or service based on indirect measures.

~~***~~ Concepts of Product and Service Quality :

Product Quality :

Products that fit Customer need and fulfill Customer expectations.

Service Quality :

Any activity or benefit that one party can offer to another party (Customer) that is essentially intangible and does not result in ownership of anything.

OR

Services involve intangible elements of quality such as environments, Customer service and Customer experience.

ProductService

- | | |
|---|---|
| ① Product is tangible. | ① Service is intangible. |
| ② Products are manufactured, stored, and transported. | ② Cannot be manufactured, stored and transported. |
| ③ Products are objects or systems made available for customers. | ③ Services are transactions where no physical goods are transferred from the sellers to the buyers. |
| ④ Product can be returned or replaced. | ④ Service cannot be returned or replaced. |
| ⑤ Products sold can be identical. | ⑤ Each delivery of a particular service is never exactly the same. |
| ⑥ Ex:- Electronic devices, Furniture, Food items and vehicles. | ⑥ Ex:- Cleaning car, repairs, medical check-up, haircuts, etc. |

Deming's 14 Principles :

- ① Create and publish the Aim and purpose of the organisation.
- ② Learn the new philosophy.
- ③ Understand the purpose of Inspection.
- ④ Stop awarding Business based on price alone.
- ⑤ Improve Constantly and forever the System.
- ⑥ Institute training.
- ⑦ Teach and Institute leadership.
- ⑧ Drive Out Fear, Create trust and Create a Climate for innovation.
- ⑨ Optimize the efforts of Teams, Groups and Staff Areas.
- ⑩ Eliminate Exhortations for the work forces.
- ⑪ a) Eliminate Numerical Quotas for the work force.
b) Eliminate Management by objective.
- ⑫ Remove Barriers that Rob people for pride of Workmanship.
- ⑬ Encourage Education and Self-improvement for everyone.
- ⑭ Take action to Accomplish the transformation.

	Deming	Juran	Crosby
Definition of Quality	Continuous Improvement	Fitness for Use	Conformance to requirements
Emphasis	Tools / System	Measurement	Motivation (behaviours)
Types of Tools	Statistical Process Control	Analytical Cost-of-quality	Minimal Use
Use of goals and targets	Not Used	Significant emphasis	Posted goals for workers.

Quality Cost :

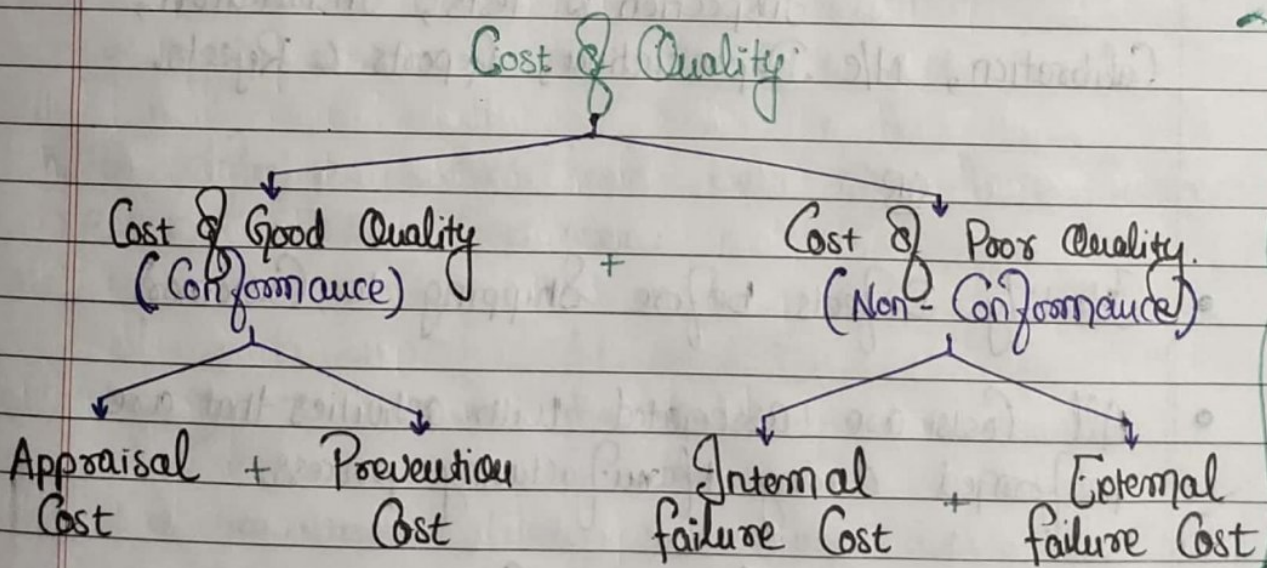
Quality Costs are all the costs that a manufacturer incurs to ensure it produces a quality product. Quality Costs include both costs to prevent low-quality production and costs that arise after a low quality product is produced.

OR

These Cost Associate with the non-achievement of product or service quality.

$$\text{Cost of Quality} = \text{Cost of Control} + \text{Cost of failure of Control}$$

$$\begin{aligned} \text{Cost of quality (COQ)} \\ = \\ \text{Cost of Control} \\ (\text{Prevention Cost} + \text{Appraisal Cost}) \\ + \\ \text{Cost of Failure of Control} \\ (\text{Internal Failure Cost} + \text{External Failure Cost}). \end{aligned}$$



Basically, there are four types of quality Cost :-

- ① Prevention Cost
- ② Appraisal Cost
- ③ Internal Failure Cost.
- ④ External Failure Cost.

① Prevention Cost:

Planning, Document, Control, Training.

OR

- Cost of Preventing defects rather than finding & removing.
- The cost incurred "to avoid or minimize the numbers of defects at first place" are known as prevention cost.

② Appraisal Cost:

Inspection & Tests, Installation, Calibration, M/c Depreciation, Reports & Rejects.

OR

- Identify Defects before shipping to Customers.
- All costs are associated with activities that are performed during manufacturing process.
- Also known as Inspection Cost.

③ Internal Failure Cost:

Scraps, Repair Rework, Design changes, Defect Failure Analysis, Retests & ReInspection, downgrading, Down time.

OR

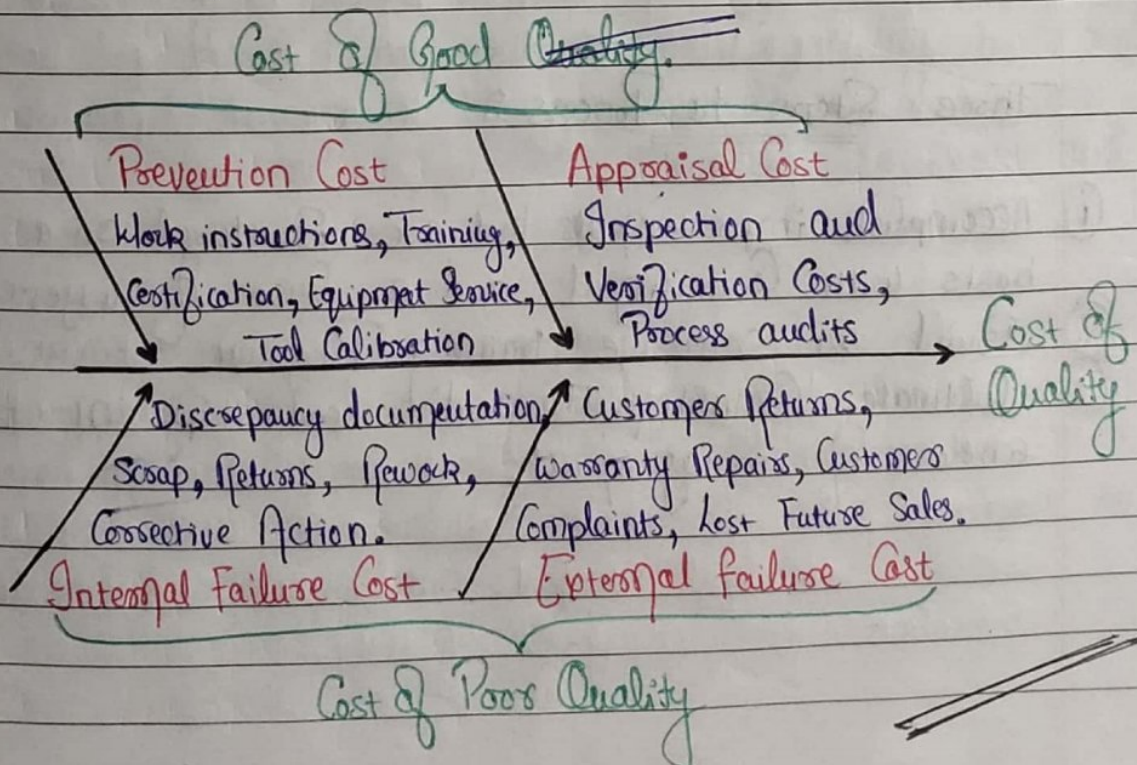
- Remove defects from the products before shipping them to Customers.
- Arise from "defects caught internally" and dealt with by discarding or repairing the defective items.

④ External Failure Cost :-

Complaints, Goodwill, Failures, Services & Replacement, Guarantee & Warranty, Compensation, Recall, Loss of Sales, Seconds Sales.

OR

- If defective products have been shipped to Customers, external failure costs arise.



Juran's ~~devised~~ Quality Philosophy :

Ten Steps to Quality :

- ① Establish awareness for the need to improve and the opportunities for improvement.
- ② Set goals for improvements.
- ③ Organize to meet the goals that have been set.
- ④ Provide training.
- ⑤ Implement projects aimed at solving problems.
- ⑥ Report progress.
- ⑦ Give recognition.
- ⑧ Communicate results.
- ⑨ Keep score.
- ⑩ Maintain momentum by building improvement into the company's regular systems.

Three Steps to Process :

- ① Accomplish improvements that are structured on a regular basis with commitment and a sense of urgency.
- ② Build an extensive training program.
- ③ Cultivate commitment and leadership at the highest echelons of management.

Process Quality Improvement

Process Quality : (Notes in last unit, @ important)

Process Quality refers to the degree to which an acceptable process, including measurements and Criteria for quality, has been implemented and adhered to in order to produce the artifacts.

OR

Process quality is a measure of Excellence of interrelated work items (like, tasks, procedures, steps). It is a measurement characteristic that indicates whether a given process is carried out with tolerable defects, minimized deficiencies, and insignificant variations. Higher quality of a process means that relationships b/w the process's components are successfully built and sustained throughout the process lifecycle. So the entire process is fulfilled according to needs and requirements of the customers.

Process quality measurements are widely used in project and business management to control, monitor and assure higher quality levels of final products.

There are various methodologies and techniques to control, manage and improve quality.

For example :-

- Six Sigma, a Project management Methodology.
- TQM (Total quality management).
- BPR (Business process Reengineering)
- PDCA (Plan-Do-Check-Act) Cycle.
- OQM (Object-oriented Quality Management).

Quality Improvement :

The ISO 9000 definition of quality Improvement states that it is a part of quality management focused on increasing the ability to fulfill quality requirements.

Quality improvement is a systematic, formal approach to the analysis of practice performance and efforts to improve performance.

OR

Quality Improvement is a structured approach to evaluating the performance of systems and processes, then determining needed improvements in both functional and operational areas. Successful efforts rely on the routine collection and analysis of data.

The Quality Improvement (QI) process is grounded in the following basic concepts.

- ① Establish a Culture of quality in your practice.
- ② Determine and prioritize potential areas for improvement.
- ③ Collect and analyze data.
- ④ Communicate your results.
- ⑤ Commit to ongoing evaluation.
- ⑥ Spread your Success.

