TOTAL QUALITY MANAGEMENT

UNIT I

INTRODUCTION

Total – whole made up of
Quality – Zero defect
Management – it's the art of getting things done through people

DEFINITION FOR QUALITY

- According to Dr. W.K. Spriegel "The quality of a product may be defined as the sum of a number of related characteristics such as shape, dimension, composition, strength, workmanship, adjustment, finish and colour".
- In the words of John D. McIIellan, "Quality is the degree to which a product conforms to specifications and workmanship standards".
- The standard of something as measured against other things of a similar kind; the degree of excellence of something.
- ISO 8402-1986 standard defines quality as "the totality of features and characteristics of a product or service that bears its ability to satisfy stated or implied needs."

$$\text{Quality} = \frac{\text{Performance}}{\text{Expectations}}$$

DEFINITION FOR TQM

- **According to the International Standard for Standardization (ISO)**, "TQM is a management approach for an organization, centered on quality, based on the participation of all its members and aiming at long-term success through customers satisfaction, and benefits to all member of the organization and to society".
- **According to Rick W. Griffin**," A strategic commitment by top management to change its whole approach to business to make quality guiding factors in everything it does".
- **According to Robbins and Coulter**, "Total quality management is a philosophy of management that is driven by customer needs and expectations and focuses on continual improvement in work process".
- A core definition of total quality management (TQM) describes a management approach to long–term success through customer satisfaction. In a TQM effort, all members of an organization participate in improving processes, products, services, and the culture in which they work.

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SCOPE OF TQM

TQM which means Total Quality Management, which focuses on improvement in the quality of product to satisfy the customers. Managerial activities of TQM are,

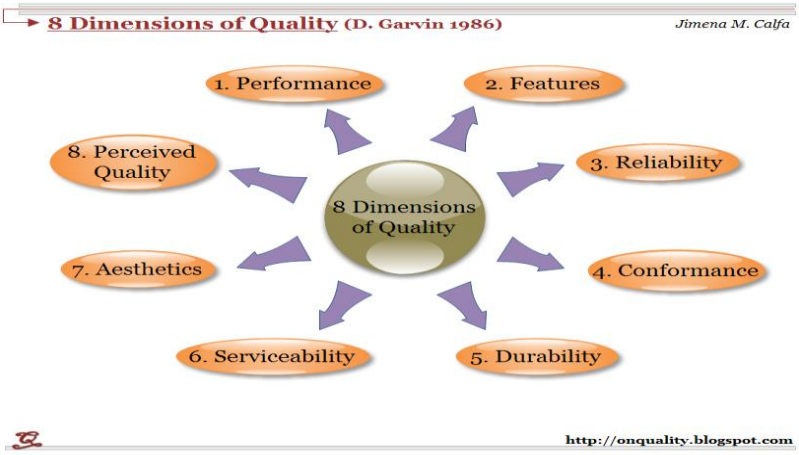
1. Continuous improvement of skills : Organization should continuously improve the culture of skills. They should develop their skills in the specific department. For this, the organization should give effective tanning and program to make employee skilled one. Creative and innovation skill makes the quality of a product which satisfy the customers and also helps to develop overall working efficiency of the organization.

2. Use of Teamwork: Use of teamwork is the important part of TQM. It helps to solve problems of any part of the organization. Team co-operates between each other and one encourages another for making process. All member comes together for taking decision related to procedure and working method.

3. Improving processes, product and service: TQM is continuous improvement in processes, product & service. It should be done by considering customers need and wants .New technology is improving the taste and demand of customers due to the mode, design and structure. So, management should encourage employees in such improvement of planning.

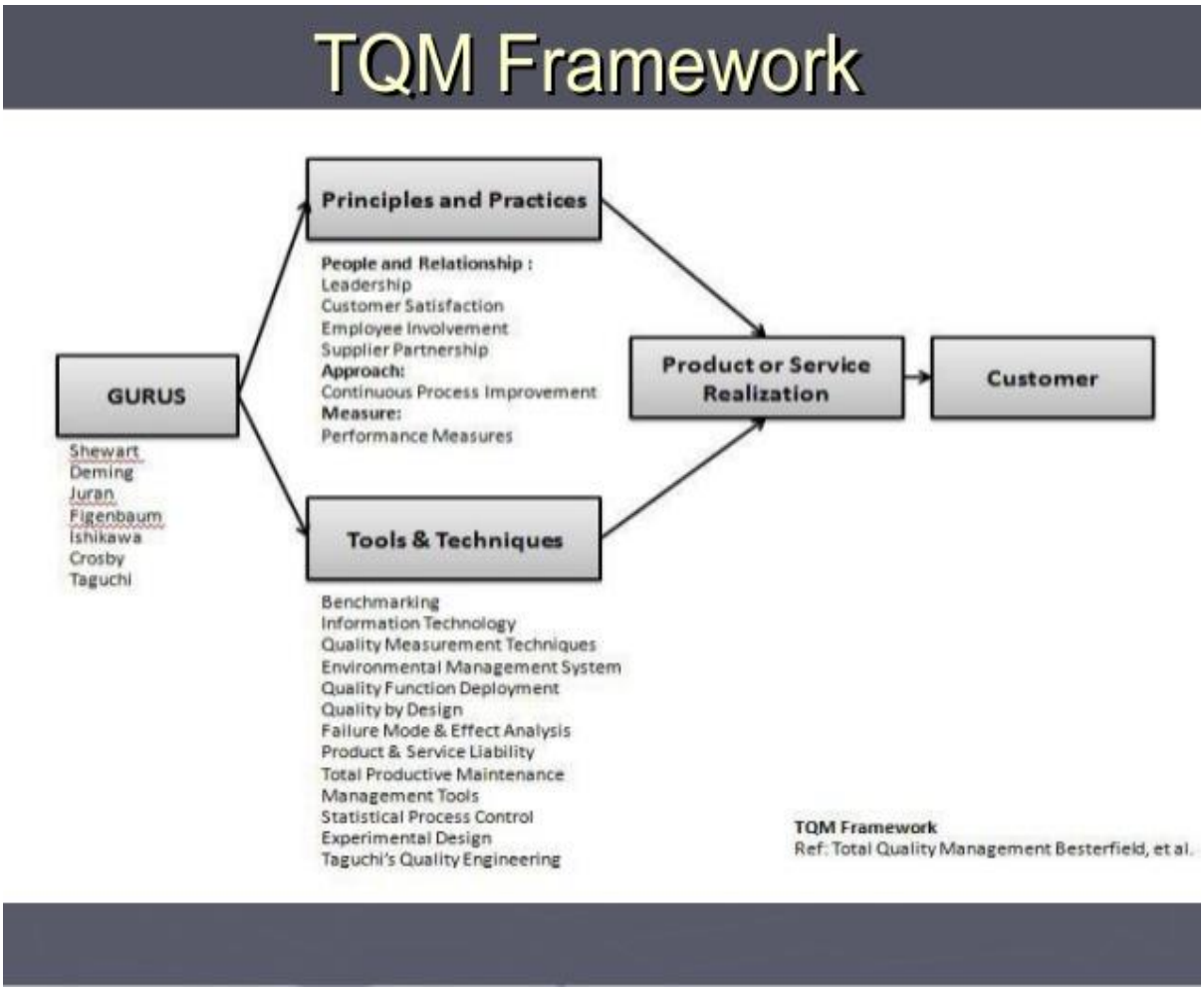
4. Focus on customer satisfaction: All the business organizations main objective is to earn profit and wealth through customers satisfaction. If we make customer satisfy in the market area, then it will increase the volume of business. So, customers are the source of revenue in an organization. Essential measure to satisfy the customers are: taking their view, identifying potential customers, studying the measures for satisfying customers and supplying goods and services on the basis of their needs and demand.

DIMENSIONS AND INGREDIENTS OF QUALITY / DIMENSIONS OF PRODUCT QUALITY / DIMENSIONS OF SERVICE QUALITY



 Performance: 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.
 Features: Features are additional characteristics that enhance the appeal of the product or service to the user.
 Reliability: 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.
 Conformance: Conformance is the precision with which the product or service meets the specified standards.
 Durability: 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.
 Serviceability: Serviceability is the speed with which the product can be put into service when it breaks down, as well as the competence and the behavior of the serviceperson.
 Aesthetics: Aesthetics is the subjective dimension indicating the kind of response a user has to a product. It represents the individual's personal preference.
 Perceived Quality: Perceived Quality is the quality attributed to a good or service based on indirect measures.

TQM FRAMEWORK



W.EDWARDS DEMING'S CONTRIBUTIONS

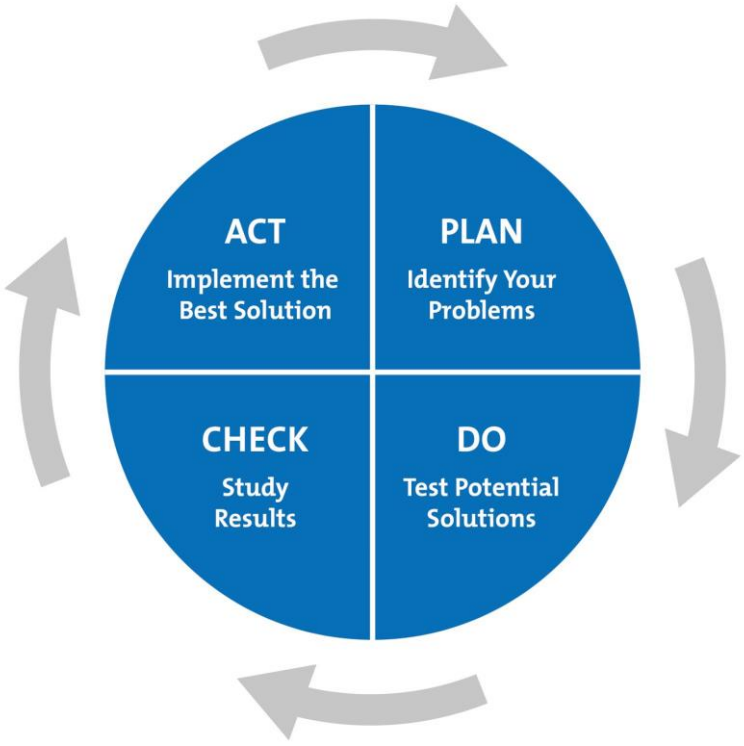
1. Deming's 14 Principle
2. Deming cycle / PDCA cycle
3. Seven deadly diseases of management
4. System of profound knowledge

DEMING'S 14 PRINCIPLE

1. **Create constancy of purpose for improving products and services.**
2. **Adopt the new philosophy.**
3. **Cease dependence on inspection to achieve quality**.
4. **End the practice of awarding business on price alone**; instead, minimize total cost by working with a single supplier.
5. **Improve constantly and forever every process for planning, production and service.**
6. **Institute training on the job.**
7. **Adopt and institute leadership.**
8. **Drive out fear.**
9. **Break down barriers between staff areas.**
10. **Eliminate slogans, exhortations and targets for the workforce.**
11. **Eliminate numerical quotas for the workforce and numerical goals for management.**
12. **Remove barriers that rob people of pride of workmanship, and eliminate the annual rating or merit system.**
13. **Institute a vigorous program of education and self-improvement for everyone.**
14. **Put everybody in the company to work accomplishing the transformation.**

DEMING CYCLE / PDCA CYCLE

Figure 1: The Plan-Do-Check-Act Cycle



SEVEN DEADLY DISEASES OF MANAGEMENT

1. Lack of **constancy of purpose** to plan product and service that will have a market and keep the company in business, and provide jobs.

2. Emphasis on short-term profits: short-term thinking (just the opposite from constancy of purpose to stay in business), fed by fear of unfriendly takeover, and by push from bankers and owners for dividends.

3. Evaluation of performance, merit rating, or annual review.

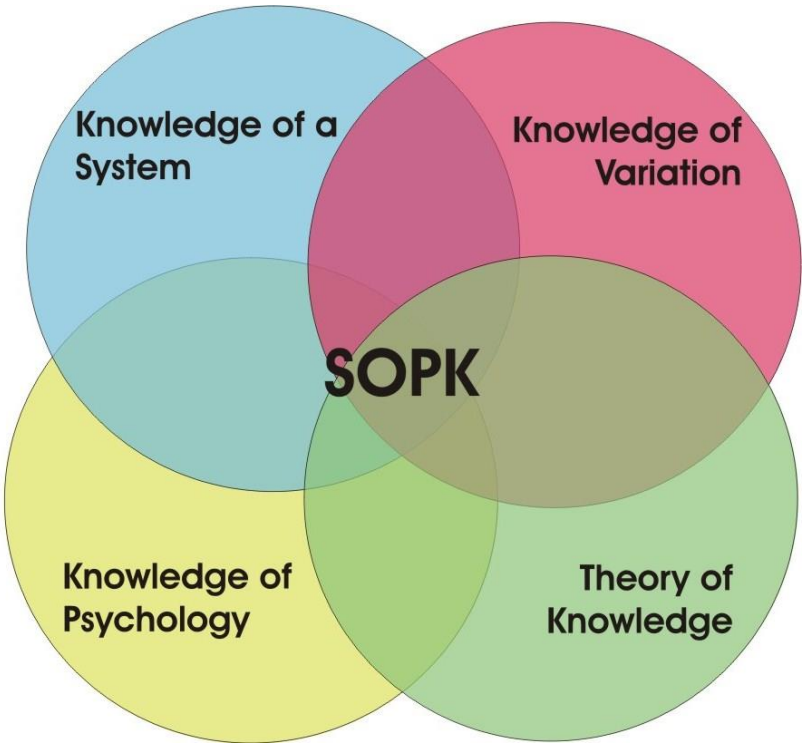
4. Mobility of management; job hopping.

5. Management by use only of **visible figures**, with little or no consideration of figures that are unknown or unknowable.

6. Excessive medical costs. As reported by Dr. Deming in *Out of the Crisis* (pages 97-98), executives shared with him that the cost of medical care for their employees was amongst their largest overall expenses, not to mention the cost of medical care embedded in the purchase price of what they purchased from their suppliers.

7. Excessive costs of liability, swelled by lawyers that work on contingency fees.

SYSTEM OF PROFOUND KNOWLEDGE



A System of Profound Knowledge

Appreciation for a System
- Interdependence, dynamism
- Non-linear cause and effect

Knowledge of Variation
- World is not deterministic
- Variation is to be expected
- Prediction - analytic studies
- Measurement is not objective

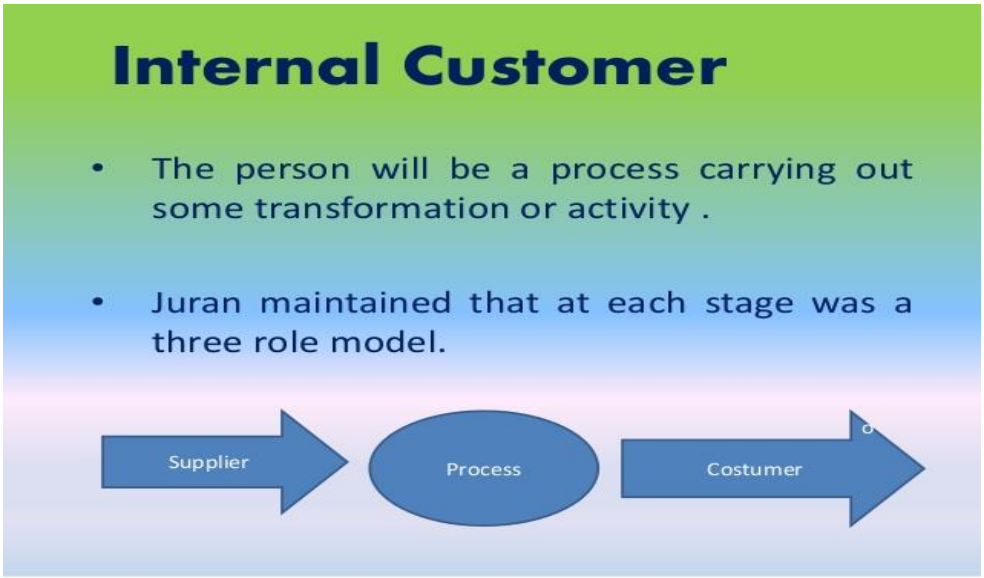
Knowledge of psychology
- Interaction between people
- Motivation
- Change

Theory of Knowledge
- Theories are not true or untrue; they are useful or not
- Theory and experience are needed to learn

JOSEPH M JURAN CONTRIBUTIONS

1. Internal customer
2. Cost of quality
3. Quality trilogy
4. Juran's 10 steps for quality improvement
5. The breakthrough concept

INTERNAL CUSTOMER



Joseph Juran

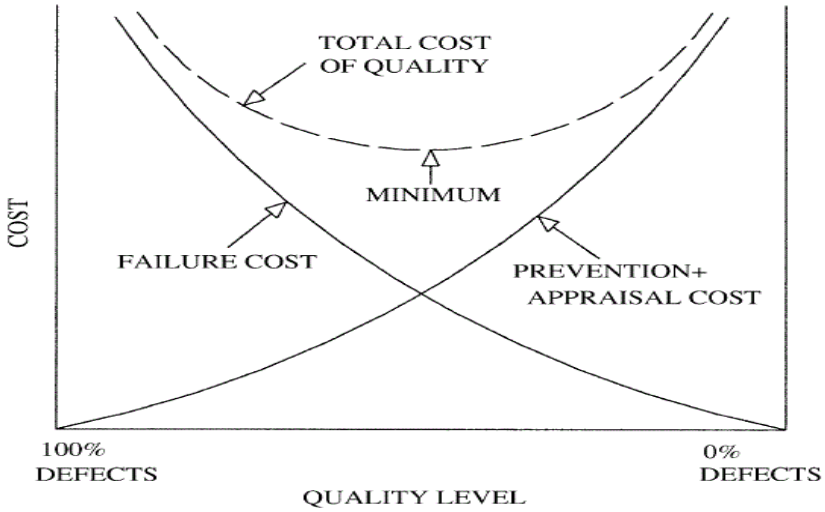
The delimitation he gave for these customers is outlined as follows.

a) Internal Customer: Are those departments or persons who supply products to each other.

b) External Customer: These are impacted by the product but are not members of the company (or other institution) which produce the product.

COST OF QUALITY

The concept of quality costs was first mentioned by Juran (Quality Control Handbook published in 1951) and this concept was primarily applied in the manufacturing industry. The price of nonconformance (Philip Crosby) or the cost of poor quality (Joseph Juran), the term 'Cost of Quality', referred to the costs associated with providing poor quality product or service.



QUALITY TRILOGY

Juran's Quality Trilogy

Juran's Quality Trilogy consists of quality planning, quality control, and quality improvement.

Quality Planning provides a system that is capable of meeting quality standards.

Quality Control is used to determine when corrective action is required.

Quality Improvement seeks better ways of doing things.

Source: Juran, J. "The Quality Trilogy." *Quality Progress*, 10,8, 1986.