Process

Objectives of measuring and assessing Quality are to:

- Manage profitability and resources.
- Manage and resolve risk.
- Manage and maintain budgets, Schedules, and quality.
- Capture data for process improvement.

Graphical and Statistical techniques for process quality improvement :

Systematic Solution approach to any quality improvement activity is critical and always emphasized by quality gurus (Juran, Deming and Shewart). Various tools and techniques are commonly used to identify the critical control variables. The very basic techniques used in

(Graphical)

Quality Management is 7 QC tools, which consist of Pareto Diagram, Process Flow Diagram, Cause and Effect diagram, Check Sheets, Histogram, Run Charts, and Scatter diagram. Additional Statistical tools used are hypothesis testing, regression analysis, ANOVA (Analysis of Variance), and Design of Experiment (DOE).

7 QC Tools:

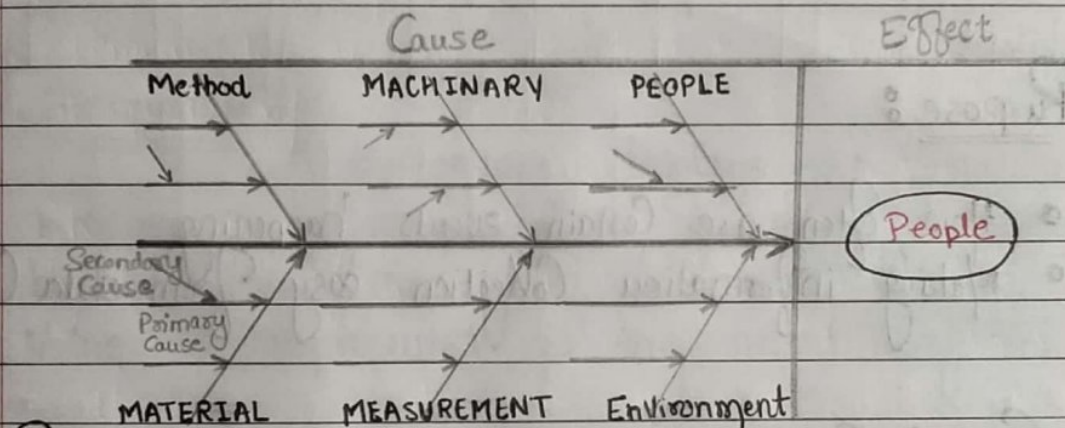
7 QC tools are the basic quality control tools which help in solving quality issues through data collection, analysing data, identification of root cause and measuring results.

- ① Cause & Effect Diagram.
- ② Check Sheet.
- ③ Control Chart.
- ④ Histogram.
- ⑤ Pareto Chart.
- ⑥ Scatter Diagram.
- ⑦ Flow Chart.

① Cause & Effect Diagram:

It is also known as fishbone diagram, it shows the relationship

of all Factors (Causes) that lead to the given Situation (Effect). It identifies major Causes and breaks them down into Sub-Causes and further Sub-divisions (if any). It is usually preceded by Cause-and-Effect Analysis.



Purpose:

- Identifies various Causes affecting a process.
- Helps groups in reaching a Common Understanding of a problem.

② Check Sheet:

A Check Sheet is a simple document that is used for collecting data in real time and at the location where data is generated.

Name of data

Assembly Check Sheet

Defect Types	Dates						Total
	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	
Product 1							
Product 2							
...							
Product 10							
Total							

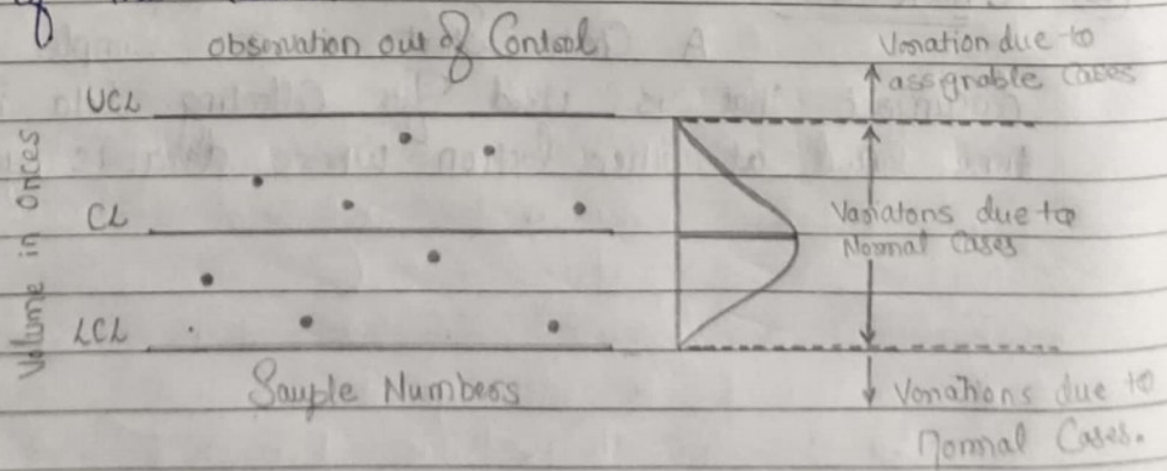
Purpose:

- How often are certain events happening.
- Making information collection easy from data (Format).

③ Control Chart:

A Control Chart is a line graph used to display variation on time ordered interval.

A Centerline and Control limits are placed on the graph to help analyze the pattern of the data.

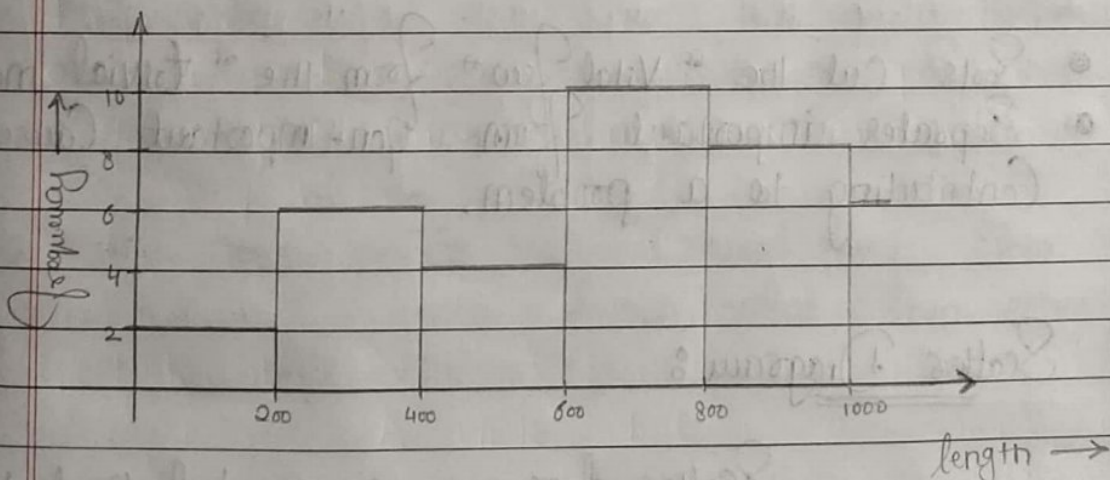


Purpose:

- Control Chart indicates whether a process is in Control or not.
- It ensures product quality level.
- To identify the dynamic or Special Causes of Variation in a separating process.

④ Histogram:

A Histogram displays the Variation within the process, also called a frequency distribution because the frequency of occurrence of any given value is represented by the height of the bars.

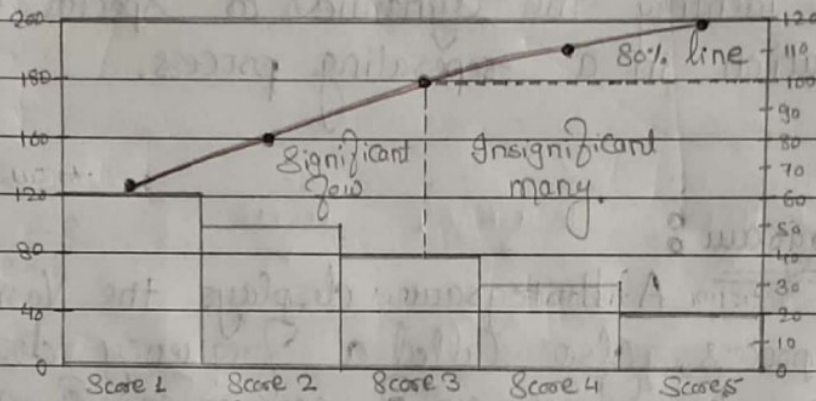


Purpose:

- To show the Frequency distribution of a set of measurements.
- Allows one to quickly visualize what's going on within a large amount of data.

⑤ Pareto Chart :

A bar Chart that helps to prioritize actions by arranging elements in descending order of occurrence.

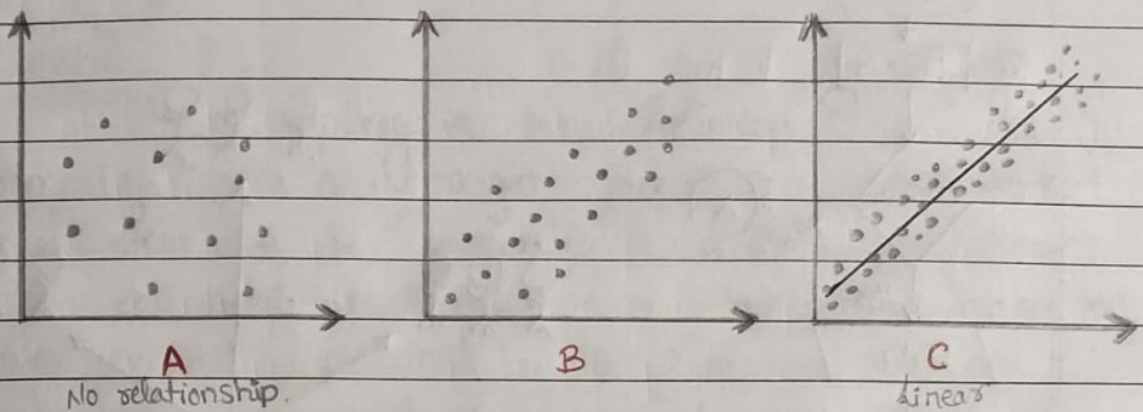


Purpose :

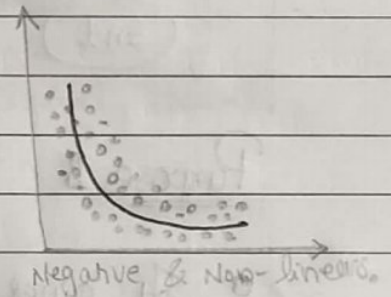
- Sorts Out the "Vital few" from the "Trivial many".
- Separates important from Non-important Causes Contributing to a problem.

⑥ Scatter Diagram :

Scatter diagram is a tool used to study the possible relationship between two Variables.



- A → Randomly Scattered points - No Correlation.
- B → Possible Positive Correlation.
- C → Strong Positive Correlation.



Purpose :

- Diagram makes it clear whether a relationship exists and shows the strength of that relationship.
- If data points are scattered very close to a trend, it shows strong relationship otherwise it is weak relationship.

⑦

Flow Chart :

A Flow Chart is a type of diagram that represents a process step by step with the help of various kind of box shapes and connecting these with arrows.