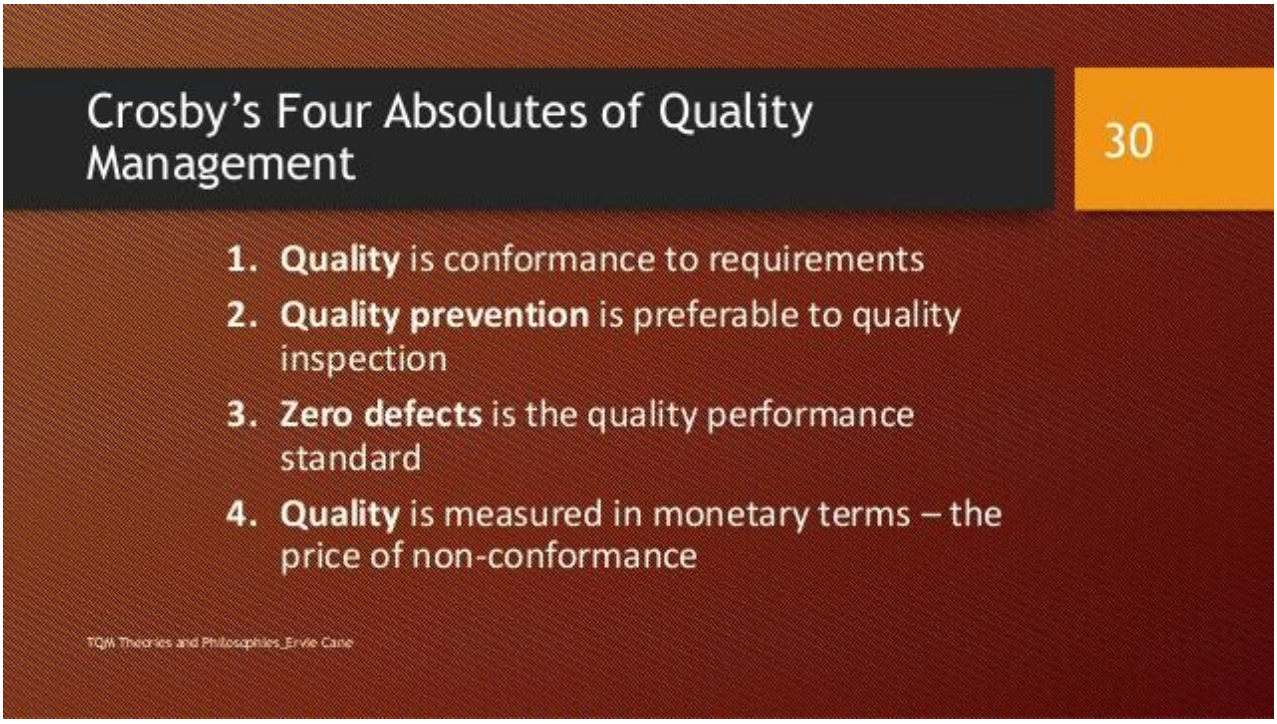
JURAN'S 10 STEPS TO QUALITY IMPROVEMENT

Juran's 10 steps to quality improvement	
1	Build awareness of opportunity to improve
2	Set-goals for improvement
3	Organize to reach goals
4	Provide training
5	Carryout projects to solve problems
6	Report progress
7	Give recognition
8	Communicate results
9	Keep score
10	Maintain momentum

PHILIP CROSBY'S CONTRIBUTION

1. Four absolutes of quality
2. Fourteen steps to quality management
3. Crosby's quality vaccine

FOUR ABSOLUTES OF QUALITY



FOURTEEN STEPS TO QUALITY MANAGEMENT

The Fourteen Steps to Quality Improvement

1. Management Commitment
2. Quality Improvement Teams
3. Measure Processes
4. Cost of Quality
5. Quality Awareness
6. Correct Problems
7. Monitor Progress
8. Train Supervisors
9. Zero Defects Day
10. Establish Improvement Goals
11. Remove Fear
12. Recognize
13. Quality Councils
14. Repeat the Cycle

CROSBY'S QUALITY VACCINE

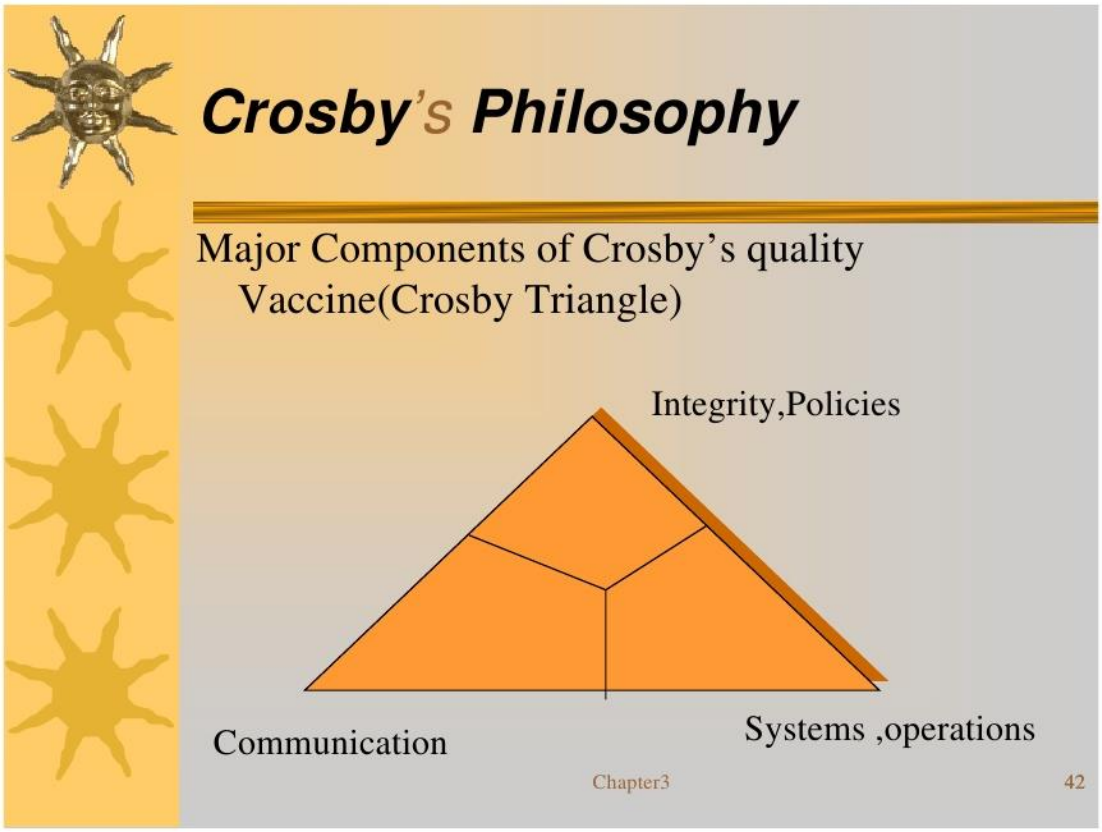
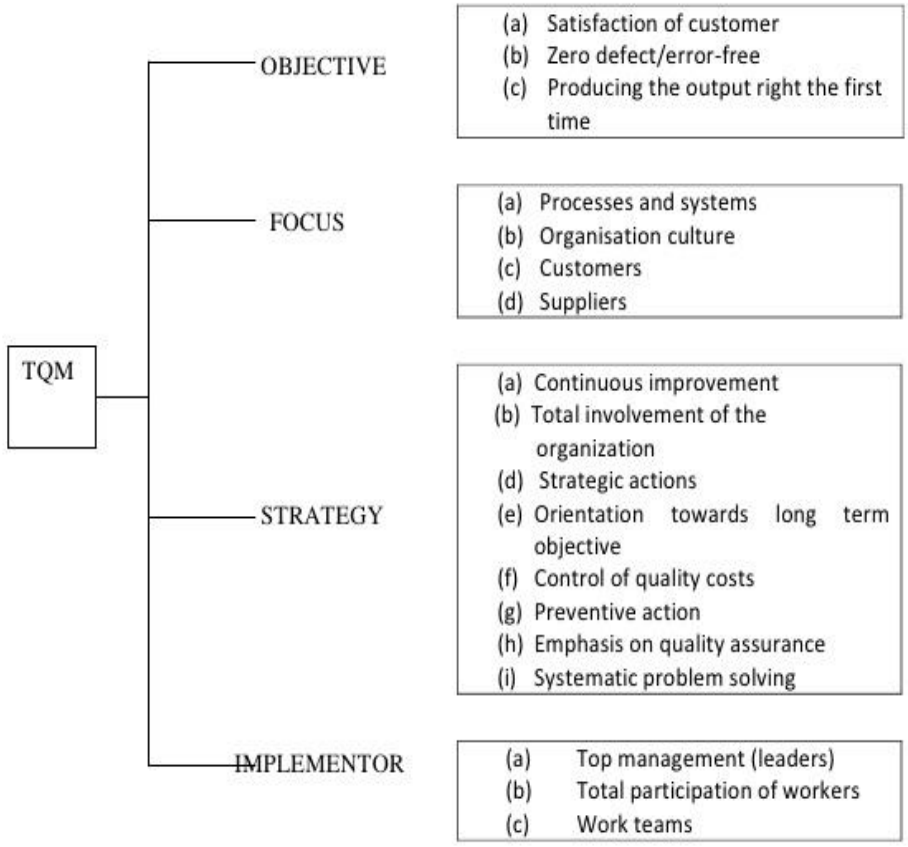


FIGURE 2: FEATURS OF TQM



8.0 Goal, objective, strategy and methods of TQM

Goal: : Total Customer Satisfaction

Objectives : To create a Culture of "Continuous Improvement" for zero defects, zero loss and zero accident.

Strategy : "Do the Right Things, right the first time, and every time."

Methodology : Review,Plan, Train, Empower, Team, Learn from Document, Standardize the Process, Reduce Variation, Auditing the performance, Reward & Recognition

9.0 PRINCIPLES OF TQM

The principles of Total Quality Management seek to satisfy the external customer as well as the company's internal customers with quality goods and services; to satisfy the external and internal suppliers; and to continuously improve processes by working smarter and using special quality methods. TQM requires that the principles of quality management should be applied in every branch and at every level in the organization with an emphasis on integration into business practices and a balance between technical, managerial and people issues. It is a company-wide approach to quality, with improvements undertaken on a continuous basis by everyone in the organization.

Organizations can successfully practice TQM if they have a conducive work environment. Conducive work environments enable successful implementation of TQM and ensure that it becomes a way of life for the organization. To create such an environment organization must emphasize on following management principles as depicted in Fig 3.

TQM

UNIT II

STEPS TO CREATING A TOTAL QUALITY MANAGEMENT SYSTEM

1. Clarify Vision, Mission and Values

Employees need to know how what they do is tied to organizational strategy and objectives. All employees need to understand where the organization is headed (its vision), what it hopes to accomplish (mission) and the operational principles (values) that will steer its priorities and decision making. Develop a process to educate employees during new employee orientation and communicate the mission, vision and values as a first step.

2. Identify Critical Success Factors (CSF)

Critical success factors help an organization focus on those things that help it meet objectives and move a little closer to achieving its mission. These performance based measures provide a gauge for determining how well the organization is meeting objectives.

Some example CSF:

- Financial Performance
- Customer Satisfaction
- Process Improvement
- Market Share
- Employee Satisfaction
- Product Quality

3. Develop Measures and Metrics to Track CSF Data

Once critical success factors are identified, there needs to be measurements put in place to monitor and track progress. This can be done through a reporting process that is used to collect specified data and share information with senior leaders. For example, if a goal is to increase customer satisfaction survey scores, there should be a goal and a measure to demonstrate achievement of the goal.

4. Identify Key Customer Group

Every organization has customers and understanding who the key customer groups are is important so that products and services can be developed based on customer requirements. The mistake a lot of organizations make is not acknowledging employees as a key customer group. Example Key Customer Groups:

- Employees
- Customers

- Suppliers
- Vendors
- Volunteers

5. Solicit Customer Feedback

The only way for an organization to know how well they are meeting customer requirements is by simply asking the question. There should be a structured process to solicit feedback from each customer group in an effort to identify what is important to them. Organizations often make the mistake of thinking they know what is important to customers and ask the wrong survey questions. This type of feedback is obtained through customer focus groups.

6. Develop Survey Tool

Next develop a customer satisfaction survey tool that is based on finding out what is important to customers. For example, customers might care more about quality than cost but if you are developing a product and trying to keep the cost down and skimping on the quality, you are creating a product that might not meet the needs of the customer. There is lots of survey software available. One I like is SurveyGizmo which is an easy to use online survey tool. You can play with it and try it for free to see if it's something that would benefit your organization.

7. Survey Each Customer Group

Each customer group should have a survey customized to their particular requirements and they should be surveyed to establish baseline data on the customers' perception of current practice. This provides a starting point for improvements and demonstrates progress as improvement plans are implemented.

8. Develop Improvement Plan

Once the baseline is established you should develop an improvement plan based on customer feedback from each group. Improvement plans should be written in SMART goals format with assignments to specific staff for follow through.

Goals May Include Some of the Following:

- Process improvement initiatives, such as: customer call hold times
- Leadership Development: Walk-the-Talk
- Management Training/Development: How to manage employees in a quality environment
- Staff Training/Development: Customer Service

- Performance Management: Setting expectations, creating job descriptions that support the vision and holding staff accountable.

9. Resurvey

After a period of time (12-18 months), resurvey key customers to see if scores have improved. Customer needs and expectations change over time so being in-tune to changing needs and expectations is critical to long-term success.

10. Monitor CSF

It is important to monitor CSF monthly to ensure there is consistent progress toward goals. This also allows for course correction should priorities and objectives change during the review period.

11. Incorporate Satisfaction Data into Marketing Plans

Once you've achieved some positive results with your satisfaction data, use it as a marketing tool! A lot of successful organizations miss the boat by not letting others know what they do well. Customers want to know how an organizations internal processes work especially if those process help to deliver an outstanding product or service!

12. Technology

Make sure technology is user-friendly and supports targeted improvements. For example, a website should be easy to navigate as well as easy to find (SEO) and the content should be easy to understand.

ADVANTAGES OF TQM

- ***Cost reduction***.

When applied consistently over time, TQM can reduce costs throughout an organization, especially in the areas of scrap, rework, field service, and warranty cost reduction. Since these cost reductions flow straight through to bottom-line profits without any additional costs being incurred, there can be a startling increase in profitability. There are a range of cost benefits associated with TQM. As part of the TQM approach, operational processes will need to be defined. Many organizations map their processes and via analytical tools such as **brainstorming**, **cause and effect**, etc., examine the performance of processes, identify areas of duplication, uncertainty, over processing and re-map out their processes to improve efficiency. **Bottleneck analysis** can be performed to identify where hold-ups and delays are arising throughout a process and implement changes to eliminate any such bottlenecks. **Cycle time analysis** can be performed to understand the % of time, people and equipment are

actively involved in value adding activity, versus the % of time spent on non-value adding activity. The net result can be quite significant in terms of **costs benefits** to the organization.

- ***Customer satisfaction*.**

Since the company has better products and services, and its interactions with customers are relatively error-free, there should be fewer customer complaints. Fewer complaints may also mean that the resources devoted to customer service can be reduced. A higher level of customer satisfaction may also lead to increased market share, as existing customers act on the company's behalf to bring in more customers. Previously we talked about identifying customer needs and expectations. A basic requirement for all organizations is excellent quality and reliability in terms of product or service provision. The quality of a product or service provided needs to meet expectations. External customer expectations will be influenced by price. Customers may expect lower quality when they pay less. However, regardless of price, quality offered, must meet expectations. TQM seeks to continually improve quality, while simultaneously driving down cost to the organization. Quality improvement is achieved via the application of fact based analytical techniques. This may involve performance of **process capability** analysis, SIPOC, **FMEA analysis**, etc.. Whatever, methods are chosen and applied, there will be continued improvements in product and process quality. This then offers opportunity for the organization to increase market share, or increase product selling price, or increase profits. Such decisions will be based on the strategic direction for the business.

- ***Defect reduction***.

TQM has a strong emphasis on improving quality within a process, rather than inspecting quality into a process. This not only reduces the time needed to fix errors, but makes it less necessary to employ a team of quality assurance personnel.

- ***Morale***.

The ongoing and proven success of TQM, and in particular the participation of employees in that success can lead to a noticeable improvement in employee morale, which in turn reduces employee turnover, and therefore reduces the cost of hiring and training new employees.

- ***Employee motivation***

Total Quality Management is focused on people. Involving people, listening to and actively encouraging participation in contributing to improving the organization. TQM is focused on building a culture where all staff feel comfortable in identifying failings and suggesting opportunities. Changing culture is a complex and uncertain science, however, there are well understood approaches to encouraging positive open cultures. This may range

from regular “town hall” meetings, newsletters, quality improvement teams through to suggestions schemes, employee of the month, etc.. Whatever approach is taken will depend on the organizational management and operating environment, however an improving culture, will create higher levels of employee motivation, lower staff turnover, more active participation and greater success rates for continuous improvement activities.

- ***Emphasizing the needs of the market***

QM helps in highlighting the needs of the market. Its application is universal and helps the organization to identify and meet the needs the market in a better way.

- ***Assures better quality performance in every sphere of activity***

Adverse and non-participative attitudes of the employees are the biggest obstacles in the organizationâ€ ™s success, growth and advancement.

TQM stresses on bringing attitudinal changes and improvements in the performance of employees by promoting proper work culture and effective team work

- ***Helps in checking non-productive activities and waste***

Every organization aims at improving productivity as well as reduction in cost so as to result in increase in profitability. Under TQM, quality improvement teams are constituted to reduce waste and inefficiency of every king by introducing systematic approach.

- ***Helpful in meeting the competition***

TQM techniques are greatly helpful in understanding the competition and also developing an effective combating strategy. Due to the cut throat competition, the very survival of many organizations has become very vital issue.

- ***It helps in developing an adequate system of communication***

Faulty and inadequate communication and improper procedures act as stumbling blocks in the way of proper development of an organization. It results in misunderstanding, low-productivity, poor quality, duplication of efforts and low morale. QM techniques bind together members of various related sections, departments and levels of management for effective communication and interaction.

DISADVANTAGES OF TQM

- ***Production Disruption***

Implementing a Total Quality Management system in a company requires extensive training of employees and these requires them to take some time of their day to day work duties. While the improvements do reduce lead time, eliminate waste and improve productivity, the

beginning stages of implementing Total Quality Management in an organization can reduce worker output.

- ***Employee Resistance***

Total Quality Management requires change in mindset, attitude and methods for performing their jobs. When management does not effectively communicate the team approach of Total Quality Management, workers may become fearful, which leads to employee resistance. When workers resist the program, it can lower employee morale and productivity for the business.

- ***Quality is Expensive***

TQM is expensive to implement. Implementation often comes with additional training costs, team-development costs, infrastructural improvement costs, consultant fees and the like.

- ***Discourages Creativity***

TQM focus on task standardization to ensure consistency discourages creativity and innovation. It also discourages new ideas that can possibly improve productivity

Barriers

BARRIERS TO TQM IMPLEMENTATION

- Lack of management commitment
- Lack of faith for support to TQM activities
- Inability to accept organizational culture
- Misunderstanding the concept of TQM
- Improper planning
- Lack of employees commitment
- Lack of effective communication
- Lack of continuous training and education
- Lack of interest
- Incompetence of leaders
- Ineffective measurement techniques
- Inadequate use of empowerment & team work
- Inadequate attention to internal & external customers
- Delay or non implementation of quality improvement team's recommendation

TOTAL QUALITY CONTROL

Meaning

Total Quality Control is the system which Japan has developed to implement Kaizen **or continuing improvement**.