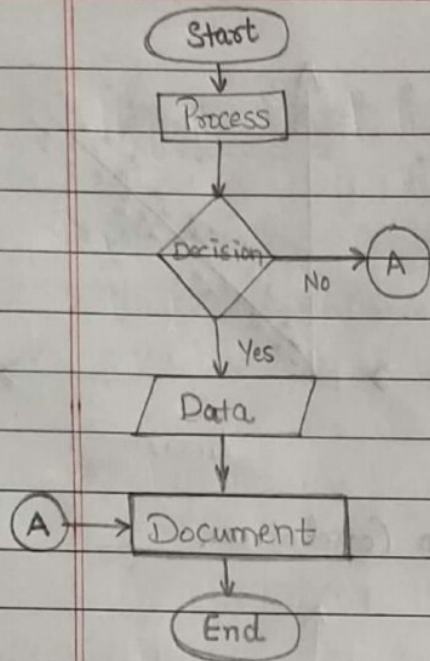


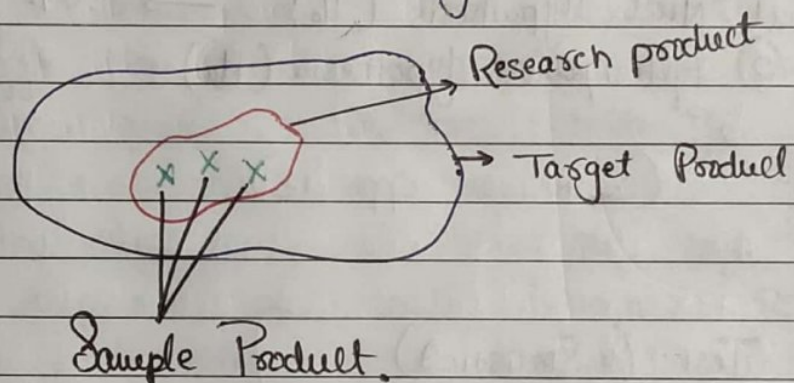
fig:- A typical diagram of stratification

Purpose :

- It gives a Visual representation of a process.
- Identify the Steps and Material needed for the process.
- Helps in quickly analyzing the process.

Sampling :

Sampling is the selection of a set of elements from a target population or product lot. Sampling is frequently used because gathering data on every member of a target population or every product produced by a company is often impossible, impractical, or too costly to collect.



Sampling Distribution :

Sampling distribution or finite-sampling distribution is the probability distribution of a given random-sample-based statistic.

If an arbitrarily large number of samples, each involving multiple observations, were separately used in order to compute one value of a statistic for each sample, then the sampling distribution is the probability distribution of the values that the statistic takes on. In many contexts, only one sample is observed, but the sampling distribution can be found theoretically.

* Sampling distributions are important in statistics because they provide a major simplification.

Hypothesis Testing :

→ Population. $\circ \circ \circ$

→ Sample $\circ \circ$

→ Hypothesis (assumption)

- ① Null Hypothesis (H_0) → 20% [20% Same from previous Results] (Same) (No Change)
- ② Alternative Hypothesis (H_a) different.

(Both are opposite)

→ Test (Statistics)

- ① χ^2 test (chi)
- ② t-Student test
- ③ Fisher's Z test.

After check from tests we determine is it null or Alternative Hypothesis so we use these ranges.

- (given in Q)
- Level of Significance (α) [5% 1%]
- Level of Confidence (C) [95% 99%]

$$\alpha + C = 1$$

if result is less than 5% then Null hypothesis (means previous and new are same) otherwise Alternative hypothesis.

Hypothesis testing :

Hypothesis testing is a Statistical procedure in which a Choice is made between a null hypothesis and an alternative hypothesis based on information in a Sample.

A hypothesis is essentially an idea about the population that you think might be true, but which you cannot prove to be true. While you usually have good reasons to think it is true, and you often hope that it is true, you need to show that the sample data support your idea. Hypothesis testing allows you to find out, in a formal manner, if the sample supports your idea about the population.

Null Hypothesis :

A Statistical hypothesis that states that there is no difference between a parameter and a specific value, or that there is no difference between two parameters.

Alternative Hypothesis :

A Statistical hypothesis that states the existence of a difference between a parameter and a specific value, or states that there is a difference between two parameters.

Importance :

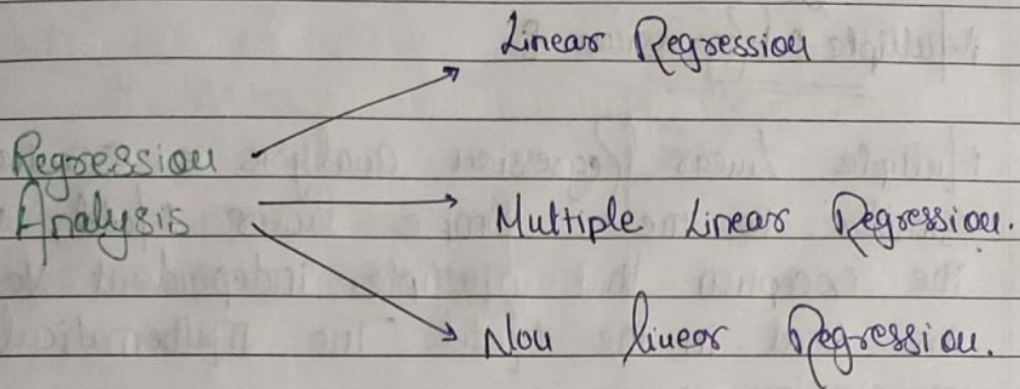
Essentially good hypothesis lead decision-makers like you to new and better ways to achieve your business goals.

Regression Analysis :

It is a method of estimating the value of one variable when that of the other is known and when the variables are Correlated.

OR

Regression Analysis is a set of ^{Statistical} ~~Statistical~~ method used for the estimation of relationships between a dependent variable and one or more independent variables. It can be utilized to assess the strength of the relationship b/w variables and for modeling the future relationship between them.



Regression Analysis includes Several Variations, Such as ~~a~~ linear, multiple linear and non linear.

The ~~&~~ most Common models are Simple linear and multiple linear. Non-linear regression analysis is Commonly used for more Complicated data sets in which the dependent and independent variables show a non-linear relationship.

Simple Linear Regression:

Simple linear Regression is a model that assess the relationship b/w a dependent variable and an independent variable. The Simple linear Model is expressed using this eq:

$$y = a + bx + e$$

y → dependent Variable

x → Independent Variable

a → Intercept

b → Slope

e → errors.

Multiple Linear Regression :

Multiple Linear Regression analysis is essentially similar to the Simple Linear Model, with the exception that multiple independent variables are used in the model. The mathematical representation is

$$Y = a + bX_1 + cX_2 + dX_3 + E$$

$Y \rightarrow$ dependent Variable

$X_1, X_2, X_3 \rightarrow$ Independent Variable

$a \rightarrow$ Intercept

$b, c, d \rightarrow$ Slopes

$E \rightarrow$ Error.

Now,

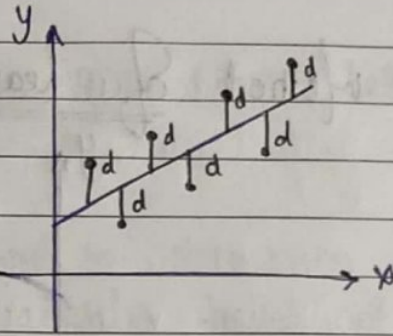
Deviations are not measured perpendicularly :

- ① Vertically
- ② Horizontally.

* Line of Regression of y on x . (Vertical deviation)

$$y = a + bx$$

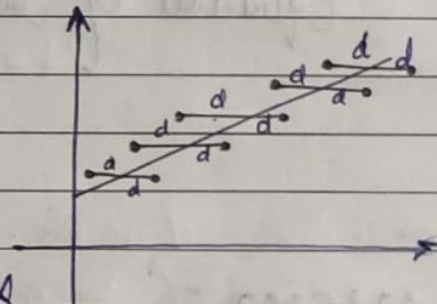
→ Used for estimating value of y for a given value of x .



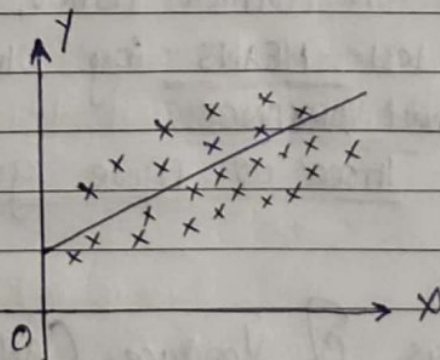
* Line of Regression of x on y (Horizontal deviation):

$$x = a + by$$

→ Used for estimating value of x for a given value of y .



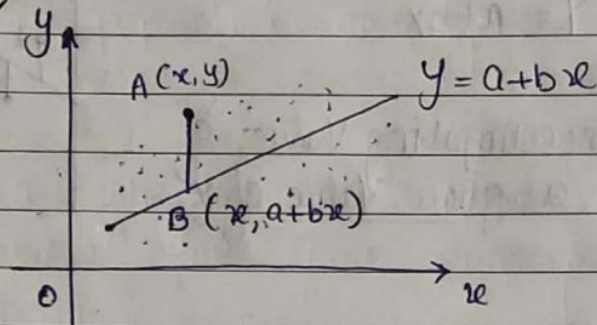
Method of Scatter Diagram:



Disadvantages:

- ① Not accurate.
- ② Better method available.

Method of Least Squares :



Equation of line is $y = a + bx$

ANOVA (Analysis of Variance) :

- ANOVA is short for Analysis of Variance.
- Developed by Sir Ronald Fisher.
- Designed to test MEANS by utilizing different estimates of the VARIANCE.
- Allowed for Three or more groups.

Analysis of Variance (ANOVA) is an analysis tool used in statistics that splits an observed aggregate (mean) variables found inside a data set into two parts: Systematic factors and random factors. The systematic factors have a

Statistical influence on the given data set, while the random factors do not.

Analysts use the ANOVA test to determine the influence that independent variables have on the dependent variable in a regression study.

The Formula of ANOVA is :-

$$F = \frac{MST}{MSE}$$

Where: $F \rightarrow$ ANOVA Coefficient.

$MST \rightarrow$ Mean Sum of Squares due to treatment.

$MSE \rightarrow$ Mean Sum of Squares due to error.

OR

ANOVA :

The Analysis of Variance (ANOVA) is used to determine whether there is any statistical significant difference b/w the means of three or more independent (unrelated) groups.

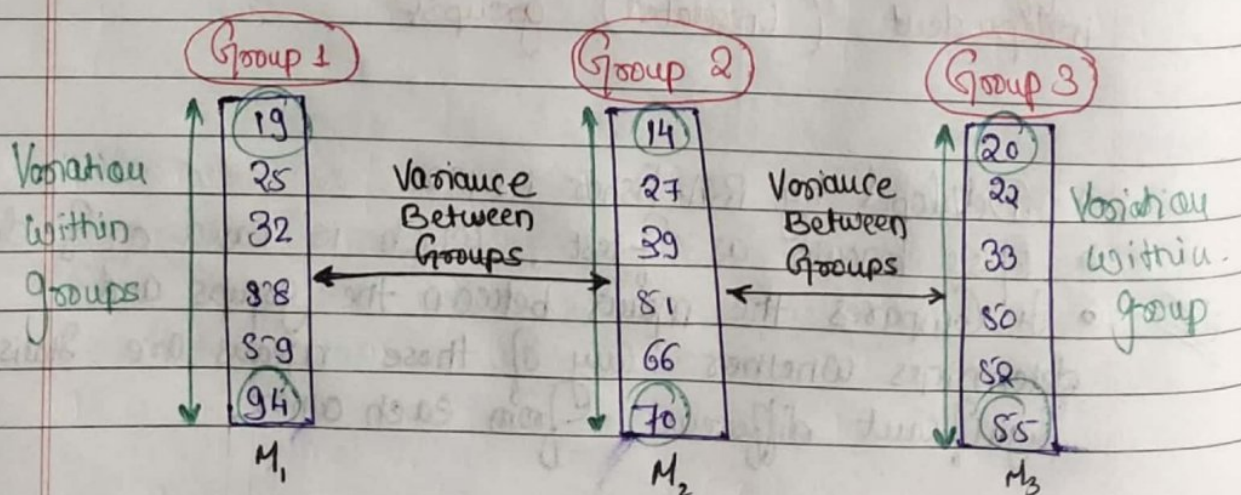
- Developed by R.A. Fisher in 1920
- Also known as F test, which is based on F-distribution.
- It compares the means between the groups and determines whether any of those means are statistically significant different from each other.