The Total Quality Control consists of

- **The** seven basic (old) tools
- **The** seven management (new) tools
- **The** seven product planning tools**,**
- Quality function deployment**, and**
- Taguchi methods **enhance the implementation of quality.**

Definition

- According to Dr. Ishikawa`s definition of quality control "To practice quality control is to develop, design, produce and service a quality product which is most economical, most useful and always satisfactory to the consumer. To meet this goal, everyone in the company must participate in and promote quality control, including top executives, all divisions, within the company and all employees"
- A system that integrates quality development, maintenance and improvement of the parts of an organization. It helps a company economically manufacture its product and deliver its services.
- "Quality control may be defined as that industrial management technique or group of techniques by means of which products of uniform acceptable quality are manufactured. It is indeed the mechanism by which products are made to measure up to specifications determined from customer's demand and transformed into sales, engineering and manufacturing requirements. It is concerned with making things right rather than the discovering and rejecting those made wrong" - Alford and Beatty
- "Quality control means the recognition and removal of identifiable causes and defects, and variables from the set standards".

TOTAL QUALITY CONTROL (TQC) Vs TOTAL QUALITY MANAGEMENT (TQM)

TOTAL QUALITY CONTROL

TQC is about **application of the quality management principles** to the business processes from the designing stage to delivery of goods to the end users. It includes various **Japanese techniques** related with quality management such as **Kaizen, Kaikaku, Kakushin, 5S, Genbashugi** which expresses various ways of increasing the productivity of the organization.

- Emphasis is placed on the process and continuous process improvement.
- Total participation is required. Employees are encouraged to generate ideas and implement them.
- It is flexible - processes and methods can be easily changed.
- The target is not absolute - good for a changing market.
- Downside: Sometimes the end result is very different from the original target - employees tend to lose sight of the goal because they are too focused on the process.

TOTAL QUALITY MANAGEMENT

TQM is a **continuous process of increasing the quality of the output by eliminating waste and the non-value adding activities** in the system. In organizational perspective, a quality product comes within a quality process, which means that quality should be built into the process. Therefore, the process needs to be managed in order to have quality output. **TQM comprises of some key elements as continuous improvement, customer focus, employee empowerment, use of quality tools, product design, process management and managing supplier quality**.

- Emphasis is placed on the target and achieving the target as soon as possible.
- The system is simple and straight-forward.
- Information delivery is accurate.
- The process is considered after the goal has been established.

FACTORS AFFECTING TQC

COMMITMENT AND UNDERSTANDING FROM EMPLOYEES

It is key to ensure that all employees within your organization know about the Total Quality Control (TQC) policies and make them an fundamental part of their work. Our employees should know your corporate goals and recognize the importance of these goals to the overall success of our organization. Employees need to know what is expected from them and why. It may sound like a no-brainer but too often this is not driven home by management. When employees understand and share the same vision as

management a world of potential is unleashed. If they are in the dark, commitment is lacking and policies will not be successfully deployed.

QUALITY IMPROVEMENT CULTURE

The organizational culture needs to be modernized on a continuous basis to encourage employee feedback. Your employees are full of valuable knowledge- embrace it! Listen to those executing the processes that keep your business moving daily. If employees have an idea on how to improve operations, they need to know management respects their ideas or they will not share.

CONTINUOUS IMPROVEMENT IN PROCESS

There is no standing still. If you are not moving forward, you are moving backwards. Total Quality Management (TQM) is a continuous process and not a program. This requires constant improvement in all the related policies, procedures and controls established by management. Do your research. Keep your ear to the market and make an effort to routinely revise all aspects of your operation. There should be a constant effort to improve proficiency – which will result in constant scopes for improvement (even if some improvements are small).

FOCUS ON CUSTOMER REQUIREMENTS

In today's market, customers require and expect perfect goods and services with zero defects. Focusing on customer requirements is significant to long term survival and essential in order to build relationships with customers. People do business based on emotion. Competitors will always be a risk. Keep your customers close and happy. Make sure precise requirements of all customers are documented and understood by everyone that touches the account.

EFFECTIVE CONTROL

It is essential to monitor and measure the performance of the business. It's easy to forget how many times in a year an employee does not conform to a controlled procedure or how many times a piece of equipment was down due to unplanned maintenance. If strict documentation is maintained, you will be able to objectively quantify areas for improvement and focus your efforts where they will provide the greatest return of both your time and financial resources.

TQM

UNIT III

BENCHMARKING

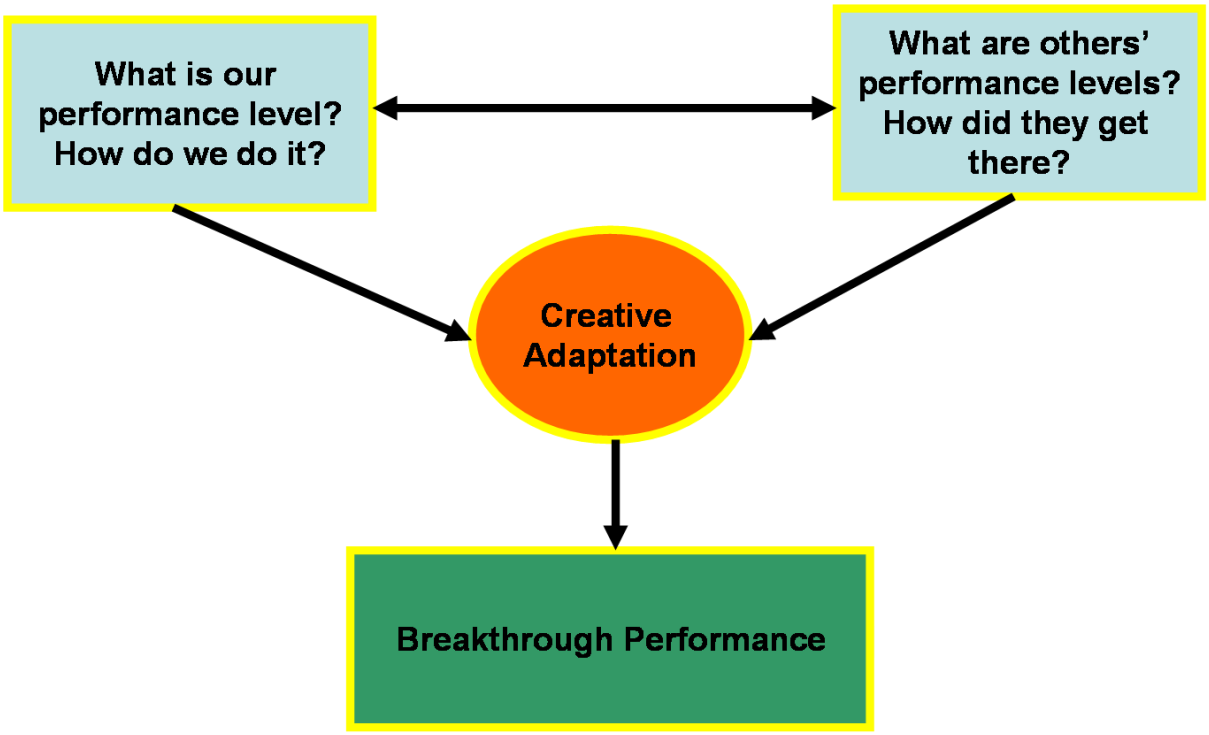
Meaning

Evaluate (something) by comparison with a standard.

Definition

- A measurement of the quality of an organization's policies, products, programs, strategies, etc., and their comparison with standard measurements, or similar measurements of its peers. The objectives of benchmarking are (1) to determine what and where improvements are called for, (2) to analyze how other organizations achieve their high performance levels, and (3) to use this information to improve performance.
- Benchmarking is the practice of comparing actual performance results with a standardize performance goal or number–a benchmark. Benchmarking is generally used in business for setting budgetary and financial performance goals. A benchmark or base number is used to compare actual results and judge the improvement of the company.

Concept of benchmarking

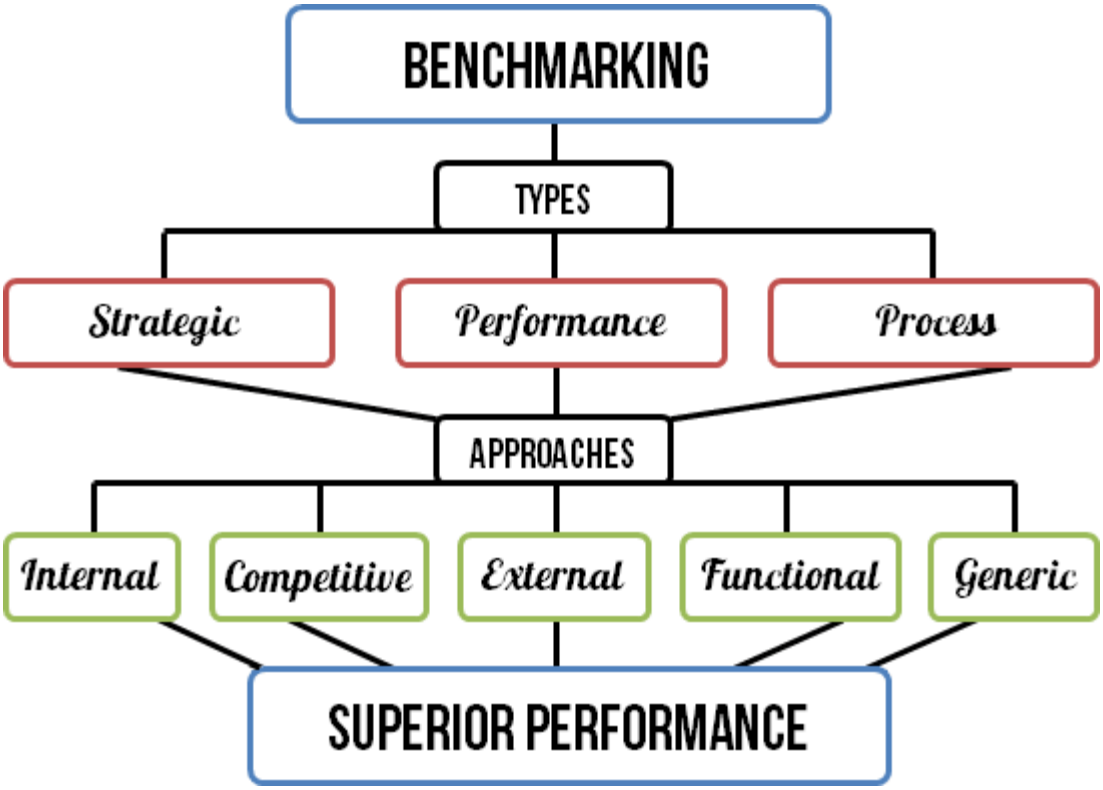


Purpose / Objective of Benchmarking

1. It analyzes and understands the organization's existing working model.
2. It compares the organization's working model with the peers of the organization.
3. Compares the various organizations working strategies with the successful other organization's working model.
4. Suggests the necessary steps to compete with the leaders in the market.
5. Compares the profit rate of the internal divisions to motivate for the betterment in weaker divisions of the organization.

Types of benchmarking

There are different types of benchmarking the managers can use. Tuominen and Bogan & English identified these 3 major types.



- **Strategic benchmarking.** Managers use this type of benchmarking to identify the best way to compete in the market. During the process, the companies identify the winning strategies (usually outside their own industry) that successful companies use and apply them to their own strategic process. It is also common to compare the strategic goals in order to spot new strategic choices.

- **Performance benchmarking.** It is concerned with comparing your company's products and services. According to Bogan & English[8] the tool mainly focuses on product and service quality, features, price, speed, reliability, design and customer satisfaction, but it can measure anything that has the measurable metrics, including processes. Performance benchmarking determines how strong our products and services are compared to our competition.
- **Process benchmarking.** It requires to look at other companies that engage in similar activities and to identify the best practices that can be applied to your own processes in order to improve them. Process benchmarking is a separate type of benchmarking, but it usually derives from performance benchmarking. This is because companies first identify the weak competing points of their products or services and then focus on the key processes to eliminate those weaknesses. For example, an organization using performance comparison identifies that their product 'X' is superior in features, manufacturing quality and design, but pricier than competitor's product 'Y'. Then the company determines, which processes add the most to the cost of the product and seek how to improve them by looking at similar, but less cost heavy processes in other companies.

Approaches Of Benchmarking

- **Internal benchmarking**

  In large organizations, which operate in different geographic locations or manage many products and services, same functions and processes are usually performed by different teams, business units or divisions. This often results in processes performed very well in one division but poorly in another. Internal benchmarking is used to compare the work of separate teams, units or divisions to identify the ones that are working better and share the knowledge throughout the company to other teams to achieve higher performance. It is usually employed by the companies that have recently expanded geographically, but haven't yet created proper knowledge sharing systems between divisions. If such systems are in place, there's no need to use internal benchmarking to look for best practices

- **External or competitive benchmarking**

  Some authors use these terms interchangeably but there are a few differences between them. First, competitive benchmarking refers to a process when a company compares itself with the competitors inside its industry. Whereas external benchmarking looks both inside and outside the industry to find the best practices, thus,

including competitive benchmarking.[9] Second, competitive benchmarking, in my opinion, will only be used with performance benchmarking to compare your products and services. Strategic or process benchmarking won't be viable options, because it'll be very hard to find a competitor, who wants to share sensitive information with you and you'll never outcompete your rival if you'll be using his strategy or processes. Besides, external benchmarking is a more beneficial approach to use due to higher possibilities of finding the best practices.

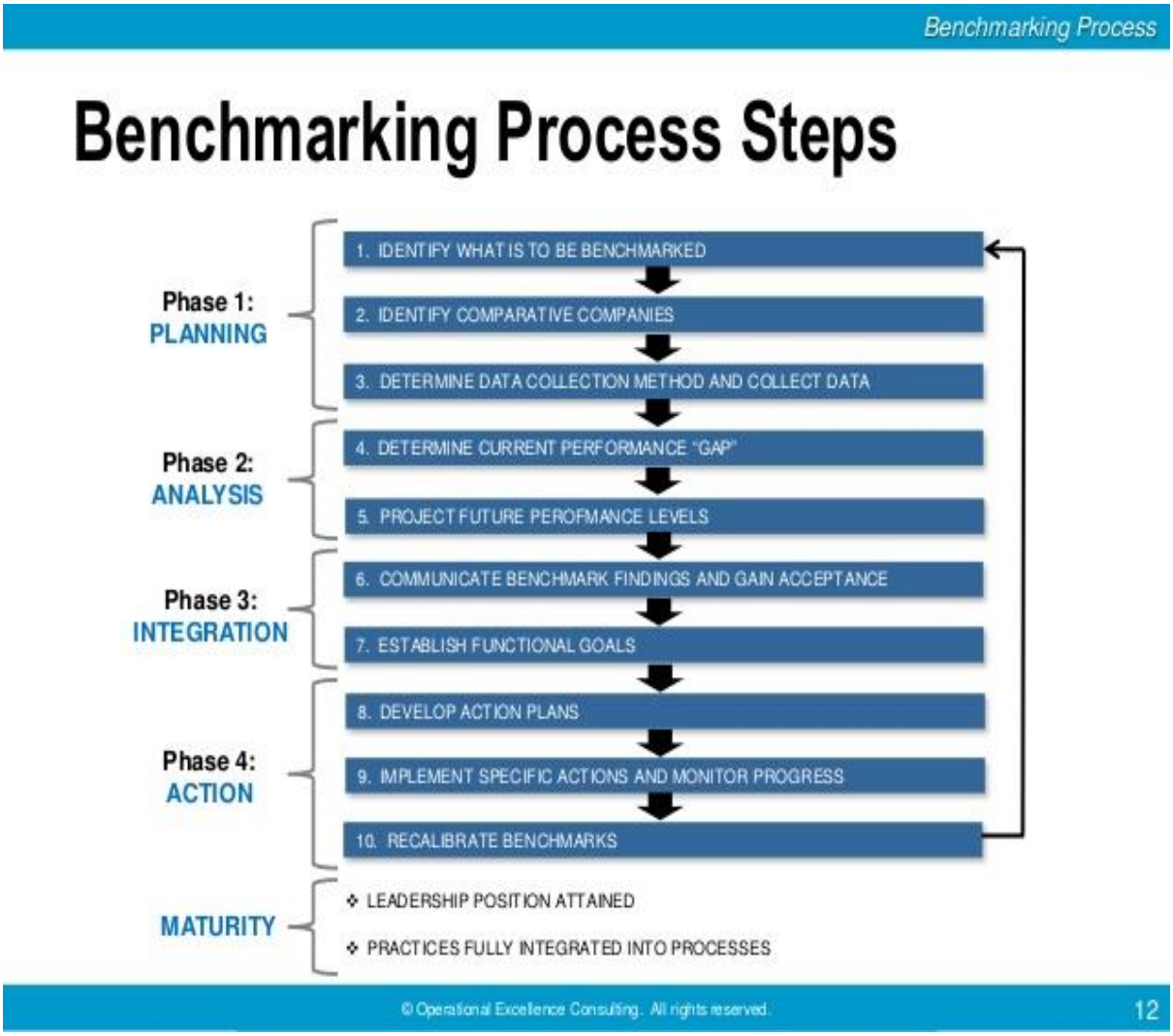
- **Functional benchmarking**

  Managers of functional departments find it useful to analyze how well their functional area performs compared to functional areas of other companies. It is quite easy to identify the best marketing, finance, human resource or operations departments, in other companies, that excel in what they do and to apply their practices to your own functional area. This way the companies can look at a wide range of organizations, even unrelated ones, and instead of improving separate processes, they can improve the whole functional areas.

- **Generic benchmarking**

  According to Kulmala,[9] it refers to comparisons, which "focus on excellent work processes rather than on the business practices of a particular organization". For example, your company tries to improve its marketing capabilities and benchmarks itself against company 'A'. While observing company's 'A' marketing processes you also notice how well their human resources are managed using 'big data' analytics. This gives you an idea to implement the data collecting and analysis team in your own company to significantly improve its overall performance.
  The other example of generic benchmarking would be to compare your processes against generally accepted best standards. For example, every organization strives to become a learning organization, because such an organization is better equipped to overcome challenges and adapt to the market changes. By comparing your company to some general standards, which would indicate that your company is a learning organization, you would be using generic benchmarking.

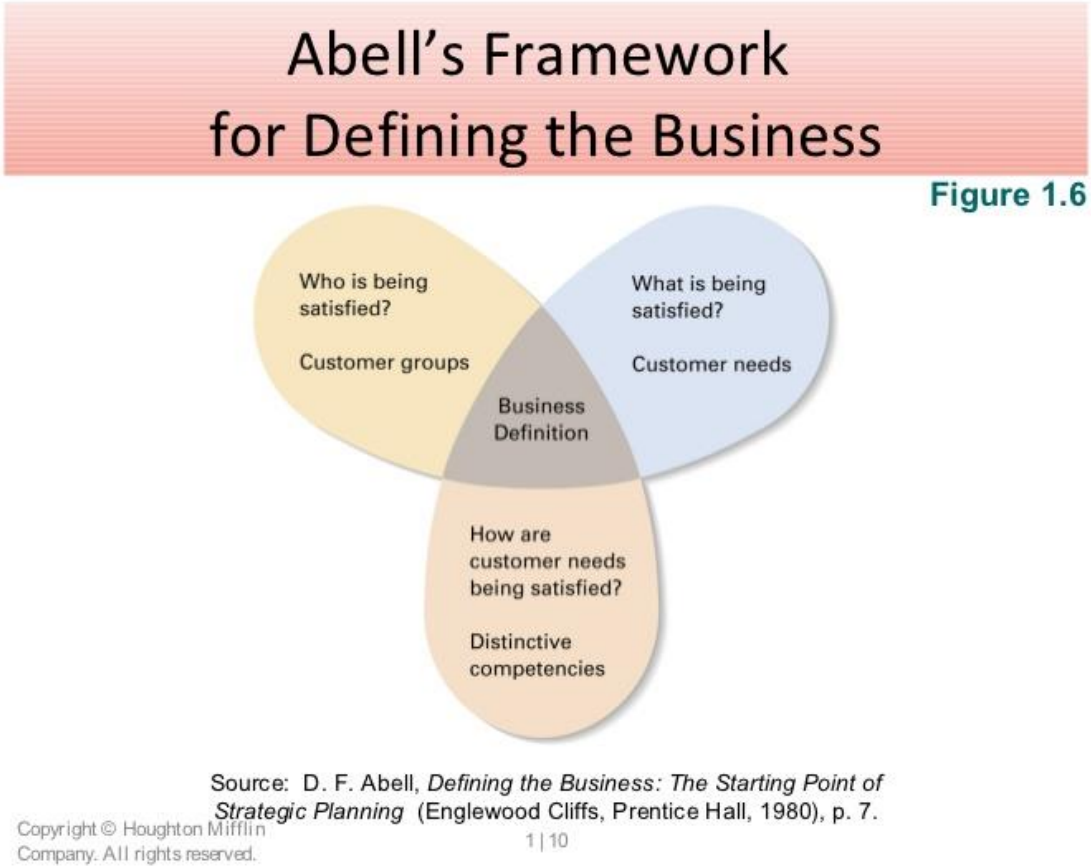
PROCESS OF BENCHMARKING



BUSINESS PROCESS REENGINEERING

Introduction of BPR

BUSINESS



PROCESS

A **series of actions or steps** taken in order to achieve a particular end.

ENGINEERING

- The branch of science and technology concerned with the design, building, and use of engines, machines, and structures.
- The action of working artfully to bring something about.

REENGINEERING

"Fundamental **rethinking and radical redesign of business process** to achieve dramatic improvements in critical measures of performance such as cost, service, and speed.".

Definition

Business process reengineering (BPR) is the analysis and redesign of workflows within and between enterprises in order to optimize end-to-end processes and automate non-value-added tasks.

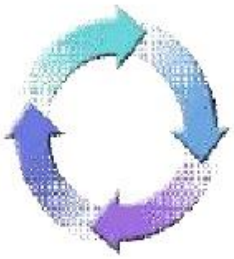
PROCESS OF BPR

ELEMENTS OF BPR

- 3 major elements of BPR

Process-related Elements

- Business procedure simplification
- Business process standardization
- Work flow



Technology-related Elements

- Information Technology
- Business Technology
- Project Management Technology

Organization-related Elements

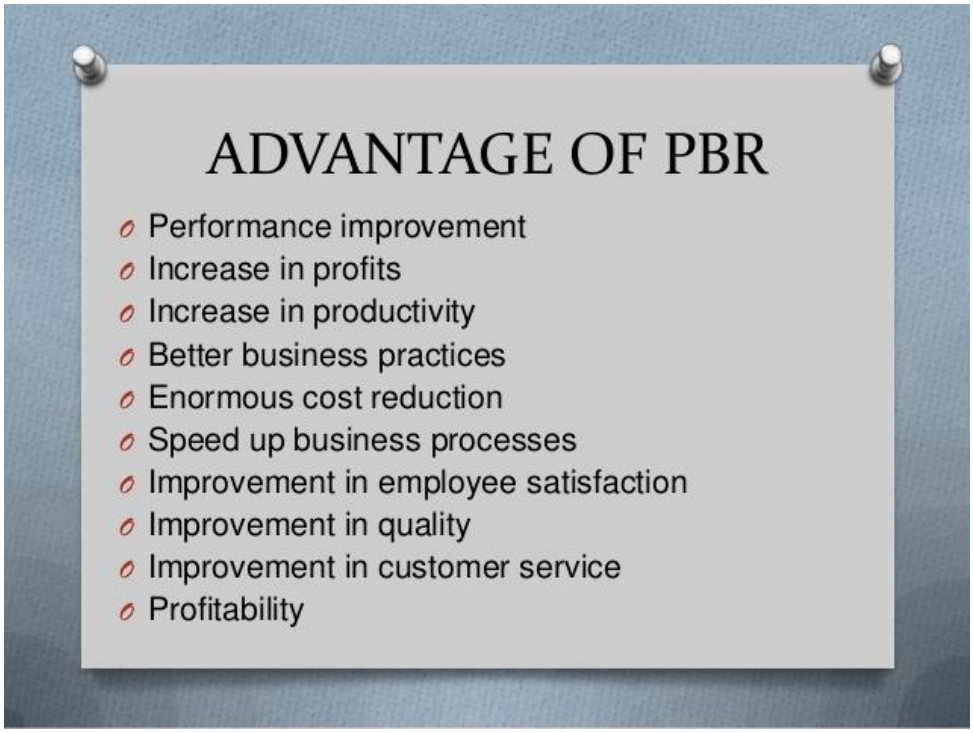
- Organization structure
- Role Assignment
- Regulation and Culture
- Incentive
- Education / Training

PRINCIPLES OF BPR

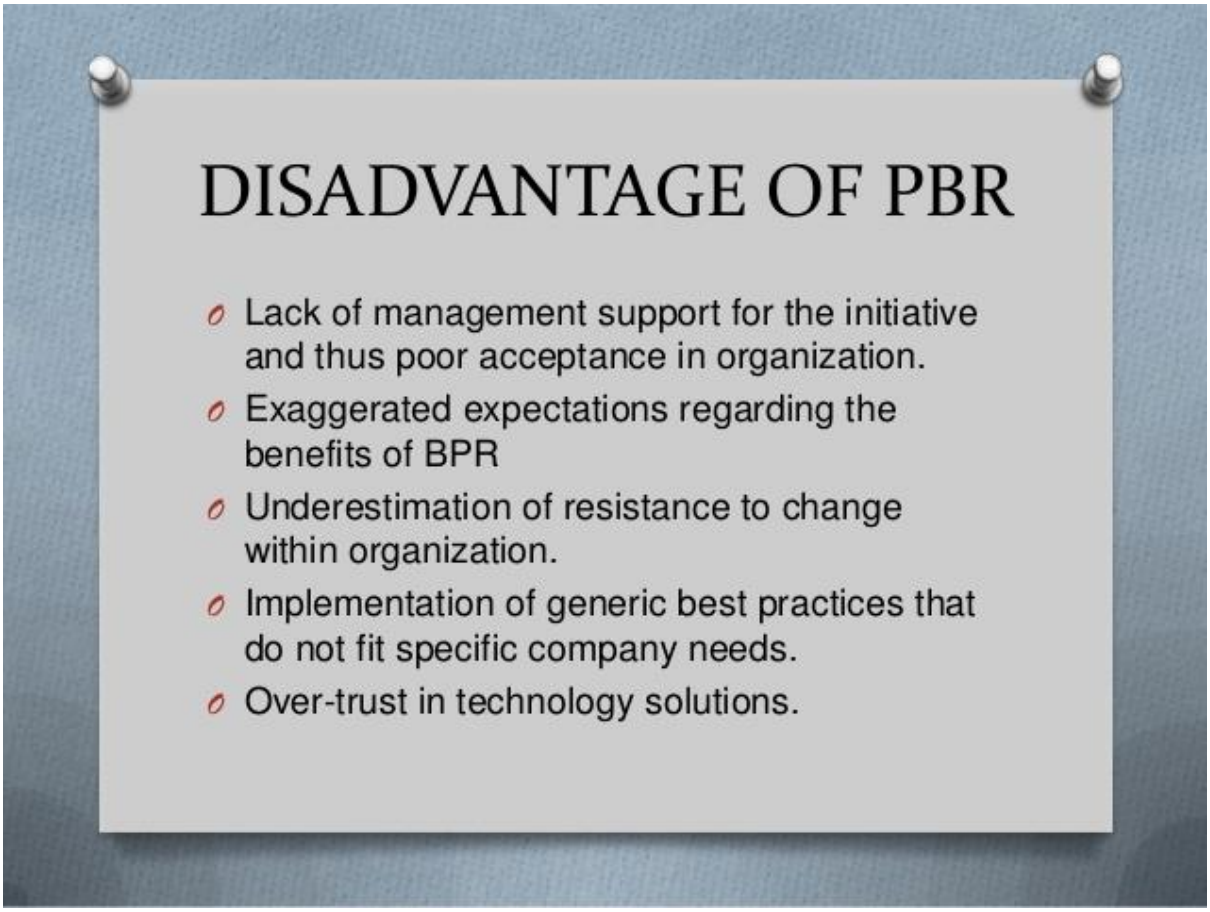
Principles of BPR

1. Organize around processes, not tasks
2. Have output user perform process
3. Have those who produce information process it
4. Treat geographically dispersed resources as centralized
5. Link parallel activities in the workflow instead of just integrating their results
6. Empower workers and use built-in controls
7. Capture information once and at the source

ADVANTAGES OF BPR



DISADVANTAGES OF BPR



SIX SIGMA

Meaning

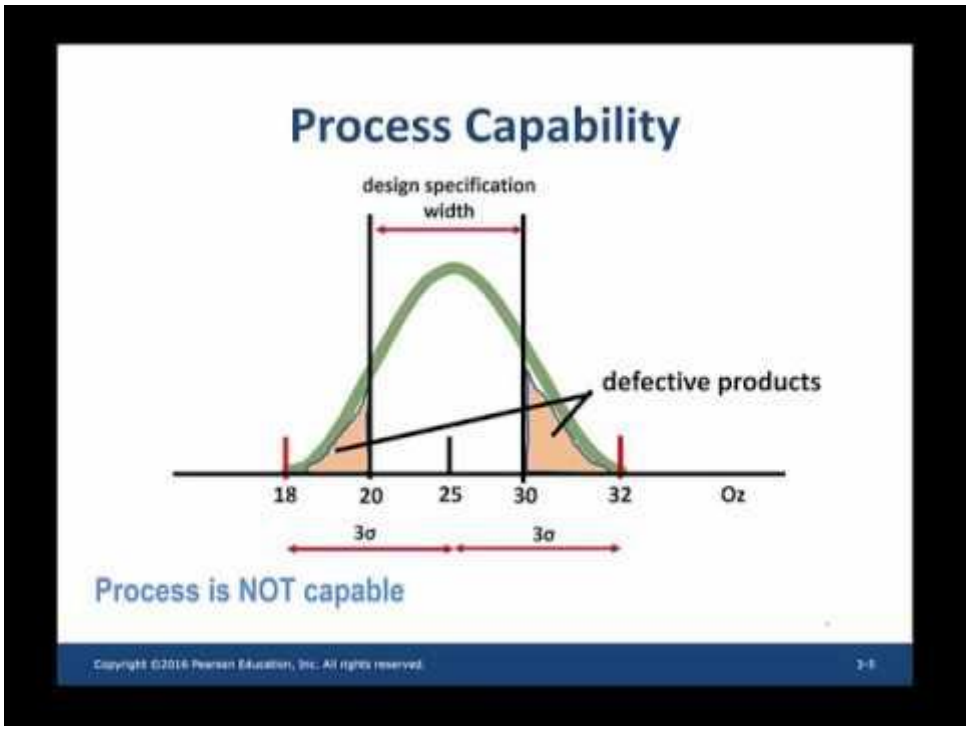
Six Sigma (**6σ**) is a **set of techniques and tools** for process improvement. It was introduced by engineer Bill Smith while working at Motorola in 1986. Jack Welch made it central to his business strategy at General Electric in 1995.

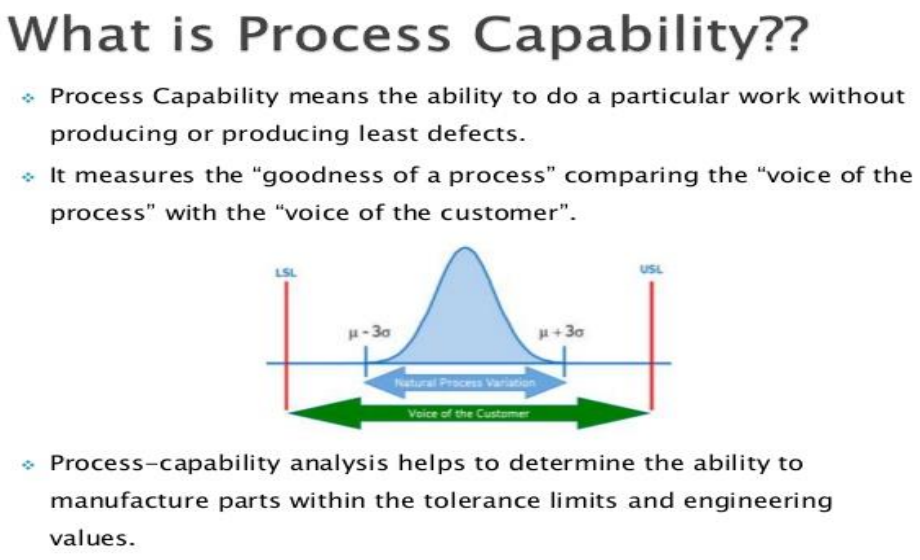
The term "six sigma" comes from statistics and is used in statistical quality control, **which evaluates** process capability. Originally, it referred to **the ability of manufacturing processes to produce a very high proportion of output within specification.** Processes that operate with "six sigma quality" over the short term are assumed to **produce *long-term defect levels below 3.4* *defects per million opportunities*(DPMO) / 99.999666 accuracy**

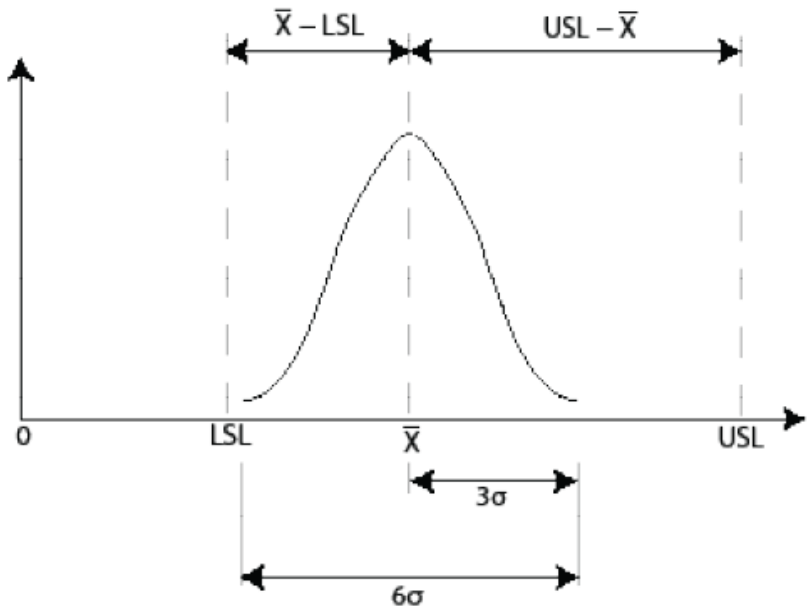
Definition

- The statistical representation of Six Sigma describes quantitatively how a process is performing. To achieve Six Sigma, a process must not produce more than 3.4 defects per million opportunities. A Six Sigma defect is defined as anything outside of customer specifications. A Six Sigma opportunity is then the total quantity of chances for a defect. Process sigma can easily be calculated using a Six Sigma calculator.

PROCESS CAPABILITY







$$Cp = \frac{USL - LSL}{6\sigma}$$

$$Cpk_L = \frac{\bar{X} - LSL}{3\sigma}$$

$$Cpk_U = \frac{USL - \bar{X}}{3\sigma}$$

$$Cpk = \min\{Cpk_L, Cpk_U\}$$

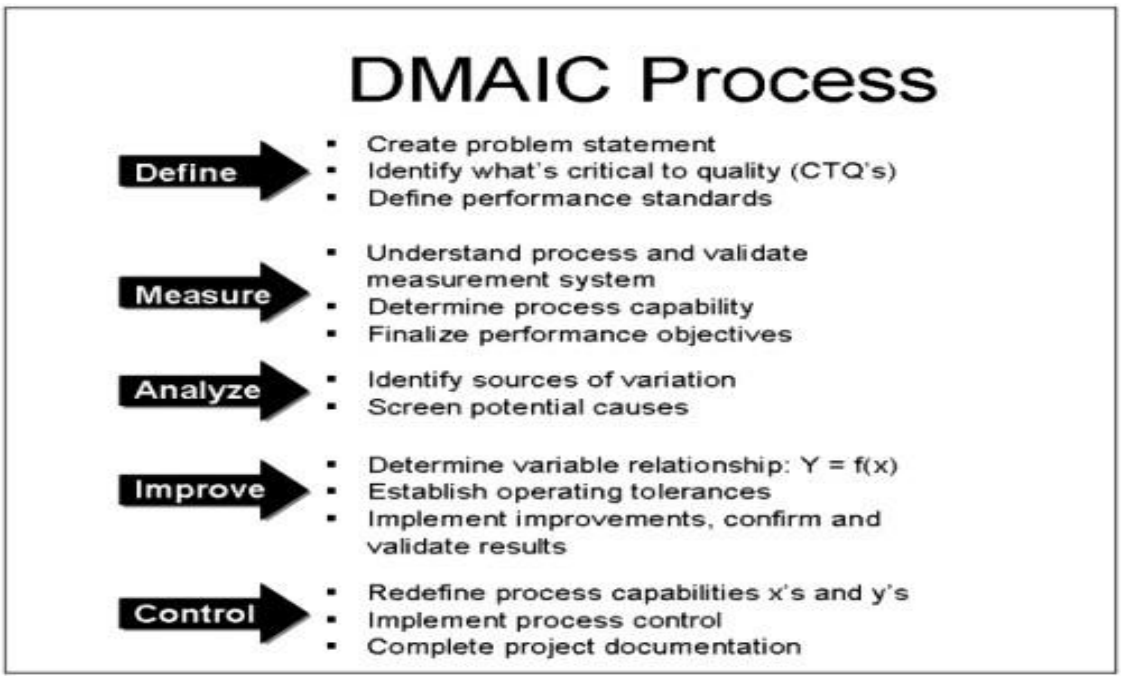
Process capability Ratio	=	Design width / Process width	= USL - LSL / UCL - LCL