- It determines whether all groups are taken from common population or not.
- ANOVA is a ratio between "Mean Sum of Squares between (MSS_b)" and "Mean Sum of Squares within (MSS_w)".

$$F = \frac{MSS_b}{MSS_w} = \frac{\text{Between Variance}}{\text{Within Variance}}$$

→ The Variation Among the observations of each specific group is called its internal variation and the totality of the internal variations is called Variability within groups.

→ The totality of variations from one group to another, i.e. variation due to group is called Variability between groups.



Design Of Experiment (DOE) :

Design Of Experiment (DOE) is defined as a branch of applied Statistics that deals with planning, Conducting, analyzing and interpreting Controlled tests to evaluate the factors that Control the Value of a parameter or group of parameters.

OR

Design Of Experiments is a Statistical tool Used by Engineers to evaluate the effect of Single or Multiple Changes to a process or Design. With that knowledge, they Can design a product that Satisfies Customer Needs and Meets or exceeds quality Standards.

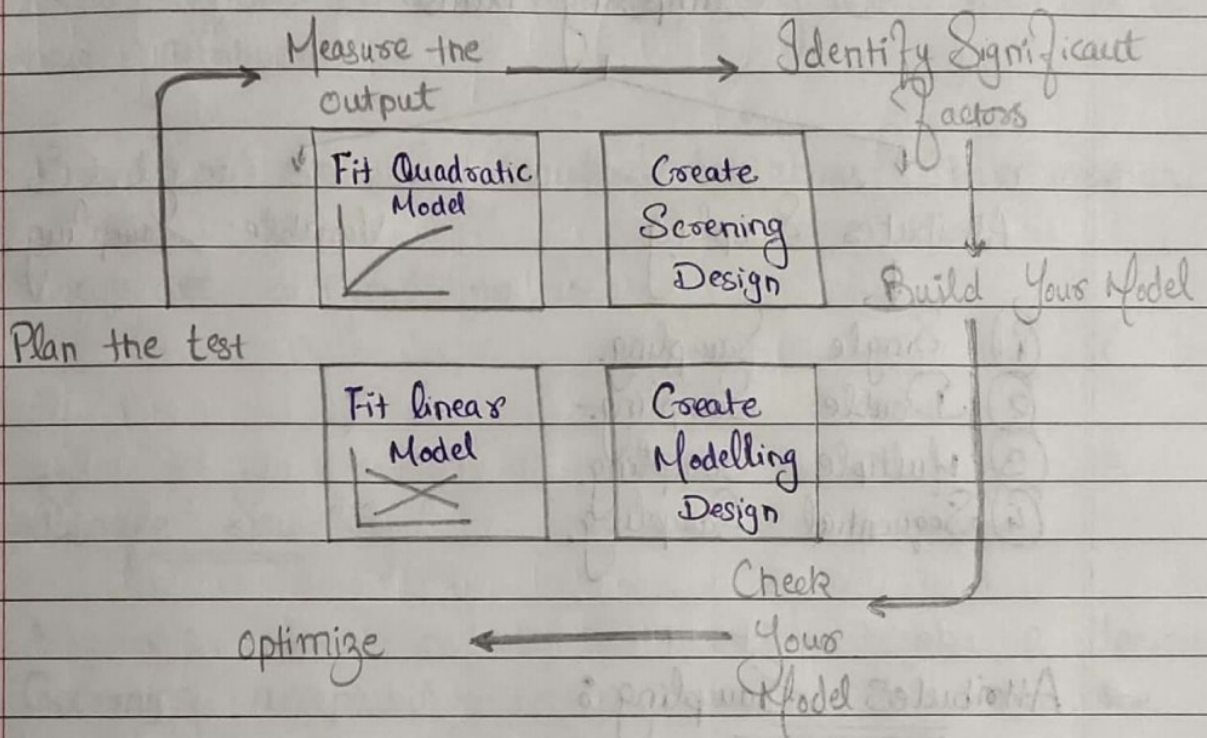
The Effective Use of DOE Methodology Can Significantly reduce the Numbers of test runs or ~~test~~ total builds → Saving project time and Uncovering hidden issues in the process. With DOE, a project team is able to identify the factors that have the most and least impact on output.

Role / Use in quality management :

- ① DOE is a Systematic Method to determine the relationship b/w factors affecting a process and the output of that process. In other words, it is used to find ~~case~~ Cause-and-effect relationships. This information is needed to manage process input in order to optimize the output.
- ② DOE Can be Used to develop a predictive equation, allowing a what-if analysis to be conducted.
- ③ Use DOE when more than one input factor is suspected of influencing an output.
For example : It may be desirable to understand the effect of temperature and pressure on the strength of a glue bond.

DOE involves following steps :

- ① Selection of independent variables.
- ② Selection of No. of level settings for each independent variable.
- ③ Selection of orthogonal array.
- ④ Assigning the independent variables to each column.
- ⑤ Conducting the experiments.
- ⑥ Analyzing the data.
- ⑦ Inference.



Acceptance Sampling Plan :

Acceptance Sampling is defined as Sampling inspection in which decisions are made to accept or reject products or services.

~~It~~ It is a decision making tool by which a Conclusion is reached regarding the acceptability of lot.

Sampling Plans

Attributes Sampling

Variable Sampling

- ① Single Sampling.
- ② Double Sampling.
- ③ Multiple Sampling.
- ④ Sequential Sampling.

Attributes Sampling :

- Attributes Sampling is most commonly used, more than 1 type of quality characteristics can be considered for each sample.
- Measurements are simpler to make.
- It requires a large sample size than variable sampling plan.

Variable Sampling :

- Variable plan need measurement type data & decision must be based only on one such measurement characteristics.

- It is efficient because Variables Carry more information than attributes.
- Based on mean & Standard deviation Characteristics.
- They are difficult to use.

① Single Sampling :

- A plan in which inspector is forced to make a decision concerning acceptability of a lot or batch on the basis of inspection of units in one sample taken from that lot.
- It can be described in terms of 3 Constants.
 - N , the lot size.
 - n , the sample size.
 - C , the acceptance number.
 - C is the maximum allowable defects in sample.
 - If sample contains C or fewer defectives, lot will be accepted & if it contains more than C lot will be rejected.

② Double Sampling :

- These are characterized by two sample size along with two sets of acceptance rejection numbers.

- The two Sample Sizes may or may not be equal.
- It Can be described in terms of C_1, C_2, C_3 .

③ Multiple Sampling :

- In this 3 or more Sample might be taken before a decision is reached regarding the acceptability of a lot.
- It results in Smaller average Sample Size.

④ Sequential Sampling :

- An extreme case of multiple Sampling in which Sampling might continue until the lot is exhausted.
- It calls for inspection on an item by item basis.
- Decision is made after each item is inspected concerning whether lot should be accepted or rejected or Sampling continued.
- Sampling & decision making continues until a clear cut decision is obtained either to accept or reject.

Advantages :

- ① Destructive testing.
- ② Less Cost and time.
- ③ Smaller staff.
- ④ Less damage to work.
- ⑤ Exerts pressure on quality improvement.

Limitations :

- ① Less information.
- ② Risk of wrong decision.
- ③ Extra planning and documentation.

Total Quality Management (TQM) :

Total Quality management (TQM) has been defined as an integrated organizational effort designed to improve quality at every level.

OR

The process to produce a perfect product by a series of measures require an organized effort by the entire company to prevent or eliminate errors at every stage in production is called total quality management.

Total: made up of the whole

Quality: degree of excellence a product or service provides.

Management: act, art or manners of Planning, Controlling, directing.

Therefore, TOM is the art of managing the whole to achieve excellence.

Principles of TOM:

- ① Produce quality work the first time and every time.
- ② Focus on the Customers.
- ③ Have a Strategic approach to improvement.
- ④ Improve Continuously.
- ⑤ Encourage mutual respect and teamwork.

Benefits of TOM:

- Improved quality.
- Employee Participation.
- Team work.
- Working relationship.
- Customer Satisfaction.
- Employee Satisfaction.
- Productivity.

- Communication.
- Profitability.
- Market Share.

The three Aspects of TQM:

Counting

Tools, techniques, and training in their use for analyzing, understanding, and solving quality problems.

Customers

Quality for the customers as a driving force and central concern.

Culture

Shared values and beliefs, expressed by leaders, that define and support quality.

Advantages:

- Improves reputation - Faults and problems are spotted and sorted quicker.
- Higher employee morale - Workers motivated by extra responsibility, team work and involvement in decisions of TQM.
- Lowers Cost.

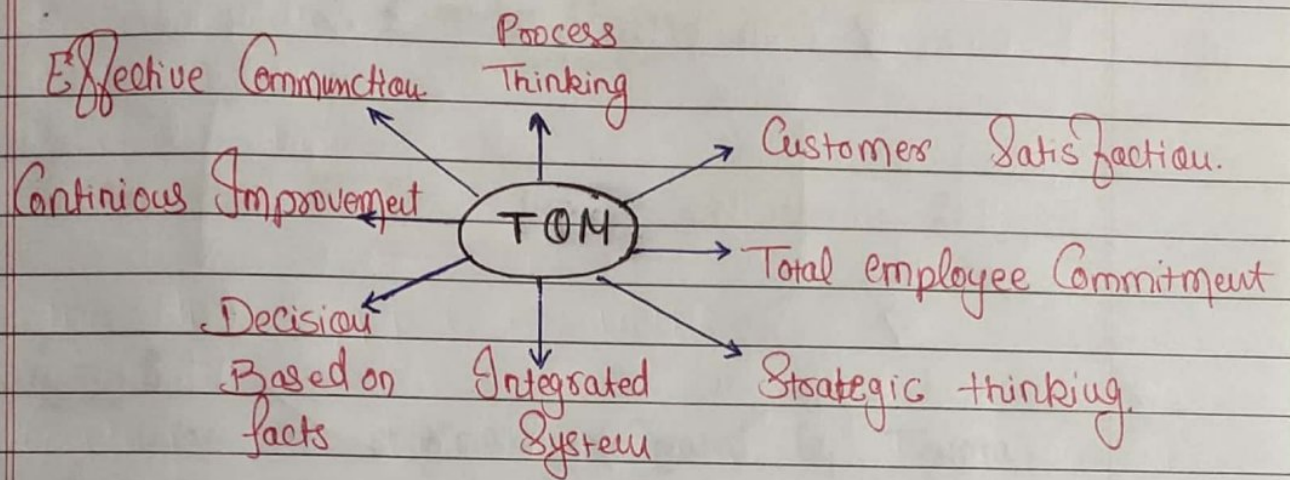
- Decrease waste as fewer defective products and no need for separate.

Disadvantages :

- Initial introduction Cost.
- Benefits may not be seen for several years.
- Workers may be resistance to change.