Where,

Upper Specification Limit (USL) = Mean + 3 **σ**

Lower Specification Limit (LSL) = Mean - 3 **σ**

SIX SIGMA PROCESS



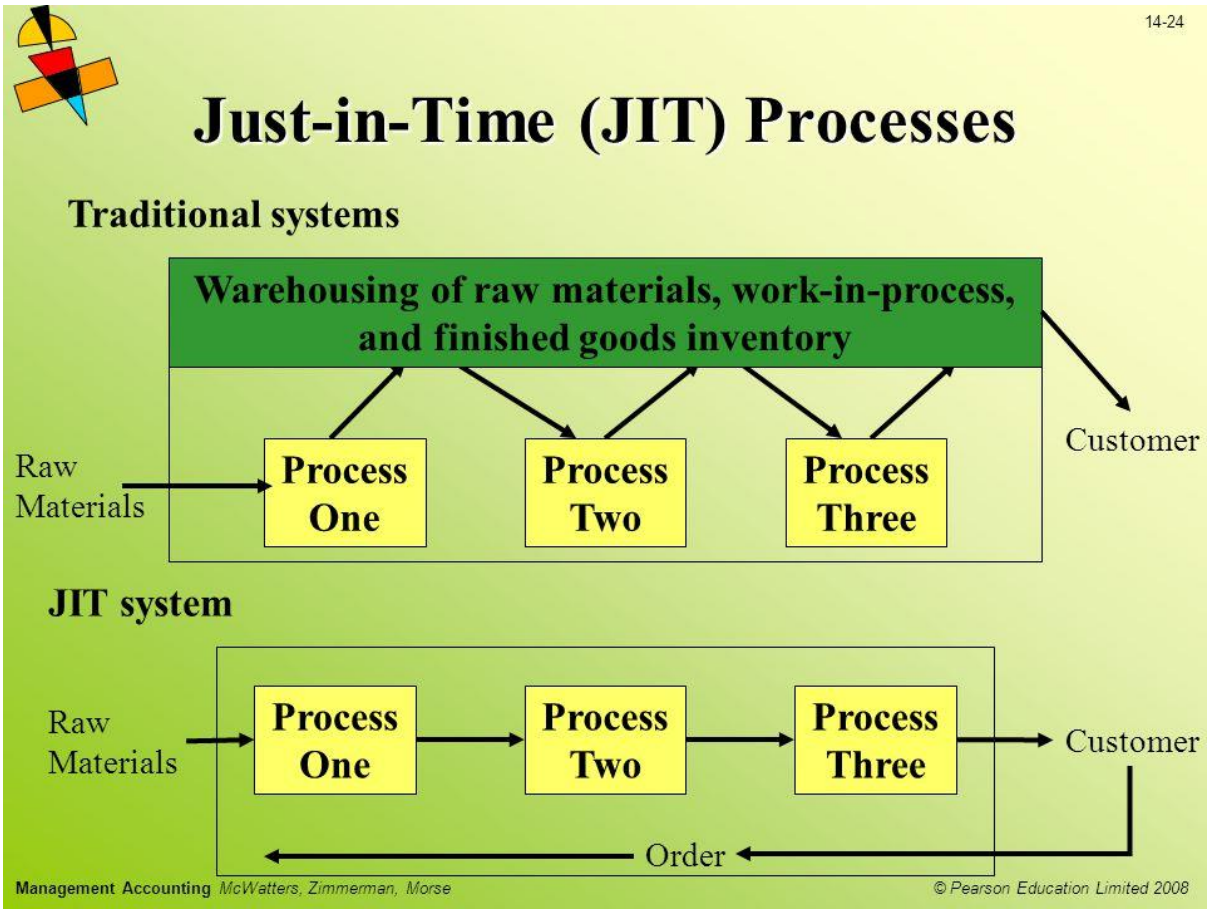
JUST-IN-TIME (JIT)

Definition

Just-in-time (JIT) manufacturing is a production model in which items are **created to meet demand, not created in surplus or in advance of need**. The purpose of JIT production is **to avoid the waste associated with overproduction, waiting and excess inventory**

JIT stands for Just in Time is a system in operation management under which the production is made as per the demand at a particular moment.

JIT PROCESS



QUALITY FUNCTION DEPLOYMENT / CUSTOMER DRIVEN ENGINEERING

Meaning

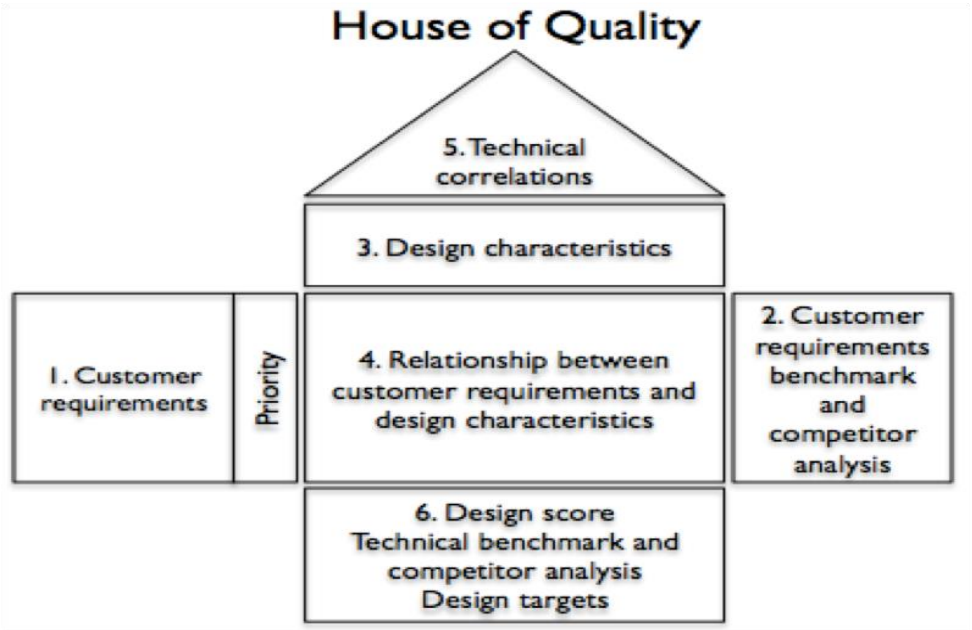
- Quality – zero defects
- Function - **An activity** that is natural to or the purpose of a person or thing.
- Deployment - The **action of bringing resources** into effective action.

Definition

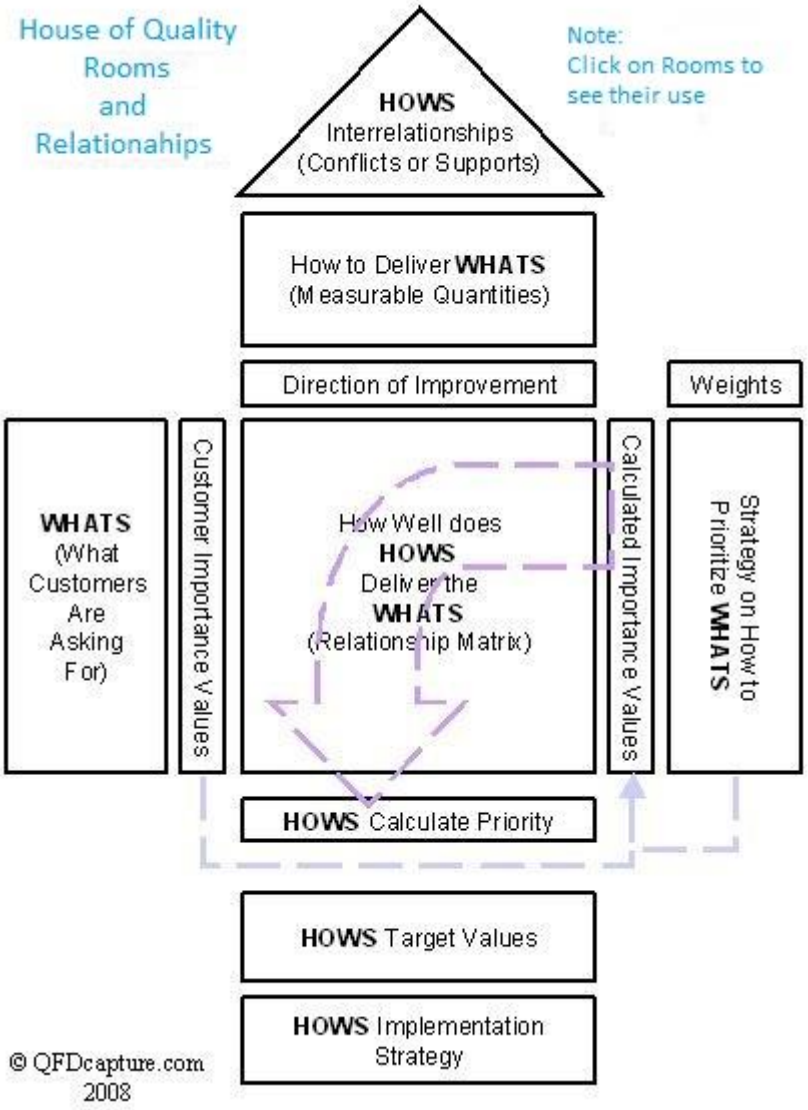
- Quality Function Deployment (QFD) is a **structured approach to defining customer needs or requirements and translating them into specific plans to produce products** to meet those needs. The "voice of the customer" is the term to describe these stated and unstated customer needs or requirements. The voice of the customer is captured in a variety of ways: direct discussion or interviews, surveys, focus groups, customer specifications, observation, warranty data, field reports, etc.
- This understanding of the **customer needs** is then summarized in a **product planning matrix or "house of quality"**. These matrices are used to translate higher level "what's" or needs into lower level "how's" – product requirements or technical characteristics to satisfy these needs.

Construction of House of quality

The initial steps in forming the House of Quality include determining, clarifying, and specifying the customers' needs. **The House of Quality is the first matrix in a four-phase QFD (Quality Function Deployment) process. It's called the House of Quality** because of the correlation matrix that is roof shaped and sits on top of the main body of the matrix. The correlation matrix evaluates how the defined product specifications optimize or sub-optimize each other.

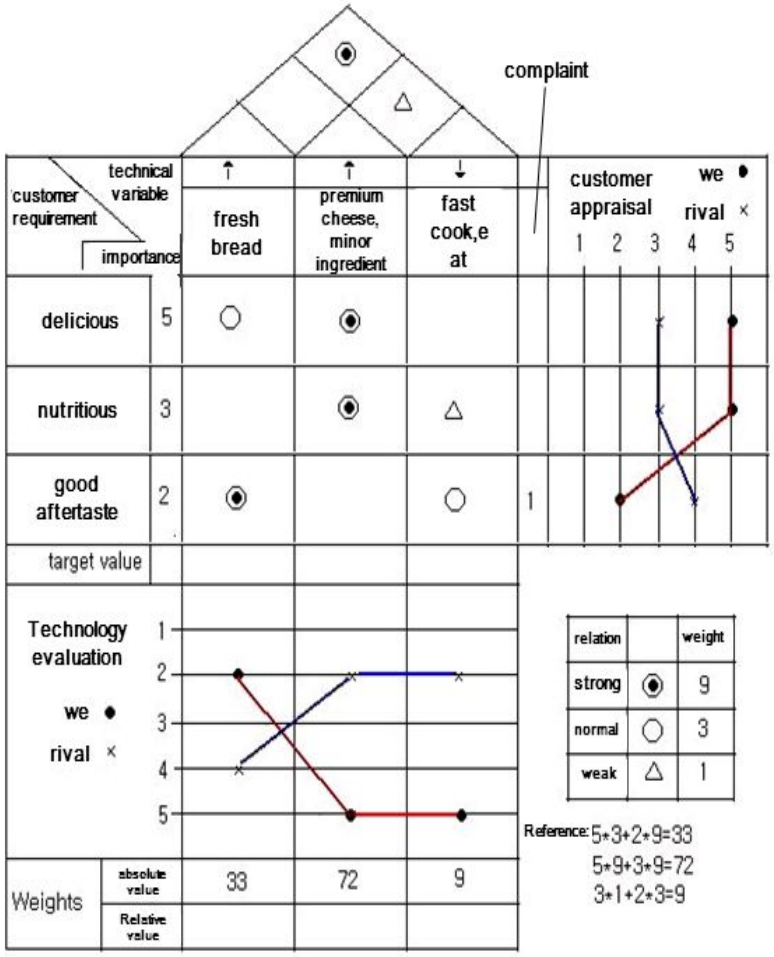


PROCESS OF HOQ



Example of HOQ

Example of HOQ (House of Quality)



POKA YOKE

Japanese approach to 'mistake proofing' in all aspects of manufacturing, customer service, procurement, etc. It employs visual signals that make mistakes clearly stand out from the rest, or devices that stop an assembly line or process if a part or step is missed. Its older name is baka yoke (fool proofing).

Poka-Yoke = Error Proofing

DEFINITION

A device which prevents a process from

- making an error or → **prediction**
- passing a defect to user → **detection**

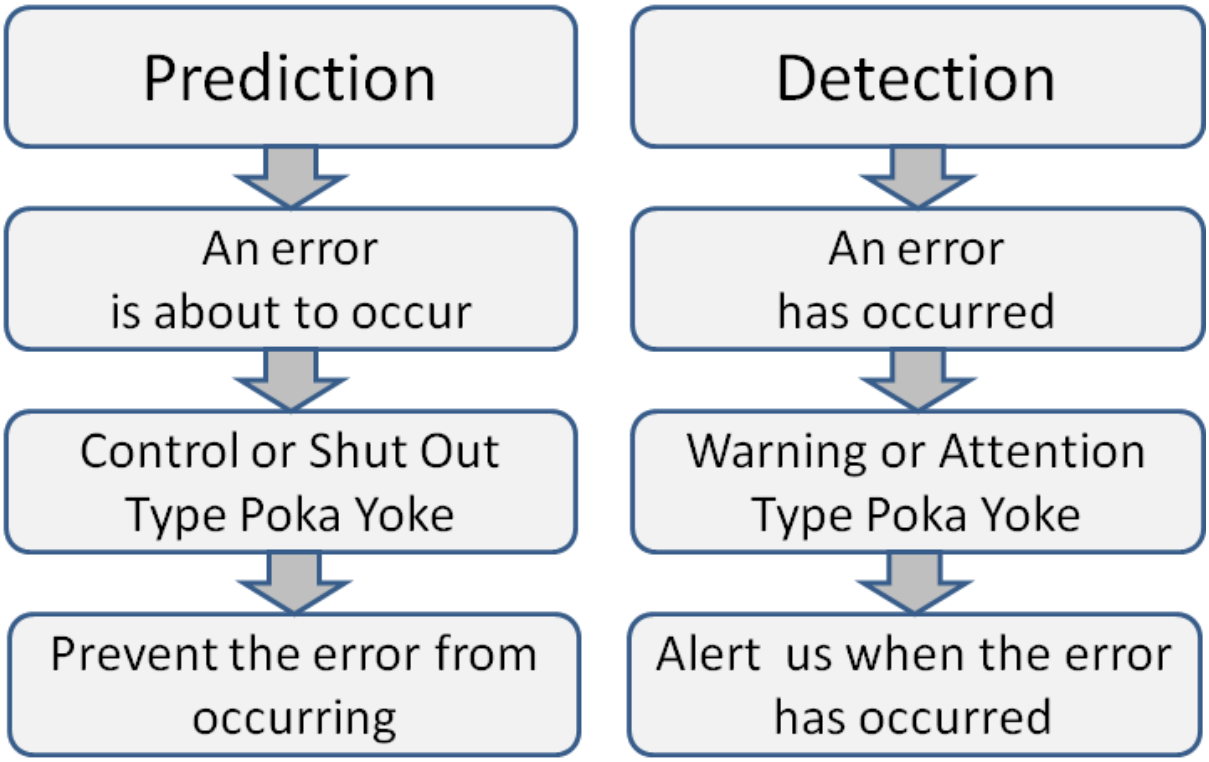
When a defect is predicted or an error detected:

- the process is **shut down** or
- a **control** prevents going ahead or
- a **warning** is sent

SEVEN STEPS TO POKA-YOKE ATTAINMENT

- Quality Processes
- Utilize a team environment
- Elimination of Errors
- Eliminate the "Root Cause" of The Errors
- Do It Right The First Time
- Eliminate Non-Value Added Decisions
- Implement a Continual Improvement Approach

PROCESS OF POKA YOKE



UNIT IV

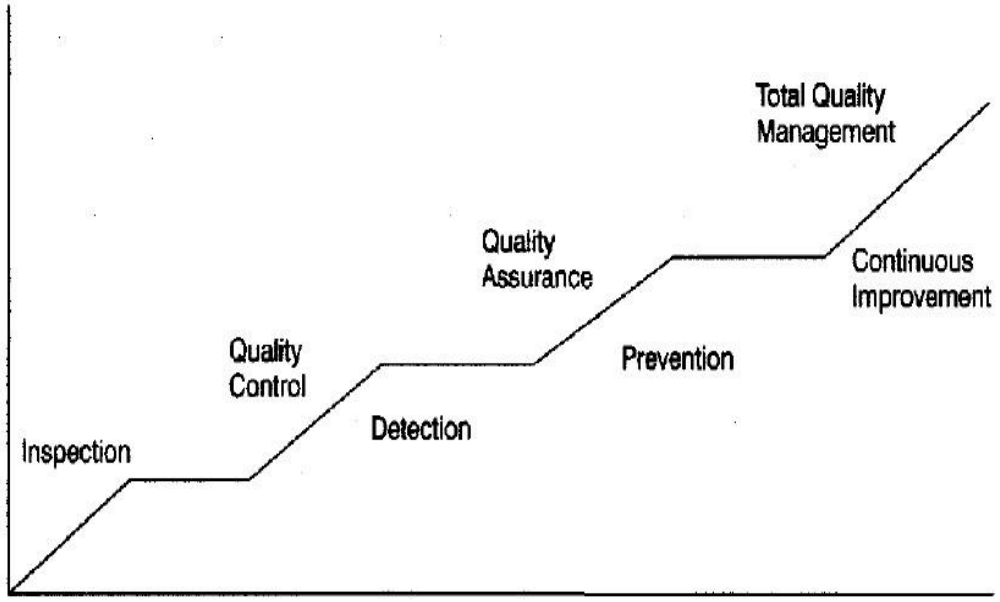
TQM

QUALITY EDUCATION

Meaning

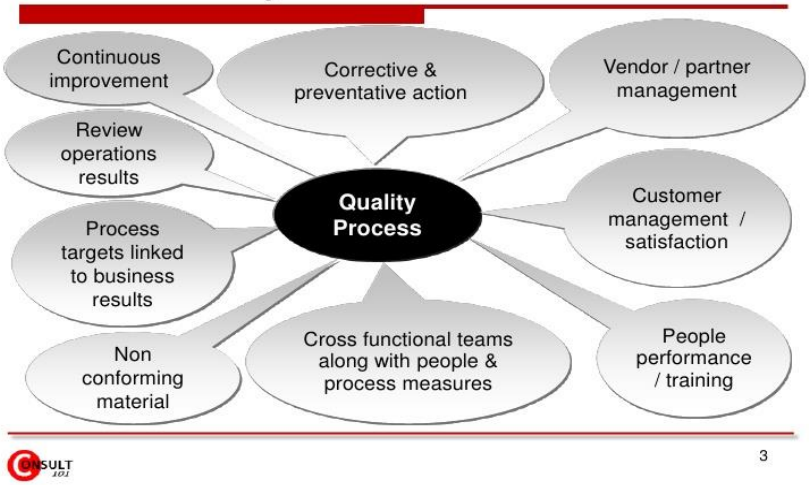
A set of methods for aligning all the components of a business to the quality requirements of the client or customer, in order to maximize quality and reduce waste. Process improvement methodologies such as Six Sigma are used to re-engineer business processes and business communications in order to identify and reduce opportunities for defects, which cause reductions in the quality of process outcomes.