Q:- How to Implement TQM :

- ① Communicate from employee.
- ② Quality Improvement Culture.
- ③ Continuous improvement in process.
- ④ Co-operation from Employees.
- ⑤ Focus on Customers Requirements.
- ⑥ Effective Control shall be laid down.



Acceptance Sampling Diagram

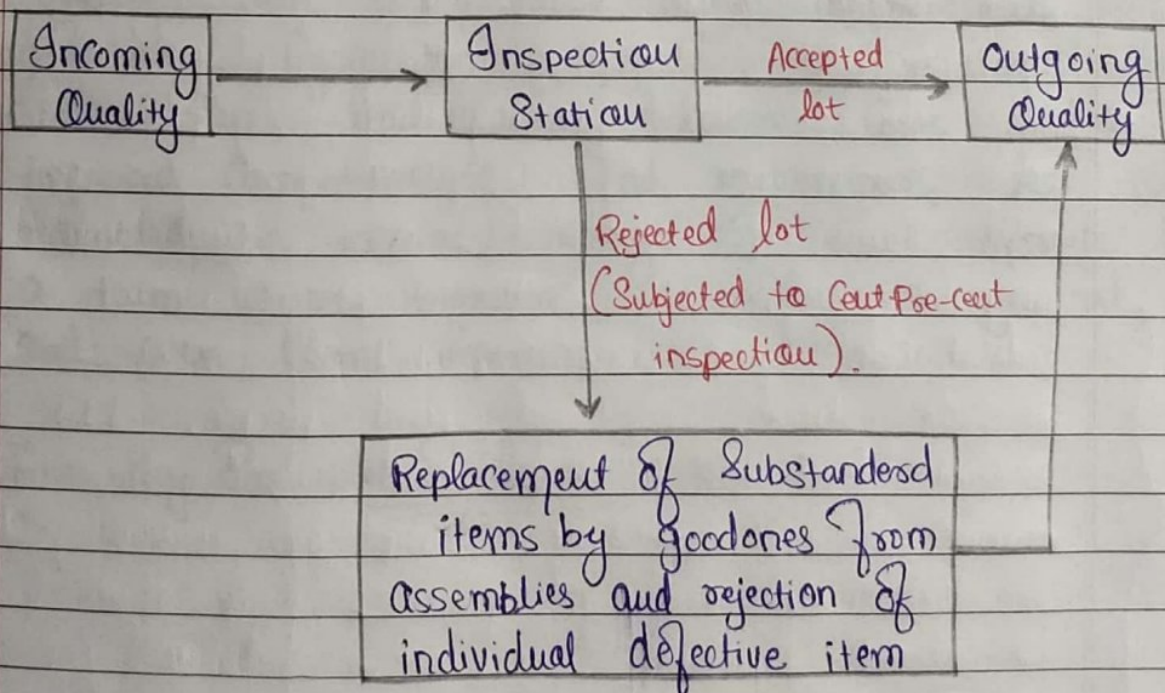


Fig:- A typical diagram acceptance Sampling plan.

Leadership

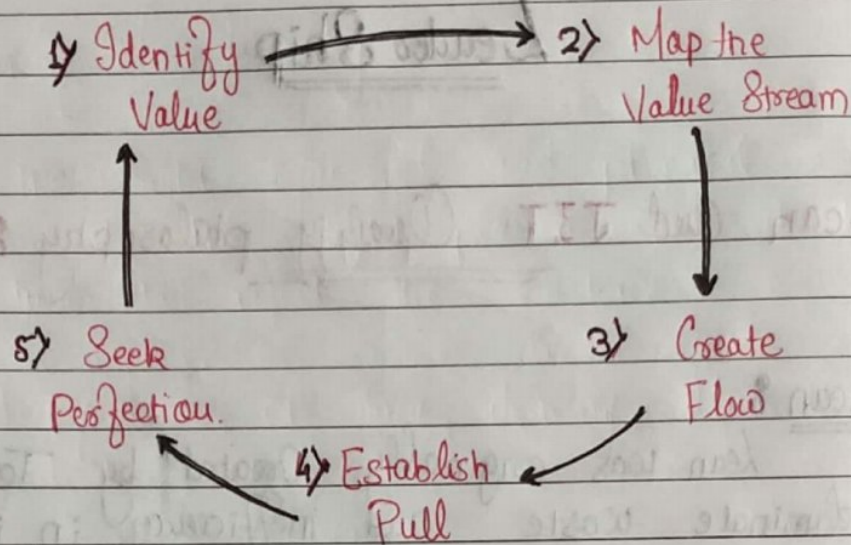
Lean and JIT Quality philosophy :

Lean :

Lean was originally created by Toyota to eliminate waste and inefficiency in its manufacturing operations.

The goal of lean is to eliminate waste - the Non-Value-added Component in any process. Unless a process has gone through lean multiple times, it contains some element of waste. When done correctly, lean can create huge improvements in efficiency, cycle time, productivity, material costs, and scrap, leading to lower costs and improved competitiveness. And remember, lean isn't restricted to manufacturing. It can improve how a team works together, inventory management, and even client interaction.

Five Key Principles of lean thinking :



JIT quality Philosophy :

Just-in-time (JIT) is not just a manufacturing technique but a philosophy of manufacturing that influences a company's relationship with its suppliers, customers and employees. The two basic underpinnings of this philosophy are elimination of anything that does not add value for the customer, and continuous improvement. Thus, the emphasis is on efficient utilization of resources, where resources can include time, material and people. JIT activities include setup and lead time reduction, minimization of inventory, employee involvement in the decision-making process, cooperative arrangements with suppliers, and a focus on meeting the needs of customers.

- The JIT philosophy fosters an environment, where continuous improvements are sought in waste reduction and quality. Another important aspect of the JIT philosophy is that improves the relationships with employees, and employees are given broad problem solving and decision-making authority.

OR

JIT :

- A set of techniques to increase, productivity; improve quality, and reduce cost of an operations.
- A management philosophy to promote elimination of waste and continuous improvement of productivity.

Elements of JIT :

- Elimination of waste.
- Quality at the source.
- Balanced and flexible work flow
- Respect for people
- Continuous improvement (Kaizen)
- Simplification and Visual Control.
- Focus on Customer needs.
- Partnerships with Key Suppliers.

Problem of Manufacturing :

- Getting the right Material and physical resources together at the right place and at the right time to meet the Customer's requirement.
- Desired Features, on time delivery, High Quality, at the best price.

Break down the problem :

- Getting the Material needed.
- Having enough inventory of Material to support production.
- Not having too much inventory and extra Costs.

Just In time :

only what is needed,

- > Right Material.
- > Right place
- > at the Right time.

The Seven Wastes :

- Waste of over production.
- Waste of Waiting.
- Waste of Transportation.
- Waste of over processing.
- Waste of inventory.
- Waste of Motion.
- Waste of Making defective products.

Without Reducing these 7 wastes we Can Not achieve Just in time (JIT).

Benchmarking :

Benchmarking is the process of Comparing the Cost, Cycle time, productivity or quality of a specific process or Method to another that is widely Considered to be an industry or best practice.

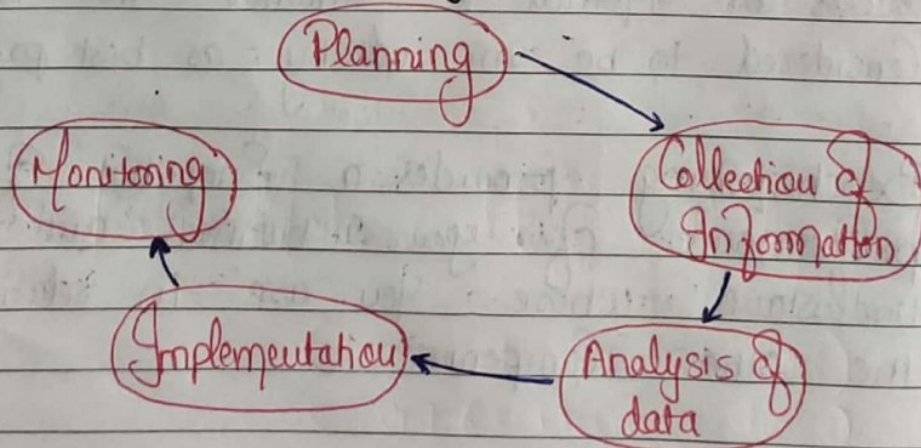
Benchmarking provides a Snapshot of the performance of your business and help you Understand where you are in relation to the other Companies.

**

Benchmarking is quality by comparison for achieving better.

- Benchmarking is an activity an organization uses to establish a leadership position.
- Benchmarking is a point of reference against which other things are compared or measured.
- Focuses on establishing a leadership position.
- Identifies world-class organization, products and business practices.
- Evaluates the reasons for their being world-class.

Process of Benchmarking :



① Planning :

Identify the product, service or process to be benchmarked.

② Collection of Information :

Information can be divided in sub texts of primary and secondary data.

Primary data refers to collection of data directly from the benchmarked company / companies itself.

Secondary data refers to the information gathered from the press, publication or websites.

③ Analysis of Data :

Once successfully data is collected, the proper analysis of such information is of foremost important.

Compare the current performance and benchmarked data and analyse the difference.

④ Implementation :

This is the stage in the benchmarking process where it become mandatory to walk the talk. And at that time we improve the quality and fulfill the difference b/w the current and benchmarked data and improve the quality of product.

⑧ Monitoring :

As with most projects, in order to reap the maximum benefits of the benchmarking process, a systematic evolution should be carried out on a regular basis.

Benchmarking in Quality Management :

In Quality Management Benchmarking is most important thing for improvement of quality of product.

In order to do so, businesses need to set standards for themselves and measure their processes and performance against recognized industry leaders or against best practices from other industries, which operate in a similar environment.

§

Imp

Process Failure Mode and Effect Analysis (PFMEA) :

(last unit important topic)

(Unit 6 : Design Failure)

(part of this topic)

In a leadership A process Failure Mode Effects Analysis (PFMEA) is a structured analytical tool used by an organization, business unit, or Cross-Functional team to identify and evaluate the potential failures of a process.

It Can,

- Identifies Design or process related Failure Modes before they happen.
- Determines the Effect & Severity of these Failure modes.
- Identifies the Causes and probability of Occurrence of the failure modes.
- Identifies the Controls and their Effectiveness.
- Quantifies and prioritizes the Risks associated with the Failure Modes.
- Develops & documents Action plans that will occur to reduce risk.

Failure Modes and Effect analysis (FMEA) is a Step-by-Step approach for identifying all possible failures in a design, a manufacturing or assembly process, or a product ~~and~~ or service. It is a Common process Analysis tool.

Types of Failures in FMEA :

- ① System FMEA
- ② Design FMEA
- ③ Process FMEA

Process of FMEA :

- ① Review the process.
- ② Potential Failure Mode.
- ③ Potential Effects of Failures.
- ④ Potential Causes of Failure.
- ⑤ Assign a Severity ranking.
- ⑥ Assign an occurrence ranking.
- ⑦ Assign a detection ranking.
- ⑧ Calculate the RPN (Risk priority numbers).
- ⑨ Develop an action plan.
- ⑩ Recalculate the RPN.

* Failure Modes : (Specific loss of a function) is a concise description of how a part, system, or manufacturing process may potentially fail to perform its functions.

* Failure Mode "Effect" : A description of the consequence or ramification of a system or part failure. A typical failure mode may have several "effects" depending on which customers you consider.

* Severity Rating : (Seriousness of the effect) Severity is the numerical rating of the impact on Customers.

* Failure Mode "Causes" : A description of the design or process deficiency (global Cause or root level Cause) that results in the Failure mode.