Hierarchy Of Quality

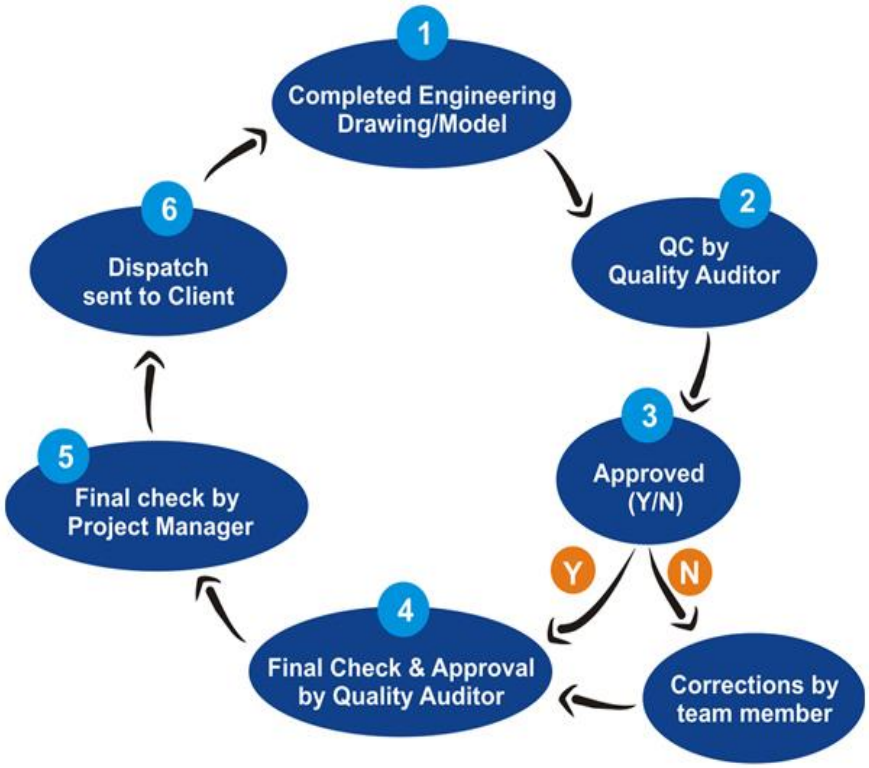


Quality Education Process

Quality Process - Definition



Quality Process Chart



QUALITY SYSTEM

QUALITY

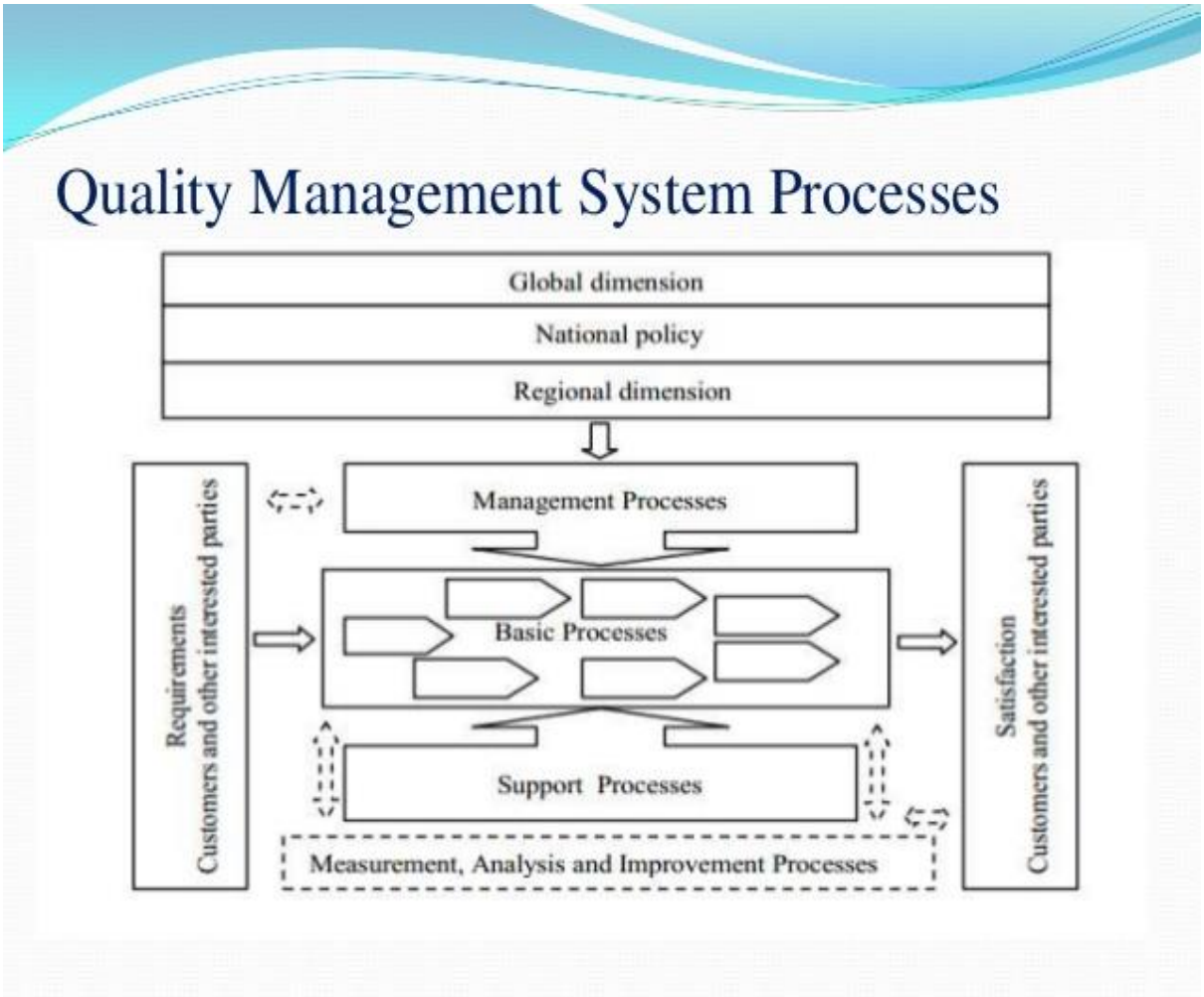
The standard of something as measured against other things of a similar kind; the degree of excellence of something.

SYSTEM

A set of principles or procedures according to which something is done; an organized scheme or method.

DEFINITION FOR QUALITY SYSTEM

- Aggregate of the organizational activities, incentives, plans, policies, procedures, processes, resources, responsibilities and the infrastructure required in formulating and implementing a total quality management (TQM) approach
- A quality management system (QMS) is 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 base.



An Effective Quality System Focusing On

- Quality management
- Quality assurance
- Evaluation analysis and quality risk management tools
- Preventive action
- Risk management
- Continuous improvement

Six Sub System Of Quality System

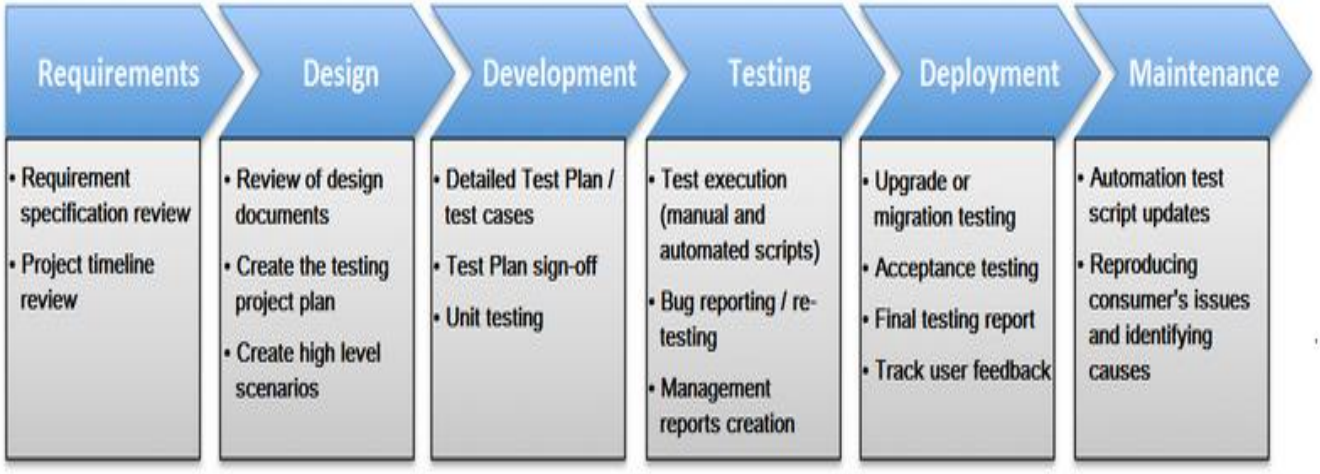
A modern quality system looks like a hub and spokes of a wheel. The quality system itself is at the centre (the hub), but it is connected to five other manufacturing systems (the spokes). When you include the quality system as a subsystem at the centre of it all, the six subsystems of a modern quality system are the:

- Quality System
- Production System
- Facilities and Equipment System

- Laboratory Controls System
- Materials System
- Packaging and Labeling System

The quality subsystem at the center provides the foundation for the five manufacturing subsystems and helps them achieve compliance. Each subsystem has an impact on the others and they all have to work together to consistently produce a quality product.

Steps in quality system



QUALITY CIRCLE

Total – Whole made up of

Quality – Zero defects

Circle - A group of people with a shared profession, interests, or acquaintances

What is quality circle (QC) / Total Quality Circle (TQC)?

- It is a work group of employees who meet regularly to discuss their quality problems, investigate causes, recommend solutions, and take corrective actions. Generally, QC is a small group of employees belonging to the same similar work area.
- This small group with every member of the circle participating to the full carries on the activities, utilising problem solving techniques to achieve control or improvement in the work area and also help self and mutual development in the process.

Meaning

A Quality circle is defined as a small group of employees who voluntarily cooperate to solve problems relating to:

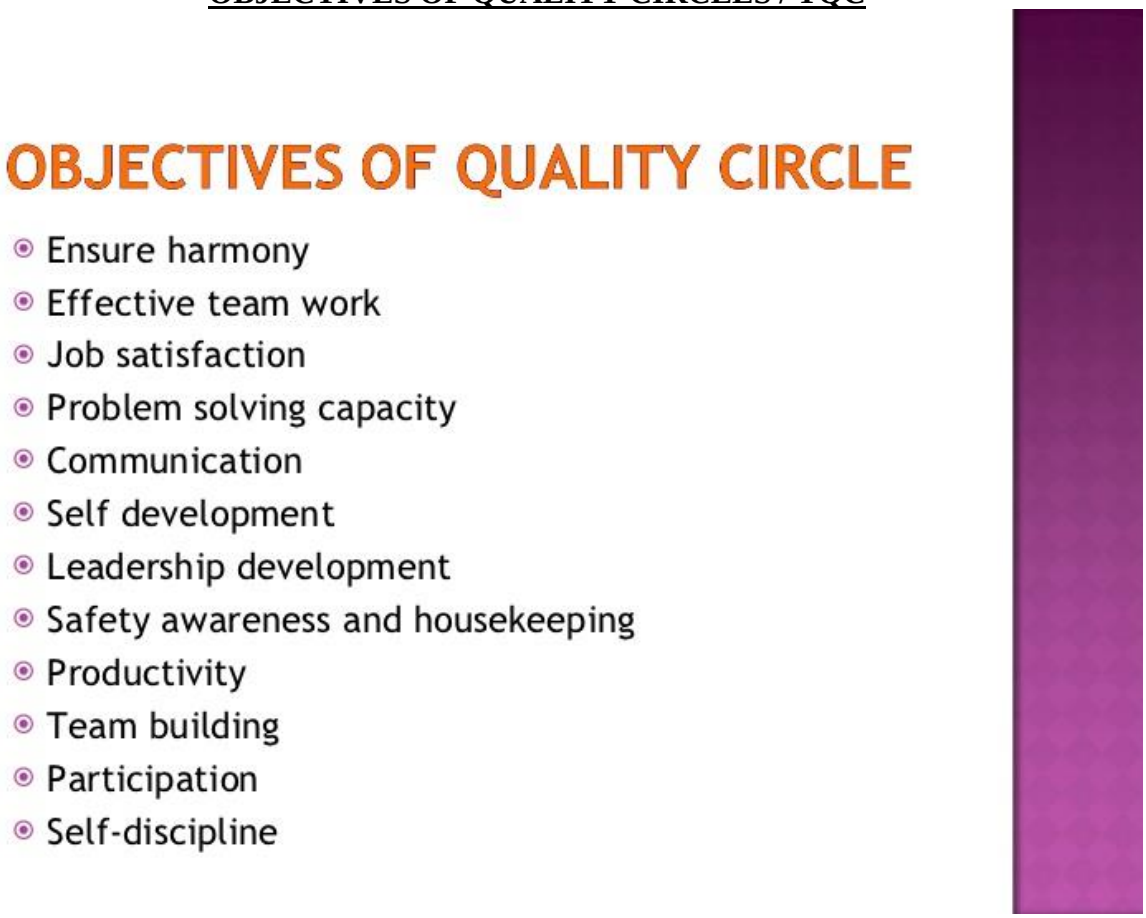
i. Production, wastage of materials,
ii. Quality of raw material, tool, semi-finished and finished goods,
iii. Work-environment, energy consumption,
iv. Scheduling, delay,
v. Maintenance,
vi. Safety and anything that acct these factors.

These groups, under the leadership of their own foreman or supervisor are trained to identify, analyze and solve the quality related problems.

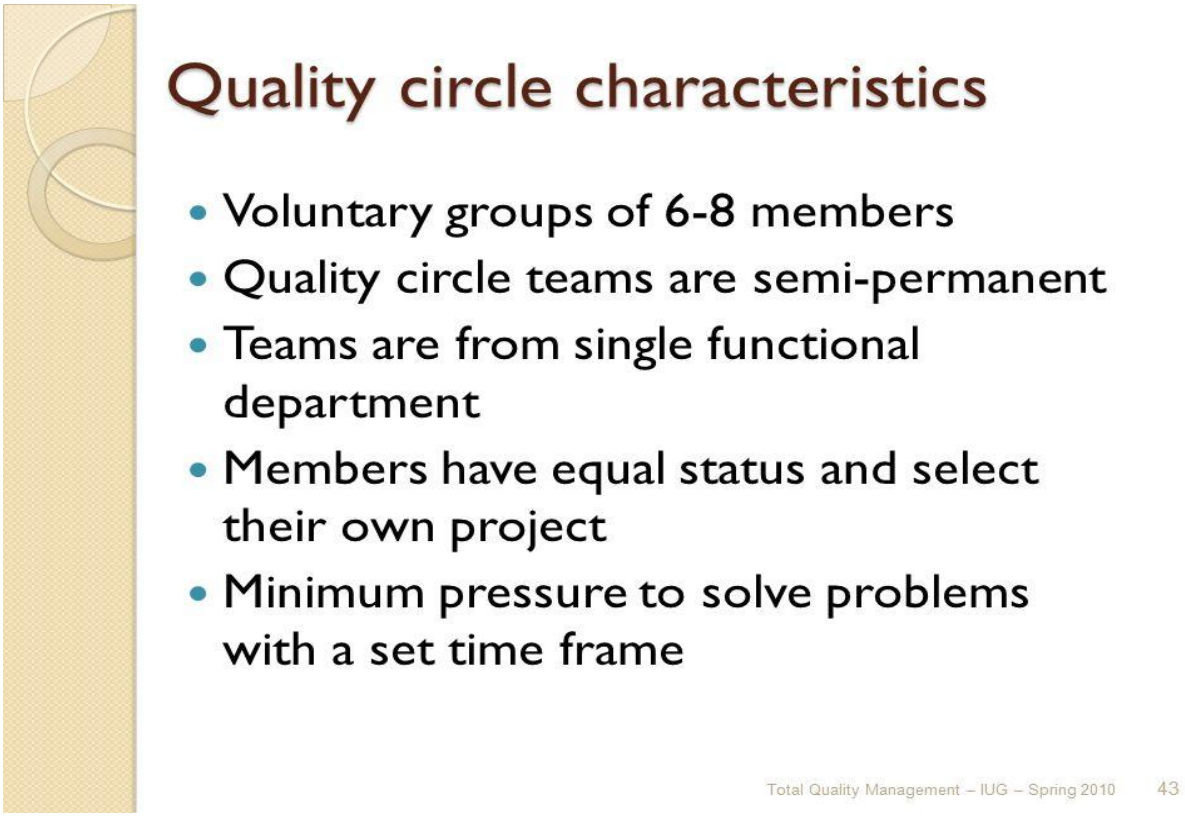
Theoretically, quality circles are groups of workers who do similar work but could be built up of individuals drawn from different positions provided they share the same work area and can identify common problems. The underlying perception in forming the quality circle is that it should be a homogeneous and coherent body for a common goal.

For example, the quality circle should not be formed with people with, say, from foundry shop, welding shop, heat treatment and design section. As these cannot form a coherent group as they do not share common problems.

OBJECTIVES OF QUALITY CIRCLES / TQC

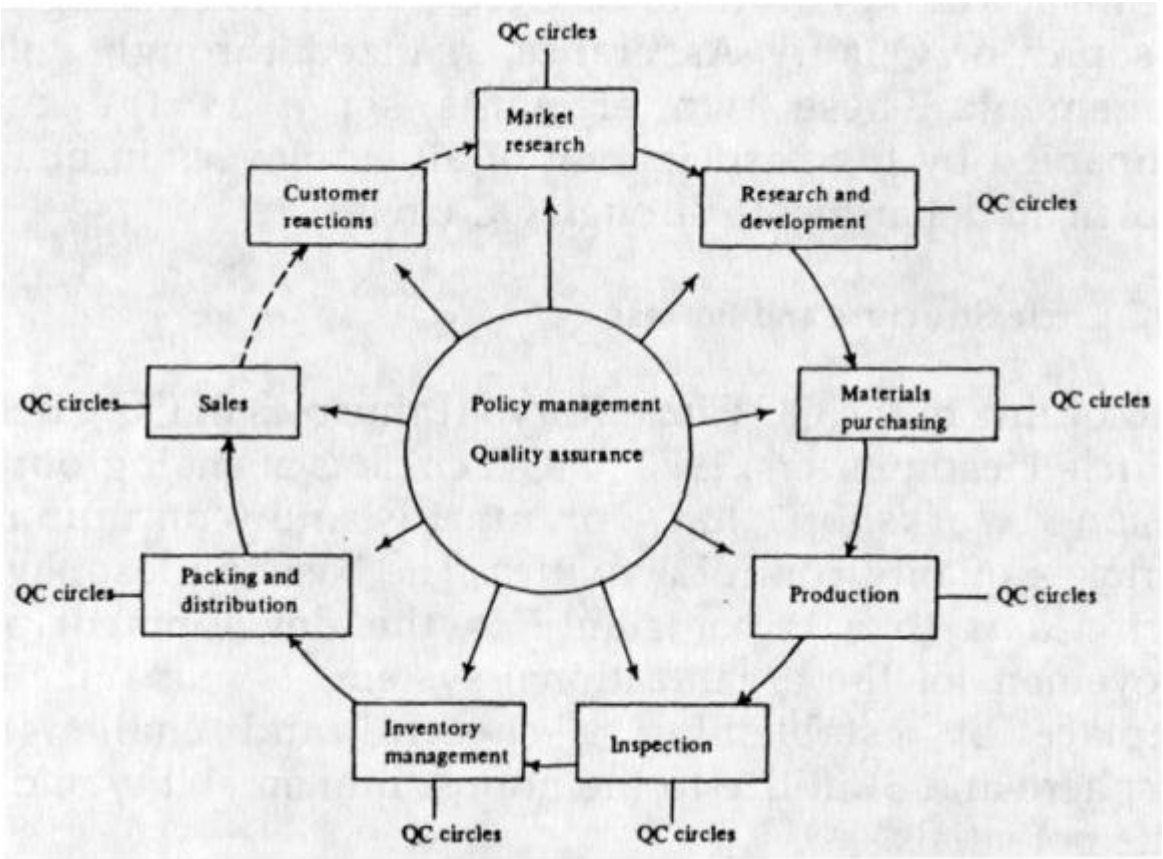


Procedure of QC



- The atmosphere should be informal, comfortable and relaxed.
- The members should feel involved and interested.
- Everyone should participate.
- The objectives should be clear to the members.
- The members should listen to each other.
- The group should feel comfortable even when there are disagreements.
- The decisions should generally be taken by a kind of consensus and voting should be minimum.
- When an action is required to be taken, clear assignments should be made and accepted by all the members.
- The leader should not dominate the group. The main idea should not be as to who controls but how to get the job done.
- Until a final solution is found and results are attained feedback is necessary.

PROCESS OF TQC



Quality objectives

QUALITY POLICY

Definition

Top management's expression of its intentions, direction, and aims regarding quality of its products and processes. In quality management system, a quality policy is a document developed by management to express the directive of the top management with respect to quality. Quality policy management is a strategic item. Section 5.2 of the ISO 9001:2015 standard requires a written, well-defined quality policy that is communicated and understood within an organization. Section 5.2 also sets out some of the requirements for quality policies

QUALITY PLANNING

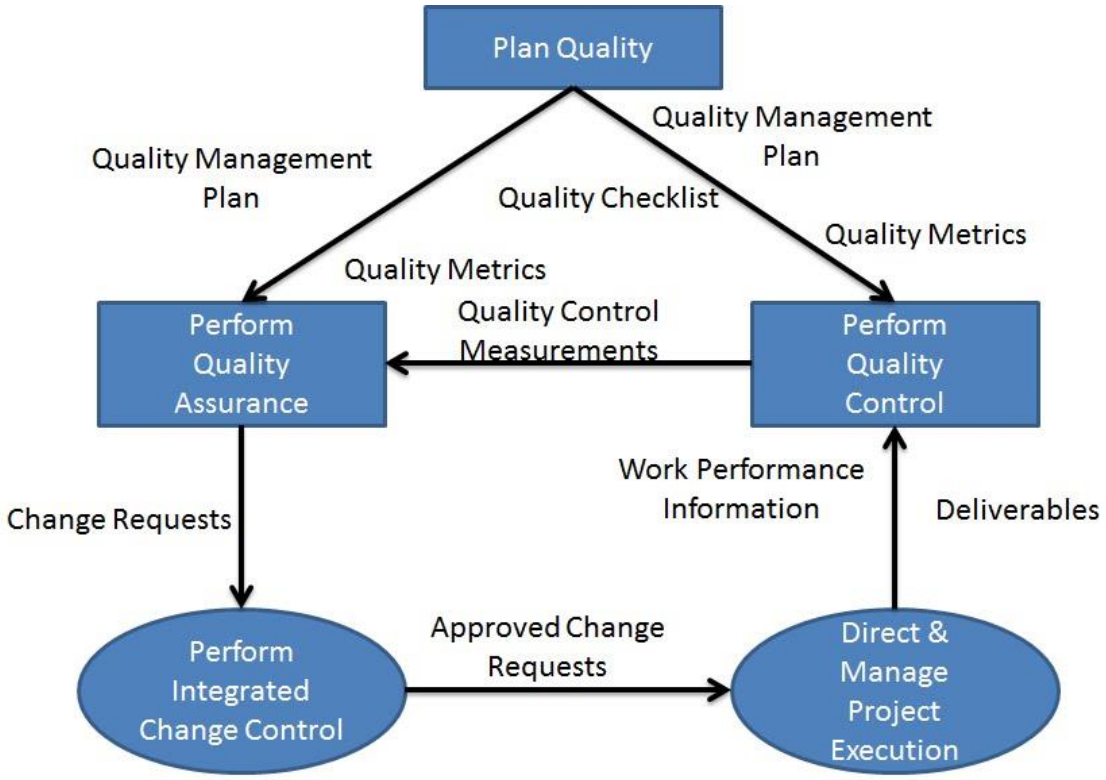
Definition

Systematic process that translates quality policy into measurable objectives and requirements, and lays down a sequence of steps for realizing them within a specified timeframe. A quality plan is a document, or several documents, that together specify quality standards, practices, resources, specifications, and the sequence of activities relevant to a particular product, service, project, or contract.

Quality plans should define:

- ***Objectives to be attained*** (for example, characteristics or specifications, uniformity, effectiveness, aesthetics, cycle time, cost, natural resources, utilization, yield, dependability, and so on)
- ***Steps in the processes*** that constitute the ***operating practice or procedures*** of the organization
- ***Allocation of responsibilities, authority and resources*** during the different phases of the process or project
- ***Specific documented standards, practices, procedures, and instructions to be applied***
- ***Suitable testing, inspection, examination, and audit programs at appropriate stages***
- ***A documented procedure for changes and modifications to a quality plan as a process is improved***
- ***A method for measuring the achievement of the quality objectives***
- ***Other actions necessary to meet the objectives***

Process of quality planning



QUALITY OBJECTIVES

- To enhance customer satisfaction
- To reduce customer complaints
- To import training to the up gradation, knowledge & skills.
- To improve existing has an requirement of customer.
- To reduce breakdown time
- To minimize rejection
- To ensure on time delivery.
- To enable continuous improvement.

QUALITY INFORMATION FEEDBACK

Quality – Zero defects

Information

Feed back

- Techniques to get quality information feedback
- Surveys
- Email
- Website pop ups
- Contact forms
- Exploratory interviews

- Focus group
- Social listening
- Branded community

QUALITY AUDIT

DEFINITION

A systematic and independent examination to determine whether quality activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives.

TYPES OF AUDITS

1. **Internal (First party / self)**

   This type includes audits by company employees, consultants and contractors.

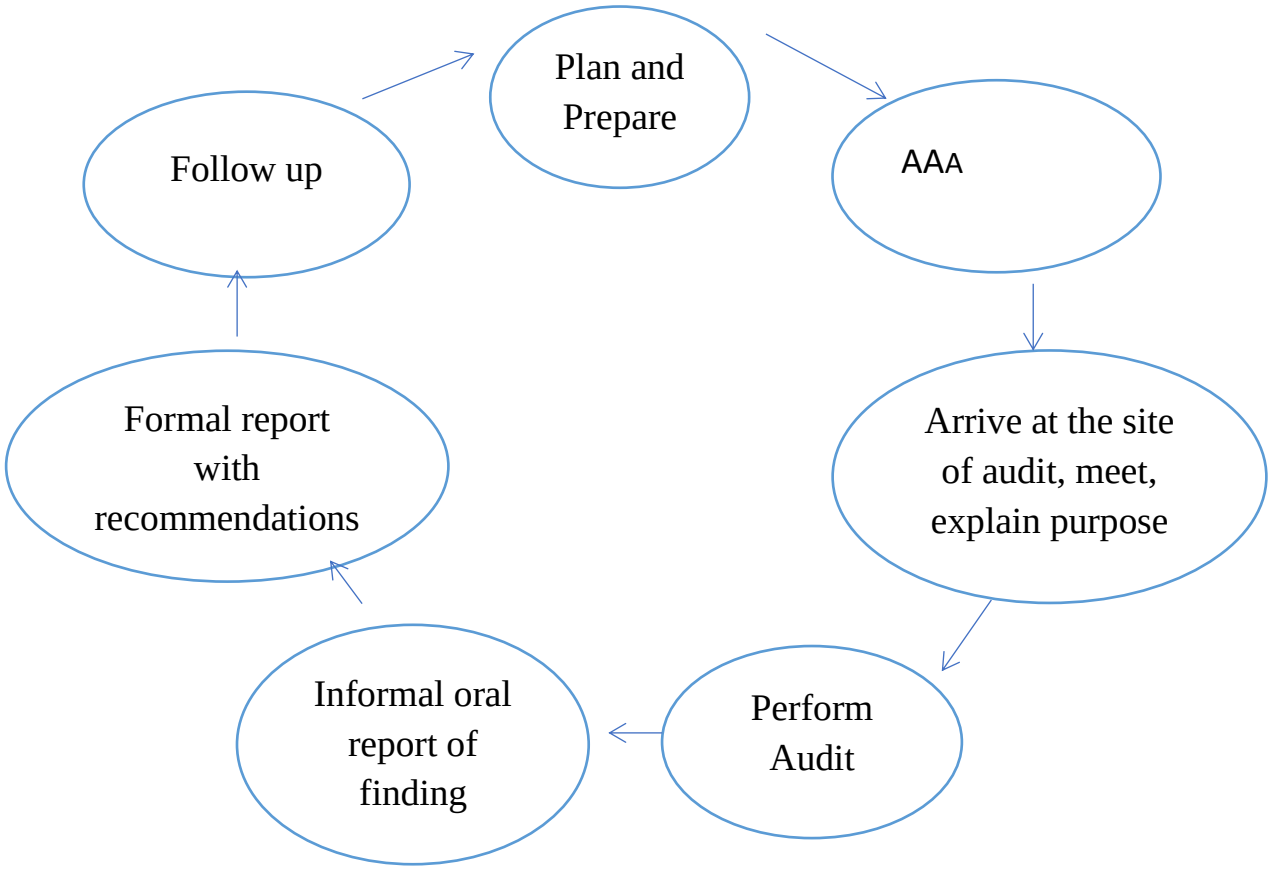
2. **External (Second party)**

   Employees audit a company which supplies your company with a product or service

3. **Independent Organization**

   A customer wants an audit of your company.

STEPS TO PERFORM QUALITY AUDIT



AUDIT SUB-TYPES

1. Compliance (do we comply with the standard)

   Example: desk audit of high level systems
2. System (the theory)

   Example: Audit of document control
3. Process (the Practice)

   Example: Audit of any process (manufacturing)
4. Product (the result)

   Example: Audit of finished products to fulfill technical specifications.

TQM

UNIT V

ISO DEFINITION

International Organization for Standardization, promotes worldwide, standards for the improvement of quality, productivity and operating efficiency through a series of standards and guidelines.

HISTORY OF ISO

- In 1946, delegates from 25 countries met in ""GENEVAGENEVA"(Switzerland)"
- Switzerland decided to create a new international organization, of which the object would be "to facilitate the international coordination and unification of industrial standards".
- The new organization, ISO, officially began operations on 23 February 1947.

FOUNDING MEMBERS

- 14 Industrialized Countries from EUROPE
- The US (ANSI)
- British Common Wealth

OPERATORS OF ISO

- 80 technical committees (TCs)
- 620 active sub committees (SCs)
- The actual standards preparation is done by ISO Technical committees (ISO/TCs).

- TCs are assisted by member country Technical Action Group (TAG)

MEMBERS OF ISO

There are 158 National members out of the 195 total countries in the World

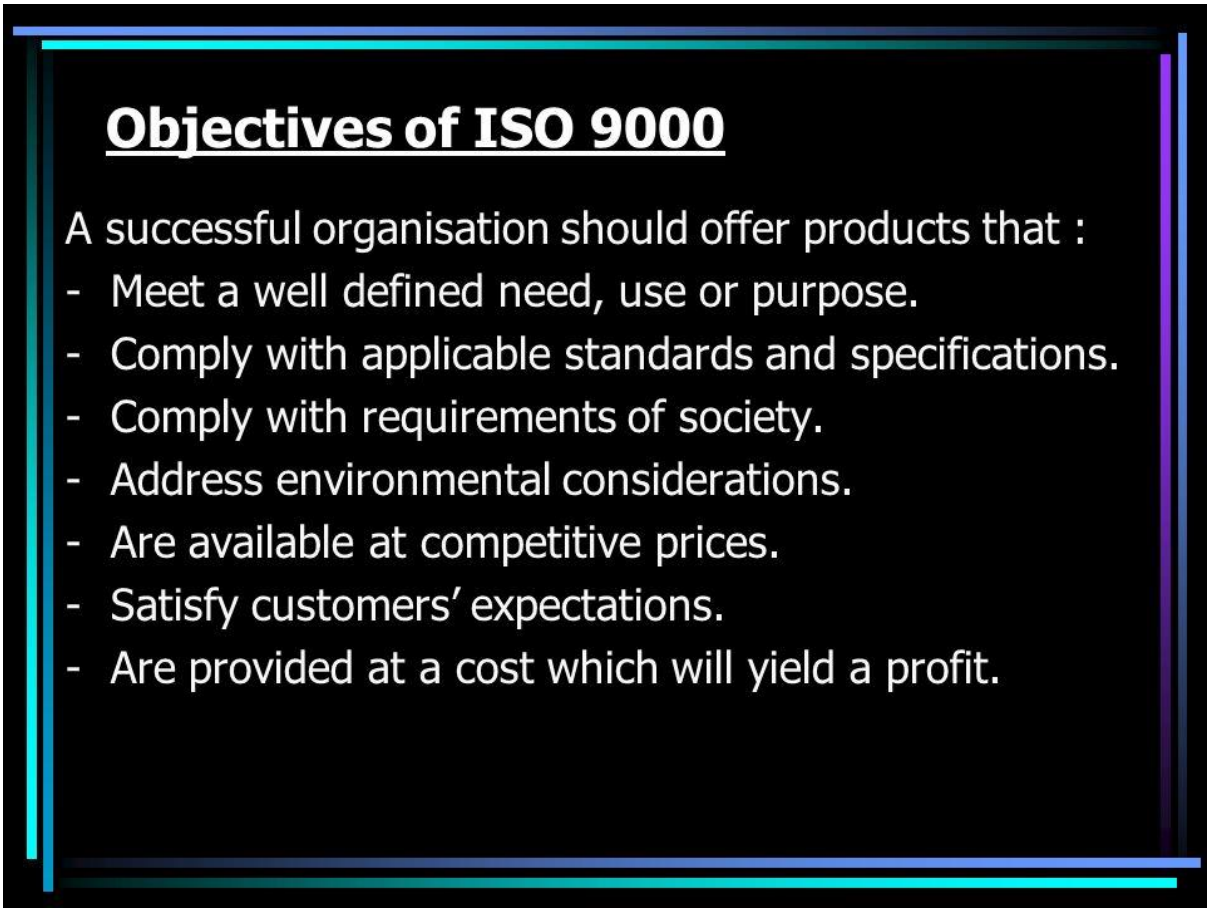
ISO has three membership category, they are:

1) Member bodies
2) Correspondent Member
3) Subscribers Member

NEED FOR ISO

- Continuous improvement
- Marketing strategy
- To meet Customer requirement

OBJECTIVES / NEED OF ISO



EVOLUTION OF ISO

The ISO 9000 standard is continually being revised by standing technical committees and advisory groups, who receive feedback from those professionals who are implementing the standard.

- ***1987 version***

ISO 9000:1987 had the same structure as the UK Standard BS 5750, with three "models" for quality management systems, the selection of which was based on the scope of activities of the organization:

- **ISO 9001:1987** Model ***for quality assurance in design, development, production, installation, and servicing*** was for companies and organizations whose activities included the creation of new products.
- **ISO 9002:1987** Model for quality assurance in ***production, installation, and servicing*** had basically the same material as ISO 9001 but without covering the creation of new products.
- ISO 9003:1987 Model for quality assurance in ***final inspection and test covered only the final inspection of finished product, with no concern*** for how the product was produced.

ISO 9000:1987 was also influenced by existing U.S. and other Defense Standards ("MIL SPECS"), and so was well-suited to manufacturing. The emphasis tended to be placed on conformance with procedures rather than the overall process of management, which was likely the actual intent.

- **1994 version**

ISO 9000:1994 emphasized quality assurance via preventive actions, instead of just checking final product, and continued to require evidence of compliance with documented procedures. As with the first edition, the down-side was that companies tended to implement its requirements by creating shelf-loads of procedure manuals, and becoming burdened with an ISO bureaucracy. In some companies, adapting and improving processes could actually be impeded by the quality system.

- **2000 version**

ISO 9001:2000 replaced all three former standards of 1994 issue, ISO 9001, ISO 9002 and ISO 9003. Design and development procedures were required only if a company does, in fact, engage in the creation of new products. The 2000 version sought to make a radical change in thinking by actually placing front and centre the concept of process management (the monitoring and optimisation of a company's tasks and activities, instead of just inspection of the final product). The 2000 version also demanded involvement by upper executives in order to integrate quality into the business system and avoid delegation of quality functions to junior administrators. Another goal was to improve effectiveness via process performance metrics:

numerical measurement of the effectiveness of tasks and activities. Expectations of continual process improvement and tracking customer satisfaction were made explicit.

ISO 9000 Requirements include

- Approve documents before distribution
- Provide correct version of documents at points of use
- Use your records to prove that requirements have been met
- Develop a procedure to control your records.

- **2008 version**

ISO 9001:2008 in essence re-narrates ISO 9001:2000. The 2008 version only introduced clarifications to the existing requirements of ISO 9001:2000 and some changes intended to improve consistency with ISO 14001:2004. There were no new requirements. For example, in ISO 9001:2008, a quality management system being upgraded just needs to be checked to see if it is following the clarifications introduced in the amended version.

ISO 9001 is supplemented directly by **two other standards** of the family:

- ISO 9000:2005 "Quality management systems. Fundamentals and vocabulary"
- ISO 9004:2009 "Managing for the sustained success of an organization. A quality management approach"

Other standards, like ISO 19011 and the ISO 10000 series, may also be used for specific parts of the quality system.

- ***2015 version***

In 2012, ISO TC 176 - responsible for ISO 9001 development - celebrated 25 years of implementing ISO 9001 and concluded that it is necessary to create a new QMS model for the next 25 years. This is why they commenced the official work on creating a revision of ISO 9001, starting with the new QM principles. This moment was considered by important specialists in the field as "beginning of a new era in the development of quality management systems." As a result of the intensive work from this technical committee, the revised standard ISO 9001:2015 was published by ISO on 23 September 2015. The scope of the standard has not changed; however, the structure and core terms were modified to allow the standard to integrate more easily with other international management systems standards.

The 2015 version is also less prescriptive than its predecessors and focuses on performance. This was achieved by combining the process approach with risk-based thinking, and employing the Plan-Do-Check-Act cycle at all levels in the organization.