* Occurance Rating : Is an estimate number of frequencies or cumulative numbers of failures (based on experience) that will occur (in our design concept) for a given Cause over the intended "life of the design".

* Failure Mode "Controls" : The mechanisms, Methods, tests, procedures, or Controls that we have in place to PREVENT the Cause of the Failure mode or DETECT the Failure mode or Cause should be occur.

* Detection Rating : A numerical rating of the probability that a given set of Controls will discovers a specific Cause of Failure mode to prevent bad parts leaving the Facility or getting to the Ultimate Customers.

* Risk Priority Numbers (RPN): Is the product of Severity, Occurrence & Detection.
$$\text{Risk} = \text{RPN} = S \times O \times D$$

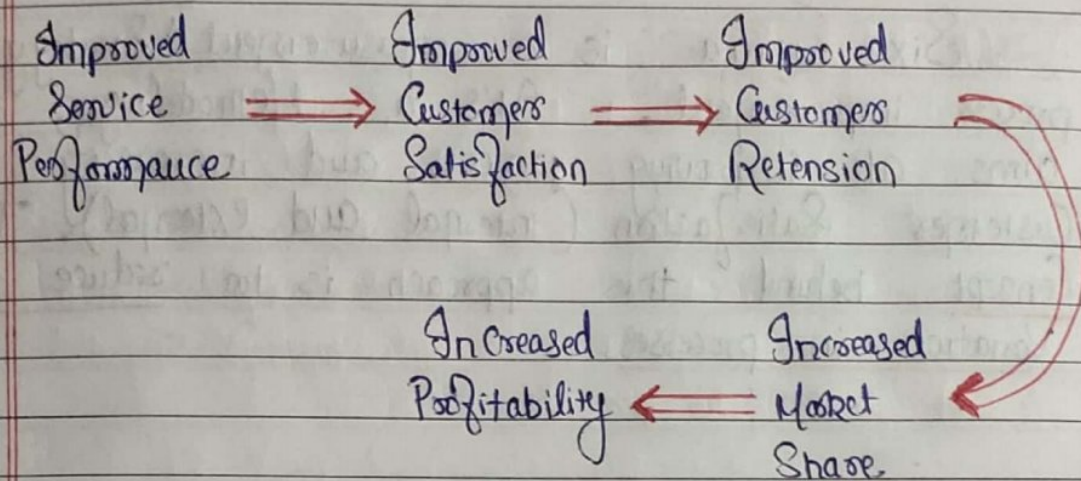
* Action Planning: A thoroughly thought out and well developed FMEA with High Risk patterns that is not followed with Corrective actions has little or no value, other than having a chart for an audit.

Service Quality:

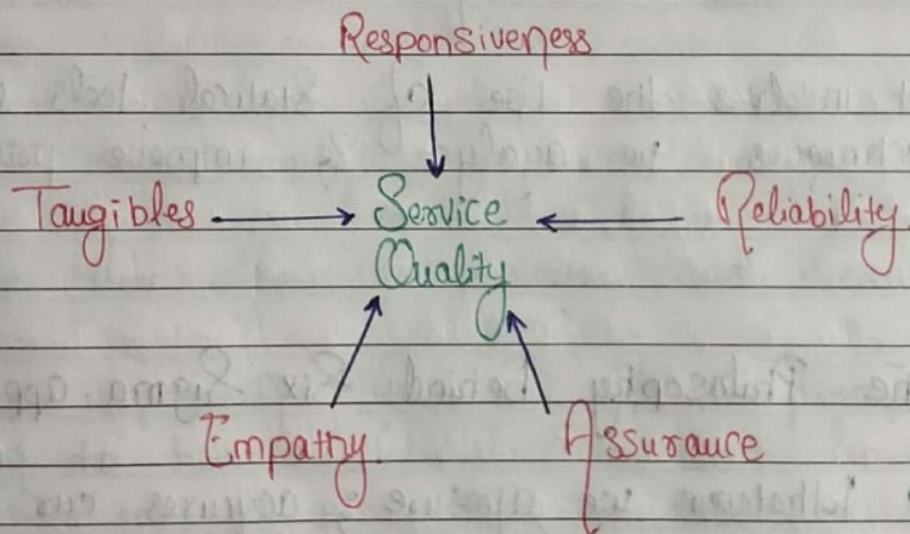
Service quality generally refers to a Customer's Comparison of Service expectations as it relates to a Company's performance.

A business with a high level of Service Quality is likely Capable of meeting Customer needs while also remaining economically Competitive in their respective industry.

Purpose of Service Quality:



Dimensions Of Service Quality :



Six Sigma For Process Improvement : (also in lost unit) Notes →

Six Sigma is a set of techniques and tools for process improvement. It was introduced by American engineers Bill Smith while working at Motorola in 1986.

Six-Sigma is a measurement^{based} strategy for process improvement. It's a methodology, which aims at improving process and increasing Customer Satisfaction (internal and external). The Concept behind this approach is to reduce the Variation in processes.

- A Systematic approach to process improvement.
- Processes can be related to design, manufacturing and administrative functions.
- It involves the use of statistical tools and techniques to analyse & improve process.

The Philosophy behind Six Sigma approach is :

- Whatever we measure ; acquires our focus.
- Whatever we focus ; leads to improvement.

Tool :

Six Sigma follows the DMAIC model for quality improvement and problem reduction (For existing processes). The well-defined process

Approach Consists of Five phases in order:

- Define
- Measure
- Analyze
- Improve
- Control.

Principles of Six Sigma:

- Always Focus on the Customers.
- Understand how work really happens.
- Make your processes flow smoothly.
- Reduce waste and concentrate on value.
- Stop defects through removing variation.
- Get buy-in from the team through collaboration.
- Make your efforts systematic and scientific.

Process improvement for one single process is always going to have a limited scope with limited considerations. But we're not talking about tinkering with single process.

ISO 9001 and QS 9000 :

ISO 9001 :

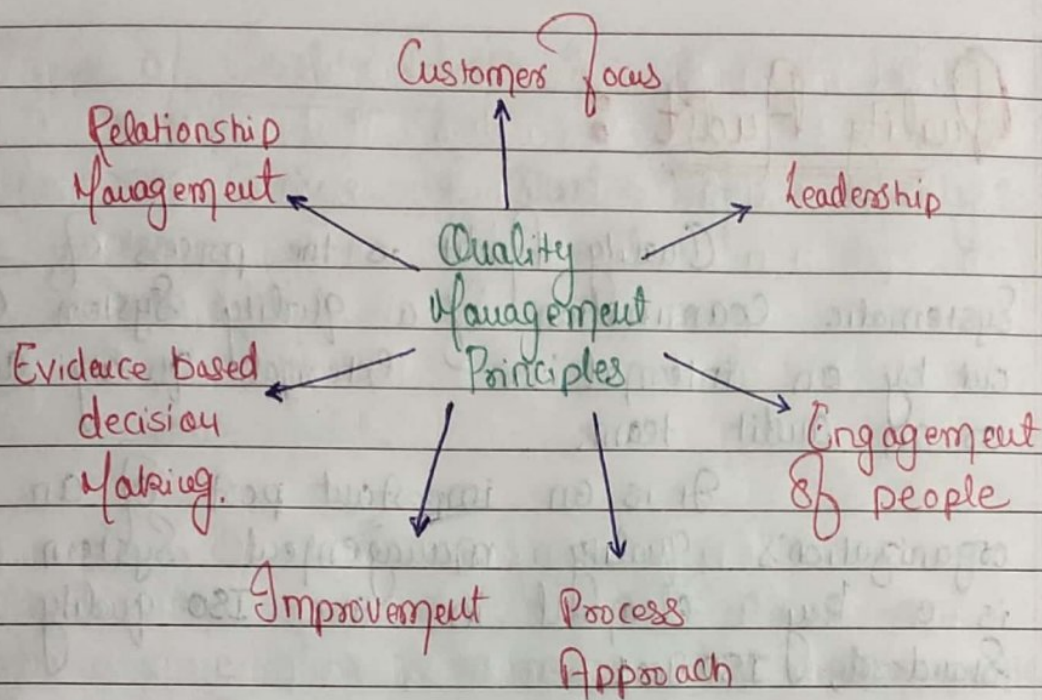
ISO 9001 Family of Quality Management System (QMS) is a set of standards that help organizations ensure they meet Customer and other Stakeholders needs within Statutory and Regulatory requirements related to a product and service.

ISO 9001 deals with the fundamentals of quality Management Systems, including the seven quality management principles that underlie the family of standards.

ISO 9001 deals with the requirements that organizations wishing to meet the standard must fulfill.

* ISO 9001 is defined as the international standard that specifies requirements for a quality management system (QMS). Organizations use the standard to demonstrate the ability to consistently provide products and services that meet customer and regulatory requirements.

Seven Quality Management Principles are :



QS 9000 :

QS 9000 is a Company level certification based on quality system requirements related specifically to the automotive industry. These standards were developed by the larger automotive companies including Ford, General Motors and Daimler Chrysler.

QS 9000 applied to Companies who supplied automotive production materials, production and service parts, heat treatment, painting, plating, and other finishing services. All suppliers of the automotive industry were not required to be certified to QS-9000 standards.

Quality Audit :

Quality Audit is the process of systematic examination of a quality system carried out by an internal or external quality auditors or an audit team.

It is an important part of an organization's quality management system and is a key element in the ISO quality system standard, ISO 9001.

- Quality Audit are typically performed at predefined time intervals and ensure that the institution has clearly defined internal system monitoring procedures linked to effective action. This can help determine if the organization complies with the defined quality system processes and can involve procedural or results-based assessment criteria.

They can also help determine whether an organization is compliant with the requirements of a specific quality system.

Types of Quality Audit :

There are 3 types of Quality Audit mainly :-

- ① Process Audit
- ② Product Audit
- ③ System Audit.

** An audit may also be classified as internal or external, depending on the interrelationships among participants. Internal Audits are performed by employees of your organization. External Audit are performed by an outside agent.

Internal Audit are often referred to as First-Party audit, while external audits can be either Second-party, or third-party.

① Process Audit :

A Verification that processes are working within established limits. It evaluates an operation or Method against predefined predetermined instructions or Standards to measure Conformance to these Standards and the Effectiveness of the instructions.

② Process Audit :

A Verification that processes are working within established limit. It evaluates an operation or method against predetermined instructions or standards to ensure conformance to these standards and the effectiveness of the instructions.

Check Conformance to defined requirements such as time, accuracy, temperature, pressure, composition, responsiveness, amperage, examine the resources (equipment, materials, people), environment and methods (procedures, instructions).

Check the adequacy and effectiveness of the process controls establish by procedures, work instructions, flowcharts, and training and process specifications.

③ System Audit :

An audit conducted on a management system.

→ ~~ISO~~ Conformance to Company policies, Contract commitments, and regulatory requirements, environment management system by environment system audit, food safety management system by food system audit, and safety management system by safety system audit.

Quality Cycle :

Quality Circles :

A quality Circle or quality Control Circle is a group of workers who do the same and similar work, who meet regularly to identify, analyze and solve work-related problems. It consists of minimum three and maximum twelve members in numbers.

Objective of Quality Circle :

- ① Improvement in quality of product manufactured by the organization.
- ② Improvement in Methods of production.
- ③ Development of employee participating in QC.
- ④ Promoting morale of employees.
- ⑤ Respect humanity and Create a happy work place worthwhile to work.

Main Features :

- ① Voluntary Groups.
- ② Small Size
- ③ Regular Meeting.
- ④ Independent Agenda.
- ⑤ Quality Focused.

① Voluntary Groups :

QC is a Voluntary group of employees generally coming from the same work area. There is no pressure from anywhere on employee to join QC.