Some of the key changes include

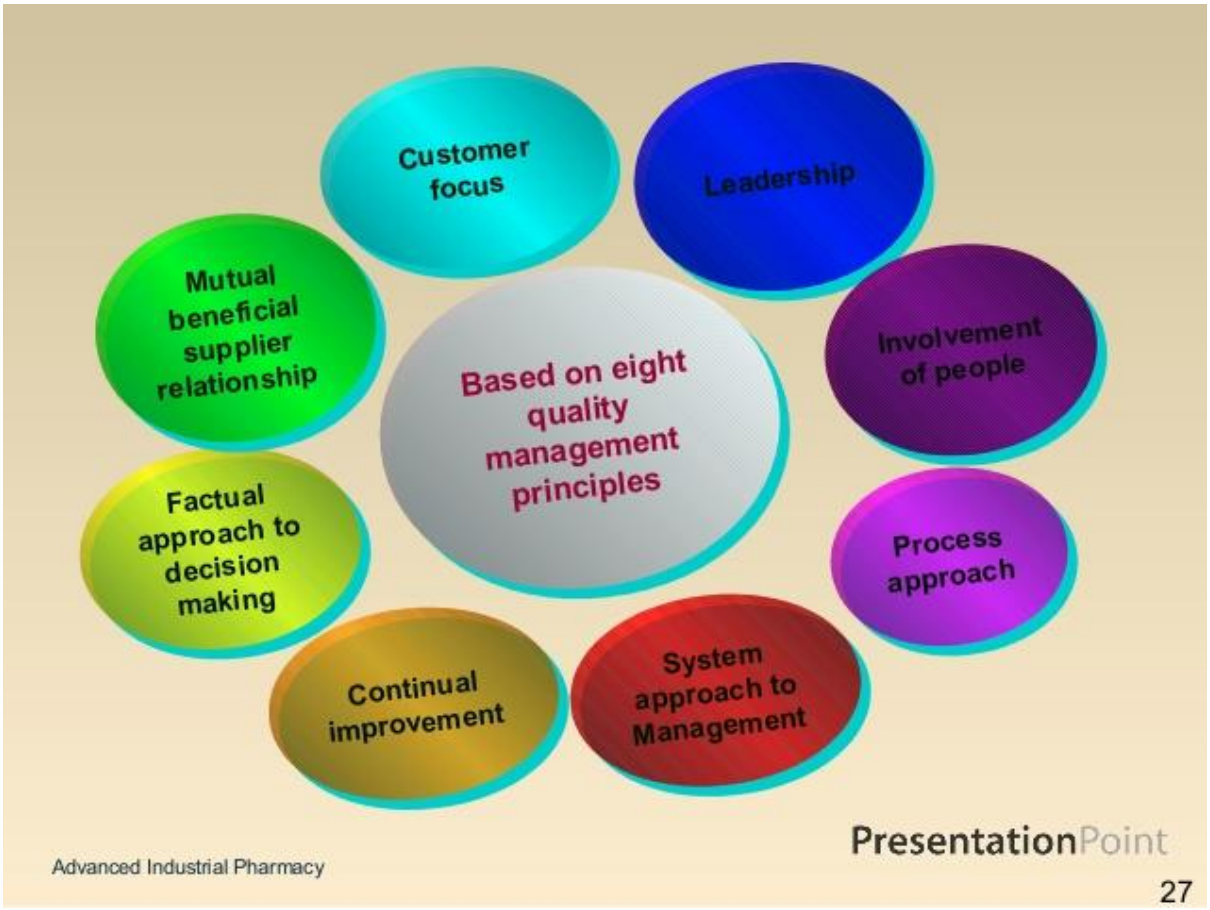
- High-Level Structure of 10 clauses is implemented. Now all new standard released by ISO will have this High-level structure.
- Greater emphasis on building a management system suited to each organization's particular needs
- A requirement that those at the top of an organization be involved and accountable, aligning quality with wider business strategy
- Risk-based thinking throughout the standard makes the whole management system a preventive tool and encourages continuous improvement
- Less prescriptive requirements for documentation: the organization can now decide what documented information it needs and what format it should be in
- Alignment with other key management system standards through the use of a common structure and core text
- Inclusion of Knowledge Management principles
- Quality Manual & Management representative is now not mandatory requirements.

ISO 9000

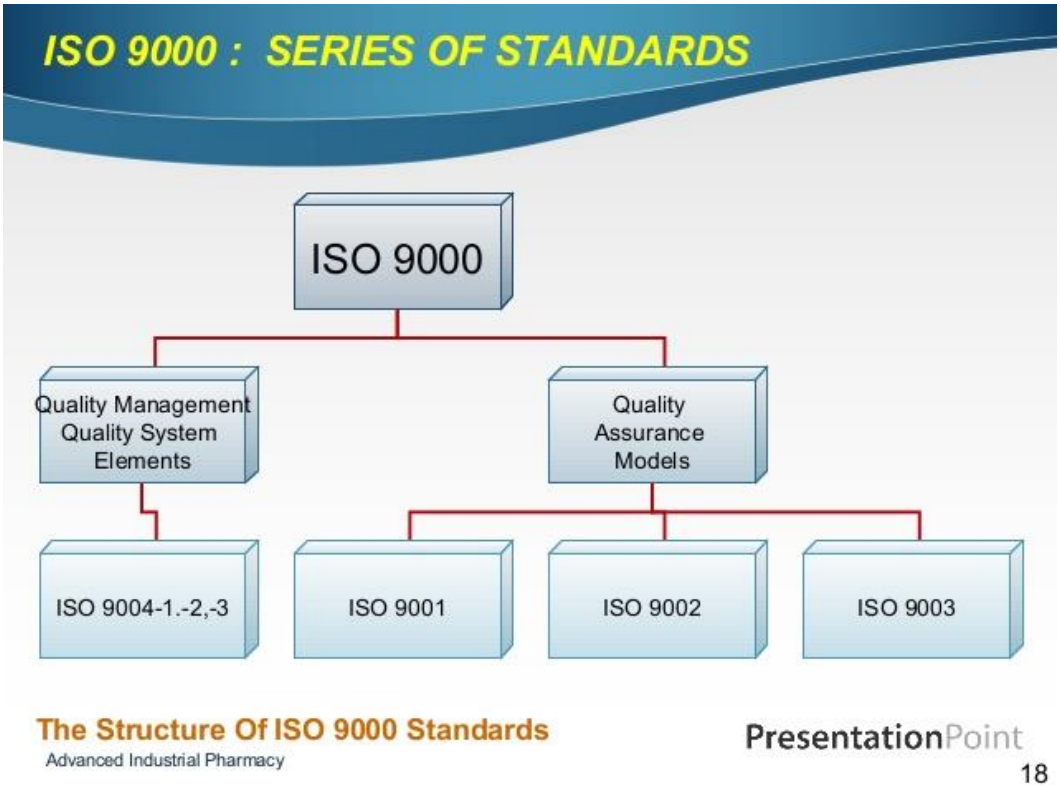
DEFINITION

They provide a framework for quality system development in all types of industries including service organizations. It is just purely a management system that will help to run business in a more organized and systematic manner which will lead organisation to a more consistent in quality of the service that it deliver to customers. Advanced Industrial Pharmacy

PRINCIPLE OF ISO 9000



ISO 9000 SERIES STANDARDS



Quality Management And Standards

- ISO 9000-1 : Guidelines for selection and use
- ISO 9000-2 : Generic guideline for the application of ISO 9001, ISO 9002
- ISO 9003 ISO 9000-3 : Guideline for the application of ISO 9001 to development, supply, and maintenance of software
- ISO 9000-4 : Guide to dependability program management
- ISO 9001 - Quality Assurance in design/ development, production, installation and servicing
- ISO 9002 - Quality Assurance in production and installation
- ISO 9003 - Quality Assurance in final inspection and test
- ISO 9004 - Quality management and quality system elements

ISO 9000:2000

ISO 9000:2000 refers to the ISO 9000 update released in the year 2000.

The Technical Committee responsible for the ISO 9000 family developed specifications for the ISO 9000:2000 revisions, leading to a significant advancement of the standards and reflecting contemporary concepts of quality management.

- ***The ISO 9000:2000 revision had five goals***
  - Meet stakeholder needs
  - Be usable by all sizes of organizations
  - Be usable by all sectors
  - Be simple and clearly understood
  - Connect quality management system to business processes

(From ISO 9000:2000 Shifts Focus of Quality Management System Standards, by Jack West.)

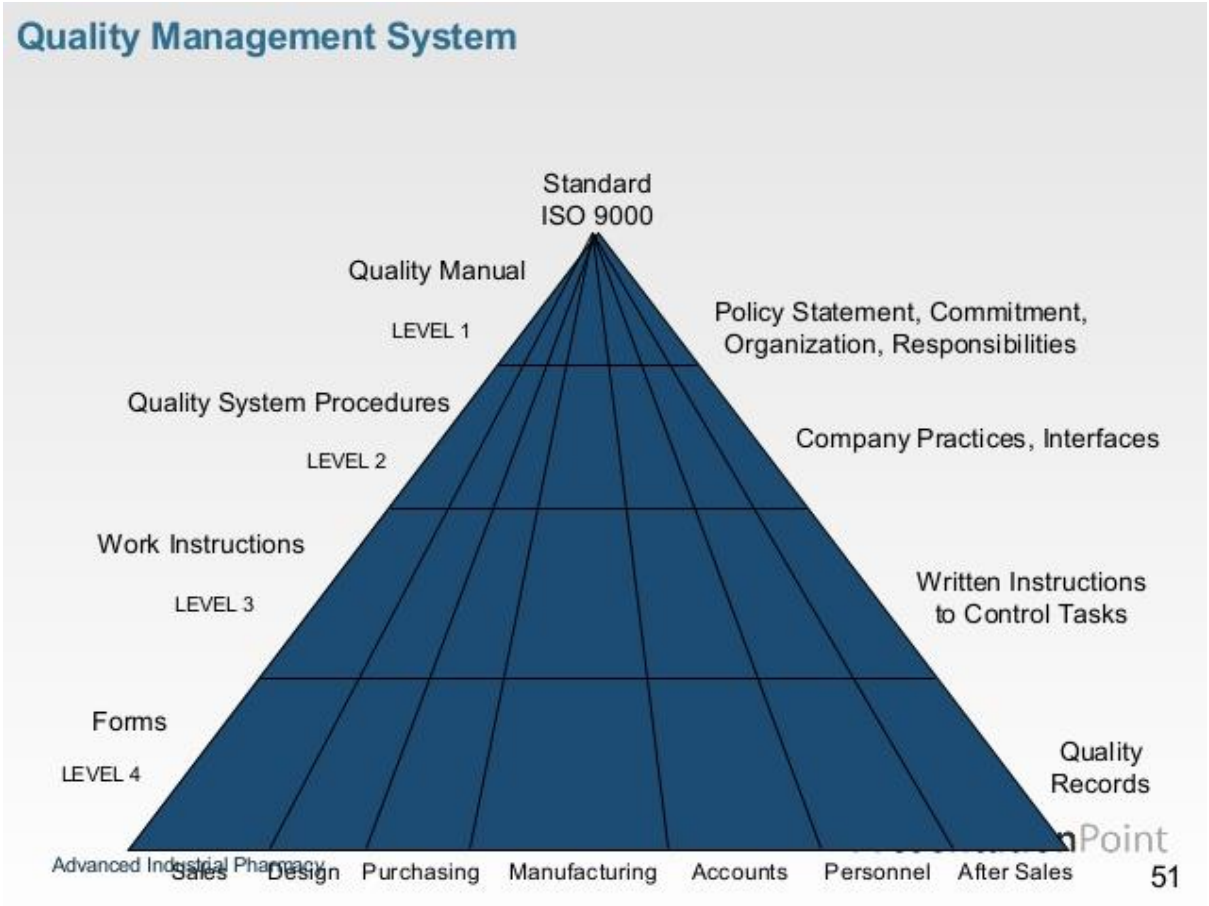
ISO 9000:2000 was again updated in 2008 and 2015.

ISO 9000:2015 is the most current version.

History & revisions: ISO 9000:2000, 2008, and 2015

- Originally published in 1987 by the International Organization for Standardization (ISO), a specialized international agency for standardization composed of the national standards bodies of more than 160 countries
- Underwent major revision in 2000; revised again in 2008
- Current versions of ISO 9000 and ISO 9001 were published in September 2015
- ISO 9000 principles of quality management

- The ISO 9000:2015 and ISO 9001:2015 standards are based on seven quality management



STRUCTURE OF ISO 9000

Fundamentals & vocabulary provides essential background for the proper understanding and implementation of ISO 9001:2015

1. Scope

The standard specifies requirements for a QMS when an organization:

1. Needs to demonstrate its ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements.
2. Aims to enhance customer satisfaction through the effective application of the system, including processes for the improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirement

2. Normative references

ISO 9000:2015 Quality management systems – Fundamentals & vocabulary. Is the normative reference

3. Terms and definition

Terms and definitions given in ISO 9000:2015 apply.

PROCESS OF OBTAINING ISO CERTIFICATION

REQUIREMENT FOR REGISTRATION OF ISO 9000

- Company Review
- Refine
- Map Functions
- Process control
- Inspection
- Purchasing
- Training
- Packaging
- Delivery
- Must reregistered every 3 years
- Helpful for companies that do not currently have a quality management

QUALITY SYSTEM REQUIREMENTS

- Management Responsibility
- Quality System
- Contract Review
- Design Control
- Document and Data Control
- Purchasing
- Control of Customer Supplied Product
- Product identification and Traceability
- Process Control
- Inspection and Testing
- Control Inspection, Measuring, and Test Equipment
- Inspection and Test Status
- Control of Non Conforming Product
- Corrective and Preventive Action
- Handling, Storage, Packaging, Preservative, and Delivery
- Control of Quality Record
- Internal Quality Audits
- Training

- Servicing
- Statistical Techniques

ADVANTAGES OF ISO

THE NEW VERSION OF ISO STANDARDS

Comparison Table	
New ISO 9001:2015	**ISO 9001:2008**
1. Scope	1. Scope
2. Normative References	2. Normative References
3. Terms and definitions	3. Terms and definitions
4. Context of the organization	4. Quality Management System
5. Leadership	5. Management responsibility
6. Planning	6. Resource management
7. Support	7. Product realization
8. Operation	8. Measurement, analysis, and improvement
9. Performance evaluation	
10. Improvement	

DOCUMENTATION

Here are the ***documents we need to produce*** if we want to be compliant with ISO 9001:2015. (Please note that some of the documents will not be mandatory if the company does not perform relevant processes.):

- Scope of the QMS (clause 4.3)
- Quality policy (clause 5.2)
- Quality objectives (clause 6.2)
- Criteria for evaluation and selection of suppliers (clause 8.4.1)
- And, here are the mandatory records (note that records marked with * are only mandatory in cases when the relevant clause is not excluded):
- Monitoring and measuring equipment calibration records* (clause 7.1.5.1)
- Records of training, skills, experience and qualifications (clause 7.2)
- Product/service requirements review records (clause 8.2.3.2)
- Record about design and development outputs review* (clause 8.3.2)
- Records about design and development inputs* (clause 8.3.3)
- Records of design and development controls* (clause 8.3.4)
- Records of design and development outputs *(clause 8.3.5)
- Design and development changes records* (clause 8.3.6)
- Characteristics of product to be produced and service to be provided (clause 8.5.1)
- Records about customer property (clause 8.5.3)
- Production/service provision change control records (clause 8.5.6)
- Record of conformity of product/service with acceptance criteria (clause 8.6)
- Record of nonconforming outputs (clause 8.7.2)
- Monitoring and measurement results (clause 9.1.1)
- Internal audit program (clause 9.2)
- Results of internal audits (clause 9.2)
- Results of the management review (clause 9.3)
- Results of corrective actions (clause 10.1)

Non-mandatory documents

There are numerous non-mandatory documents that can be used for ISO 9001 implementation. However, I find these non-mandatory documents to be most commonly used:

- Procedure for determining context of the organization and interested parties (clauses 4.1 and 4.2)
- Procedure for addressing risks and opportunities (clause 6.1)
- Procedure for competence, training and awareness (clauses 7.1.2, 7.2 and 7.3)
- Procedure for equipment maintenance and measuring equipment (clause 7.1.5)
- Procedure for document and record control (clause 7.5)
- Sales procedure (clause 8.2)
- Procedure for design and development (clause 8.3)
- Procedure for production and service provision (clause 8.5)
- Warehousing procedure (clause 8.5.4)
- Procedure for management of nonconformities and corrective actions (clauses 8.7 and 10.2)
- Procedure for monitoring customer satisfaction (clause 9.1.2)
- Procedure for internal audit (clause 9.2)
- Procedure for management review (clause 9.3)

ISO 14000

MEANING

Focuses on environmental management system that will ensure all operational processes are consistent and effective and will achieve environmental objectives of the organization. A company should review and continually improve its environmental management system, with the objective of improving its overall environmental performance

ISO 14000 is similar to ISO 9000 quality management in that both pertain to the process of how a product is produced, rather than to the product itself. As with ISO 9001, certification is performed by third-party organizations rather than being awarded by ISO directly. The ISO 19011 and ISO 17021 audit standards apply when audits are being performed

DEFINITION OF ISO 14000

ISO 14000 is a series of international, voluntary environmental management standards, guides, and technical reports. The standards specify requirements for establishing an environmental policy, determining environmental impacts of products or services, planning environmental objectives, implementing programs to meet objectives, and conducting corrective action and management review.

ISO 14000 HISTORY

- The first environmental management system standard, BS 7750, was published in 1992 by the BSI group
- In 1996, the International Organization for Standardization (ISO) created the ISO 14000 family of standards
- ISO 14001 underwent revision in 2004
- The current revision of ISO 14001 was published in September 2015

CONCEPT

ISO 14000 is a family of standards related to environmental management that exists to help organizations

(a) Minimize how their operations (processes, etc.) negatively affect the environment (i.e. cause adverse changes to air, water, or land)

(b) Comply with applicable laws, regulations, and other environmentally oriented requirements; and

(c) Continually improve in the above.

LIST OF ISO 14000 SERIES STANDARDS

- ISO 14001 Environmental management systems - Requirements with guidance for use
- ISO 14004 Environmental management systems - General guidelines on implementation
- ISO 14006 Environmental management systems - Guidelines for incorporating ecodesign
- ISO 14015 Environmental management - Environmental assessment of sites and organizations (EASO)
- ISO 14020 to 14025 Environmental labels and declarations
- ISO/NP 14030 Green bonds -- Environmental performance of nominated projects and assets; discusses post-production environmental assessment
- ISO 14031 Environmental management - Environmental performance evaluation - Guidelines
- ISO 14040 to 14049 Environmental management - Life cycle assessment; discusses pre-production planning and environment goal setting
- ISO 14046 Environmental management - Water footprint - Principles, requirements and guidelines
- ISO 14050 Environmental management - Vocabulary; terms and definitions

- ISO/TR 14062 Environmental management - Integrating environmental aspects into product design and development
- ISO 14063 Environmental management - Environmental communication - Guidelines and examples
- ISO 14064 Greenhouse gases; measuring, quantifying, and reducing greenhouse gas emissions
- ISO 19011 Guidelines for auditing management systems; specifies one audit protocol for both 14000 and 9000 series standards together

BENEFITS OF ISO 14000

The ISO 14001 standard provides specific requirements for an EMS and shares some common management system principles with the ISO 9000 series of standards, including the "plan-do-check-act model" mentioned above and the requirement for top management commitment. The basic focus of the ISO 14000 series of standards is environmental protection, while the ISO 9000 series of standards focuses on quality and customer needs.

It should be noted that ISO 9000 is not a prerequisite for ISO 14001, although companies that have both have successfully integrated the two management systems.

An effective EMS provides many benefits to the implementing organization, its customers and stakeholders, and to regulators, including:

- Reduced environmental risk.
- Proactive environmental management.
- Improved employee environmental awareness and performance.
- Increased operating efficiency and cost-effectiveness.
- Increased operating efficiency and cost-effectiveness.
- Enhanced relationships and communication with employees, regulators, and Stakeholders