② Small Size :

The size of the QC is generally small consisting of six to eight members.

③ Regular Meeting :

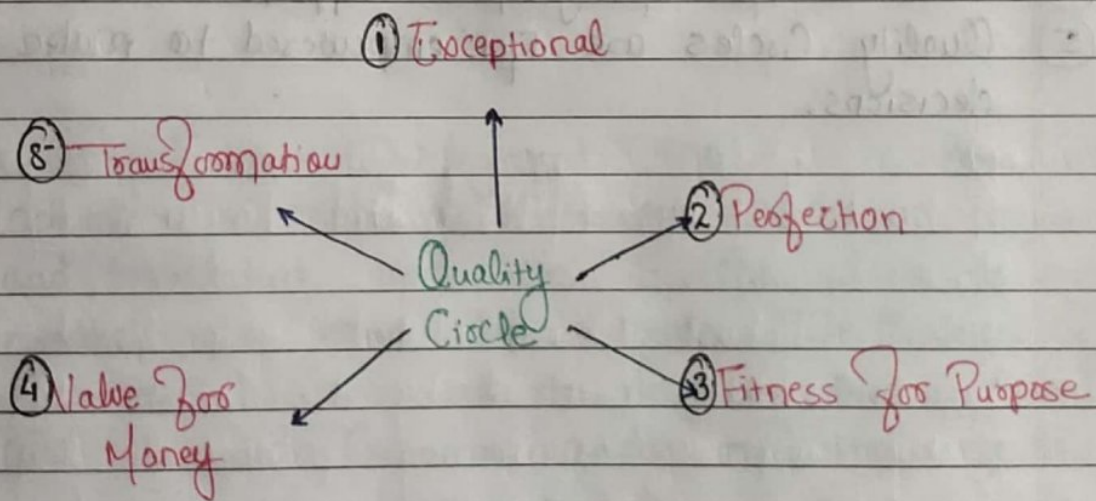
QC Meetings are held once a week for about an hour on regular basis. The members meet during working hours usually at the end of the working day in consultation with the managers. The time of the meeting is usually fixed in advance in consultation with the managers and members.

④ Independent Agenda :

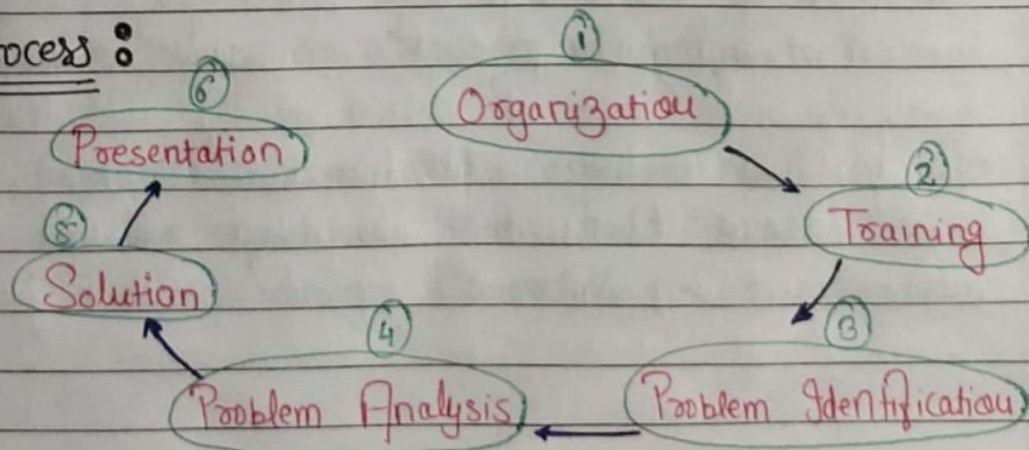
Each QC has its own agenda with its own terms of reference. Accordingly, each QC discusses its own problems and takes corrective actions.

⑤ Quality Focused :

As per the very nature and intent of QC, it focuses exclusively on quality issues. This is because the ultimate purpose of QC is improvement in quality of product and working life.



Process :



Quality Circle processes

Advantages :

- ① Promotion of teamwork.
- ② Develops employee positive attitudes.
- ③ Positive working environment.
- ④ Increased quality and productivity.

Disadvantages :

- ① Employees not sure of the purpose.
- ② Not enough relevant training.
- ③ Participation not voluntary.
- ④ Little or no management support.
- ⑤ Quality Circles are not empowered to make decisions.

Product Quality Improvement

Quality Function ~~Development~~ Deployment

Quality Function ^{deployment} development (QFD) is a Comprehensive methodology Used to translate the Customer requirements (Voice of Customer) to design (technical) Characteristics and build a quality product after benchmarking against the Competition.

OR

Quality Function Deployment (QFD) is a Structured approach to defining Customer needs or requirements and translating them into Specific plans to produce products to meet those needs. The "Voice of the Customer" is the term to describe these Stated and Unstated Customer needs or requirements.

Quality Function deployment helps to:

- Capture Spoken and Unspoken Needs of Customers.
- Uncovers qualities that could 'wow' the Customers.
- Translate design Characteristics to deliverable actions.

Basic Steps Of Quality Function Deployment product Quality improvement process:

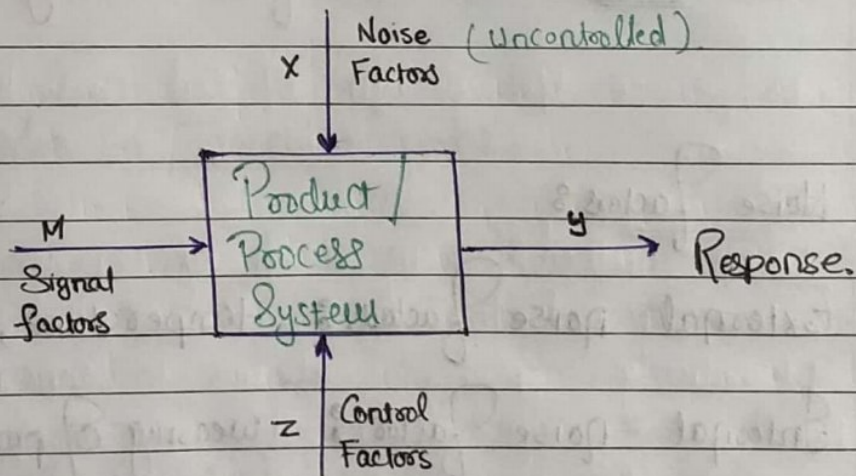
- ① Identify the Voice Of Customers (VOC).
- ② Define your process elements based on Voice Of Customers.
- ③ Relationship between WHATs and HOWs
- ④ Customer benchmarking.
- ⑤ Solution benchmarking.
- ⑥ Trade-off between different HOWs.
- ⑦ Set up Integrated Matrix.
- ⑧ Define Specifications.

Robust Design Method And Taguchi Method:

Robust Design Method, also called the Taguchi Method, pioneered by Dr. Genichi Taguchi, greatly improves engineering productivity. By consciously considering the noise factors (environmental variation during the product's usage, manufacturing variation, and component deterioration) and the cost of failure in the field. The Robust Design method helps ensure customer satisfactions. Robust design focuses on improving the fundamental function

of the product as process, thus facilitating flexible designs and Concurrent engineering. Indeed, it is the most powerful method available to reduce product cost, improve quality, and simultaneously reduce development interval.

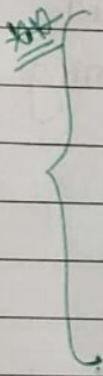
The Robust Design Method prescribes a systematic procedure for minimizing design sensitivity and it is called Parameters Design. An overwhelming majority of product failures and the resulting field costs and design iterations come from ignoring noise factors during the early design stages.



P-diagram

In the design of a new product, any design activity can be called Robust, if it leads the product:

- To have longer life (higher reliability)
- To be more consistent with use.
- To be more consistent from product to product
- To perform consistently as temperature and other conditions change.



- It is defined as reducing variation in various product characteristics.
- In other words, making the product or process insensitive to variations. This variation (sometimes called noise) can come from a variety of factors.

Noise Factors :

- External noise factors : temperature, humidity.
- Internal noise factors : wearing of parts, manufacturing imperfections.
- Unit to Unit or Variational noise factors :
It indicates the difference b/w individual products, which are produced to same specifications.

~~***~~ Taguchi Suggested a robust design Method, which is a systematic Method for identify process parameters that are most Sensitive to inherent process Variation and minimize the effect of Causes of Variation.

~~*~~ It can improve the Quality of Manufactured goods.

~~***~~ Taguchi's Work includes three principal Contributions to Statistics :

- ① A Specific Loss Functions.
- ② The philosophy of off-line quality Control.
- ③ Innovations in the design of experiments.

~~***~~ Steps involve in Taguchi Method :

- ① Identify the main Function and its Side Effects.
- ② Identify the Noise Factors, testing Condition and quality Characteristics.
- ③ Identify the objective Function to be optimized.
- ④ Identify the Control Factors and their levels.
- ⑤ Select a Suitable Orthogonal Array and Construct the Matrix.
- ⑥ Conduct the Matrix experiment.
- ⑦ Examine the data; predict the optimum Control Factors levels and its performance.
- ⑧ Conduct the Verification experiment.

Ques: Taguchi Method are Statistical Method, Sometimes Called robust design Method, developed by Genichi Taguchi to improve the quality of manufactured good and more recently also applied to engineering, biotechnology, marketing and advertising. Professional Statisticians have welcomed the goals and improvement brought about by Taguchi methods, particularly by Taguchi's development of designs for studying Variation, but have Criticized by inefficiency of some of Taguchi's proposals.

Q: Difference b/w design Method and taguchi method System.

Ans: Design Method: The design of experiment (DOE) is explained by Lye, as a methodology for systematically applying Statistics to experiments. In DOE, a sequence of tests is designed in which powerful vary the input parameters (factors) of a product or process to examine the reasons of the Variation in the output response. By the end of the twentieth Century, DOE was no longer viewed as merely a stand-alone tool, because it was packaged together with a structured initiative for business improvement known as Six-Sigma. •

DOE is a good tool to Understand and optimize products or process parameters. It is quick as well as Cost-effective.

Advantages:

- ① A good amount of data can be obtained with lesser resources (experiments, time, material).
- ② The estimates of the effect of each factor (Variable) on the response are more precise.
- ③ It is a systematic way to estimate the interactions b/w the process factors.
- ④ There is experimental information in a larger region of the factor space.

Taguchi Method:

In Taguchi Method, we assume that we are designing an engineering system - it might be a machine that performs some intended function or it might be a production process. We use the knowledge of fundamental about the system and process parameters for efficient experimentation. We can skip all the extra effort that might have gone in to investigating interactions. By this, we can decrease the number of factors. Taguchi categorize the factors in two sets:

- ① Control Factors, which are under our control.
- ② Noise Factors, which are not under our control, except during experiments in the laboratory.

Advantages 8

- ① The foundation of the DOE in Taguchi method (TM) is orthogonal array design that is very simple method for analyzing the outputs.
- ② The key step of the TM is to increase the quality level with less affecting the cost factors.
- ③ TM provides the optimal settings for the processes which can improve quality, and these settings attained from TM are also insensitive to the variation of noise factors.

Design Failure

Design Failure :

Failure Modes and Effect analysis (FMEA) is a Step-by-Step approach for identifying all possible failures in a design, a manufacturing or assembly process, or a product or service. It is a Common process Analytical tool.

A design failure is a design that is low value or that destroys value. It is Common for such failures to damage results, reputation, brand image and quality of life. Design failures can also represent risks to health, safety, financial stability and the environment.

Design FMEA : Analysis is at the Subsystem level (made up of various components) or Component level.

Types of Design Failure in quality Management :

- Value Proposition
- Naive Design
- Feature Fatigue
- Context of Use
- Quality.
- Accidental Complexity.
- Less is a Bore
- Architecture
- Human Factors.
- Edge Cases

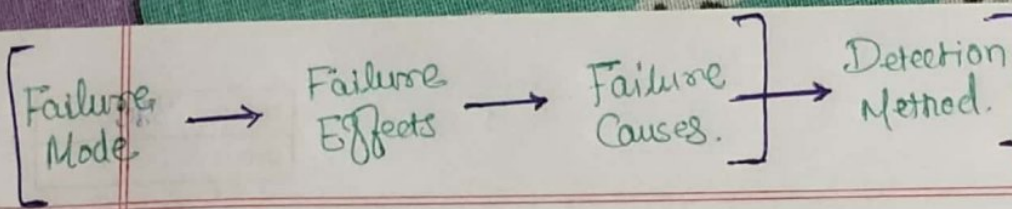
- Sensory design
- Bliss point
- User engagement
- Style
- Balance
- Colour Scheme
- Errors defect
- Design for Failure.
- Productivity.
- Efficiency.
- Ease
- Information Structure.

Unit 4

Q:- Failure Mode and Effect analysis Explain and discuss its application and apply in the Main role in Quality Management.

Ans:- Failure Mode and Effect analysis (FMEA) is a method designed to:

- Identify and fully understand potential Failure Modes and their Causes, and the effects of Failure on the System or end Users, for a given product or process.
- Assess the Risk associated with the identified Failure modes, effects and Causes, and prioritize issues for corrective action.
- Identify and Carry out corrective actions to address the most serious concerns.



The three Most Common types of FMEA's are:

- ① System FMEA
- ② Design FMEA
- ③ Process FMEA

① System FMEA : Analysis is at highest-level analysis of an entire system, made up of various subsystems. (~~related to Product/Service/~~ System/Component failure)

② Design FMEA : Analysis is at the subsystem level (made up of various components) or component level. (Related to Product/Service/ System/Component failure)

③ Process FMEA : Analysis is at the manufacturing/assembly process level. (Related to manufacturing failure)

Role in Quality Management :

- For process FMEA, Consider the effect at the manufacturing or assembly level, as well as at the system or end users.
- Based on the Criteria from a Severity level.
- To obtain the best possible results from FMEA, Companies need to focus on Key Success Factors.

Design Failure Mode and Effect Analysis :

DFMEA is a methodical approach used for identifying potential risks introduced in a new or changed design of a product / service.

The design FMEA initially identifies design functions, failure modes and their effects on the customers with corresponding severity ranking / dangers of the effect. Then, causes and their mechanisms of the failure mode are identified.

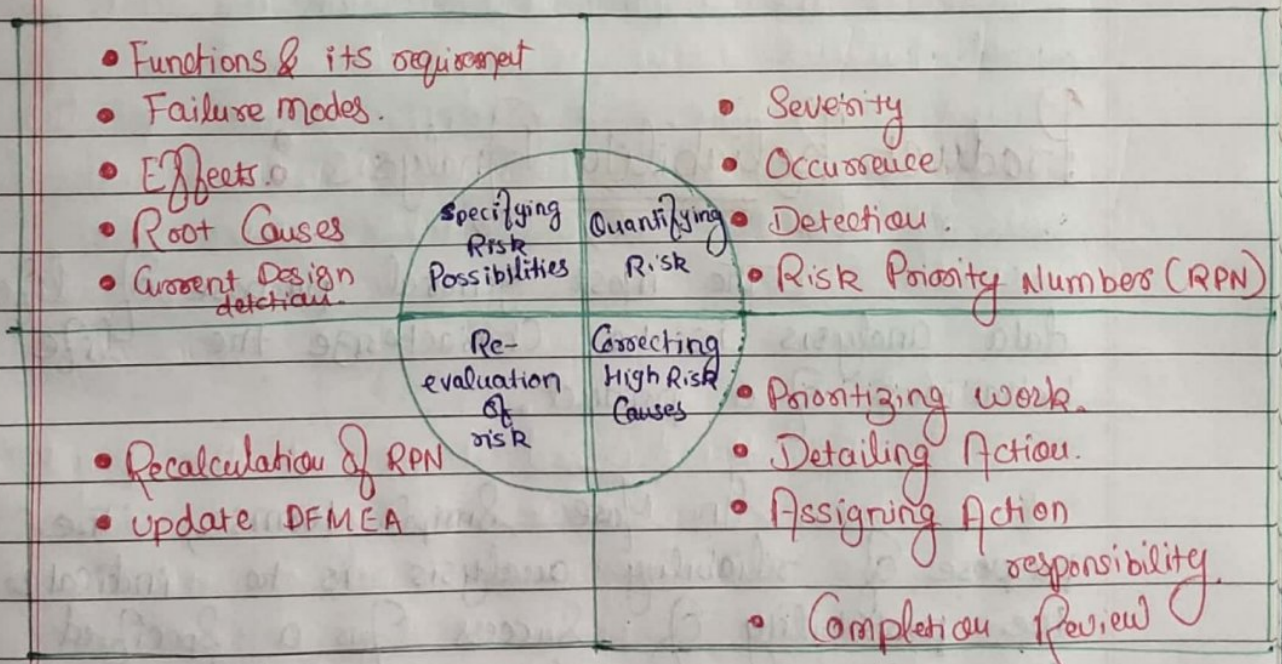
High probability causes, indicated by the occurrence ranking, may drive action to prevent or reduce the cause's impact on the failure mode. The detection ranking highlights the ability of specific tests to confirm the failure mode / causes are eliminated.

The design FMEA also tracks improvements through Risk priority numbers (RPN) reductions. By comparing the before and after RPN.

* At any time any System or Component doesn't satisfy the design requirements or doesn't perform its intended functions.

* Design Failure Can be -

- No Functioning (100% not working)
- Partial Functioning (Partially working)
- Intermediate Functioning (Stop for short time & then start again : Repeat again).



Failure Modes : Failure Modes, means the ways, or Modes, in which something might fail. Failures are any errors or defects, especially ones that effect the Customer, and can be potential or actual.

Effects Analysis : Effects analysis refers to studying the consequences of those failures.

Product Reliability Analysis :

The most general purpose of life data analysis is to characterize the life behaviour of a product.

In more simple terms, the purpose of reliability analysis is to indicate the probability of success for a specified time. This probability is called the reliability and is always associated with a given time.

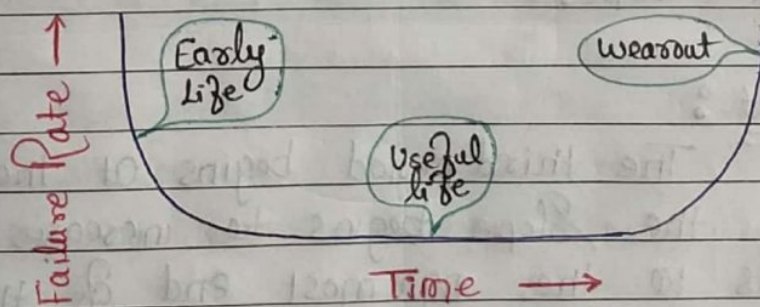
* Product Reliability is defined as the probability that a device will perform its required function, subjected to stated conditions, for a specific period of time.

Product Reliability is quantified as MTBF (Mean time Between Failures) for repairable product and MTTF (Mean Time To Failure) for non-repairable product.

We can measure it, or better yet and predict it by the famous Bathtub Curve.

The Famous Bathtub Curve :

instantaneous failure rate λ vs time.



The life of a population of devices (a group of devices of the same type) can be divided into three distinct periods :

① Early life :

If we follow the slope from the leftmost start to where it begins to flatten out this can be considered the first period. The first period is characterized by a decreasing failure rate. It is what occurs during the "early life" of a population of units. The weaker units fail leaving a population that is more vigorous.

② Useful life :

The next period is the flat bottom portion of the graph. It is called the "useful life" period. Failures occur more in a random sequence during this time. It is difficult to predict which failure mode will occur, but the rate of failures is predictable. Notice the constant slope.

③ Wearout :

The third period begins at the point where the slope begins to increase and extends to the rightmost end of the graph. This is what happens when units become old and begin to fail at an increasing rate. It is called the "wearout" period.

Mean time Between Failure (MTBF) = T/R

T = Total time

R = No. of Failures.

Mean time to failure (MTTF) = T/N

T = Total time

N = No. of Units Under test.

* Reliability may or may have existing procedures or guidelines to support the development team.

Some important process of reliability :

- During the Concept phase of product development, we should focus on setting reliability goals.
- During the detailed design phase, reliability plays a role in Component Selection through Stress Strength or detecting Analysis.
- During Component Qualification Characterizing the variability of potential Component parameters may provide insights on potential System Failure root Causes and the establishment of Control plans.

- Essentially any Steps in the process, allows reliability engineers to understand the relative chances of errors, out of Specification Components or Subsystems, and ultimately the impact on reliability performance of process Capability.

also in Unit 4

Six Sigma in Product development :

Six Sigma is a business process that guides Companies to produce high-Quality products, reduce Costs, and improve Efficiency.

DFSS Concepts can be included into an existing product development process or can be used to Create a new product development process within an organization.

Employing Six-Sigma can also increase profit of existing products, processes, and Services.

First introduced by Motorola, the System relies on Using rigorous data to drive decision making.

By implementing Six-Sigma process, Companies outside the medical industry, Such as General electric, Honeywell, Raytheon, and IBM, have realized billion of dollars in Cost Savings, process improvement, quality improvement and product development.

The Six-Sigma process detailed below is a Five-Step process that is widely Used around the world.

- ① Define.
- ② Measure.
- ③ Analyze.
- ④ Improve.
- ⑤ Control.

① Define : Customer requirements, the problems, the project Scope, and the Customer goals.

② Measure : The ~~product~~ Current product as process Capability.

③ Analyze : What is Wrong and identify possible root Causes.

④ Improve : Find and test the possible Solutions.

⑤ Control : implement, monitor, and Sustain the optimal Solution.

Q:- Explain process Quality improvement process and analysis its Applications.

Ans:- Quality Improvement is a Structured approach to evaluating the performance of Systems and processes, then determining needed improvements in both functional and operational areas. Successful efforts rely on the routine Collection and analysis of data. A quality improvement plan describes an ongoing, or Continuous, process through which an Organization's Stakeholders Can monitor and evaluate initiatives and results.

Quality Improvement process Shows the Characteristics :

- Quality Improvement is data driven and regards the quantitative approach as the only reliable means to influence the quantitative elements. The principle is expressed by W. Edwards Deming: "The Right data in the Right Format in the right hand at the right time."
- QI focuses on processes, not people. In other words, the individual is never at fault.
- QI involves people as part of the improvement solution and looks for what is attributed to Deming as "the Smart Cogs", the employees who are

directly involved in and best Understand the processes in an organization.

Main Purpose of Quality Improvement :

Quality Improvement is data driven and regards +

Quality Improvement aims to Create efficiencies and address the needs of Customers. In health care, the main purpose of quality improvement is to improve outcomes. In health care settings, quality improvement may be associated with Continuous quality Improvement, the method used to identify problems and implement, monitor, and provide corrective action.

The Benefits of Quality Improvement Process :

- Solutions that focus on failures in processes, not flaws in people.
- Improvements that provide better Customer Service, increased efficiency, greater safety, and higher revenues.

- Data Collection to monitor improvement efforts, which can provide the basis for reimbursement and certification programs, particularly in health care organizations.