TQM- MODULE 5

a) **Total Productive Maintenance (TPM):**
Definition, Types of Maintenance, Steps in introduction of TPM in an organization, Pillars of TPM – 5S, Jishu Hozen, Quality Maintenance, Planned Maintenance.

b) **Quality by Design (QbD):** Definition, Key components of QbD, Role of QbD in Pharmaceutical Industry, Benefits and Challenges of QbD.

c) **Environmental Management Systems (EMS):** Definition, Basic EMS, EMS under ISO 14001, Costs and Benefits of EMS.

CONTENTS

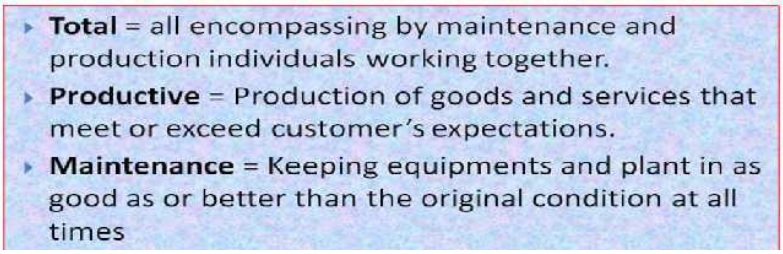
TOTAL PRODUCTIVE MAINTENANCE (TPM)

TPM (Total Productive Maintenance) is a unified approach used for equipment maintenance TPM aims to make the production process free from breakdown, defect free, slowing down of the production line, and setup time losses. It also aims to provide safe working conditions. TPM ensures everyone works together in the industry to achieve peak performance and productivity.

- Keeping the current plant and equipment at the highest productive level through the cooperation of all the areas of organization
- Total – everyone working together
- Productive – production of goods and services to meet or exceed the expectation of the customer
- Maintenance – keep equipment in good or better than original condition at all times

Total Productive Maintenance (TPM) is a maintenance program which involves a newly defined concept for maintaining plants and equipment.

TPM seeks to maximize equipment's effectiveness throughout the life time of that equipment. It strives to maintain optimum equipment conditions in order to prevent unexpected break downs, speed loses, and quality defects arising from process activities.



Goals of **Total Productive Maintenance**(TPM)

- Maintaining and improving equipment capacity
  Maintaining equipments for life
- Using support from all areas of the operation
- Encouraging inputs from all employees
- Using teams for continuous improvement

- Goal of the TPM program is to markedly increase production while, at the same time, increasing employee morale and job satisfaction.
- TPM brings maintenance into focus as a necessary and vitally important part of the business. It is no longer regarded as a non-profit activity. Down time for maintenance is scheduled as a part of the manufacturing day and, in some cases, as an integral part of the manufacturing process.
- The goal is to hold emergency and unscheduled maintenance to a minimum.

Why TPM / the objective of TPM

TPM was introduced to achieve the following objectives:

• Avoid wastage in a quickly changing economic environment.

• Producing goods without reducing product quality.

• Reduce cost.

• Produce target quantity at the earliest possible time.

• Goods send to the customers must be non-defective.

To fulfil those objectives and the goal TPM has dual targets: 1. Zero defects, zero accidents and zero loss; 2. Zero breakdown (100% equipment availability). It is true that when defects and breakdown are reduced the operating costs come down and hence productivity increases and the products are delivered to the customer

at a reasonable cost and at the right time.

Eight Pillars of TPM

Eight pillars of TPM are displayed in the following picture. TPM is achieved with the help of 5S seiri (Sort), seiton (Set in Order), seiso (Shine), seiketsu (Standardise), and shitsuke (Sustain). 5 S make the foundation for a TPM program. TPM begins by making setting everything in order, in right place, neat and tidy.

Focused Improvement: In TPM, everyone focuses towards improvement. Small focus work groups improve the quality continuously by removing root causes of errors. They work together to reduce the number of defects.

Autonomous maintenance: Autonomous maintenance makes works responsible for maintenance of machines they work with. This eliminates the need for an expert and also develops a sense of ownership among workers. This is termed as *JISHU HOZEN* in Japanese language. Workers become more knowledgeable about work and the machine they are working with.

Planned maintenance: In planned maintenance, we follow proactive methods to avoid breakdown than firefighting. This significantly reduces the work stoppages and unnecessary inventory buildup.
Training and education: Training and education is an integral part of TPM program. Everyone are trained and educated to make them understand the benefits of TPM. Workers are trained about their machines; managers are trained about principles of TPM and human resource management.

Six core principles of TPM

1. Obtain Minimum 90% OEE (Overall Equipment Effectiveness) Run the machines even during lunch. (Lunch is for operators and not for machines!)

2. Operate in a manner, so that there are no customer complaints.

3. Reduce the manufacturing cost by 30%.

4. Achieve 100% success in delivering the goods as required by the customer.

5. Maintain an accident free environment.

6. Increase the suggestions by 3 times. Develop Multi-skilled and flexible workers.

Direct benefits of TPM

1. Increase productivity and OPE (Overall Plant Efficiency) by 1.5 or 2 times.
2. Rectify customer complaints.
3. Reduce the manufacturing cost by 30%.
4. Satisfy the customer needs by 100 % (Delivering the right quantity at the right time, in the required quality)
5. Reduce accidents.
6. Follow pollution control measures.

Indirect benefits of TPM

1. Higher confidence level among the employees.
2. Keep the work place clean, neat and attractive.
3. Favorable change in the attitude of the operators.
4. Achieve goals by working as team.
5. Horizontal deployment of a new concept in all areas of the organization.
6. Share knowledge and experience.
7. The workers get a feeling of owning the machine.

Steps in Introduction of TPM in an Organization

Stage A-Preparatory Stage

1 - Announcement by Management to all about TPM introduction in the organization:

Proper understanding, commitment and active involvement of the top management in needed for this step. Senior management should have awareness programmes, after which announcement is made to all. Publish it in the house magazine and put it in the notice board. Send a letter to all concerned individuals if required.

2- Initial education and propaganda for TPM:

Training is to be done based on the need. Some need intensive training and some just an awareness. Take people who matters to places where TPM already successfully implemented.

3 - Setting up TPM and departmental committees:

TPM includes improvement, autonomous maintenance, quality maintenance etc., as part of it. When committees are set up it should take care of all those needs.

4 - Establishing the TPM working system and target:

Now each area is benchmarked and fix up a target for achievement.

5 - A master plan for institutionalizing:

Next step is implementation leading to institutionalizing wherein TPM becomes an organizational culture. Achieving PM award is the proof of reaching a satisfactory level.

Stage - B - Introduction Stage

This is a ceremony and we should invite all. Suppliers as they should know that we want quality supply from them. Related companies and affiliated companies who can be our customers, some may learn from us and some can help us and customers will get the communication from us that we care for quality output.

Stage C - Implementation

In this stage eight activities are carried which are called eight pillars in the development of TPM activity. Of these four activities are for establishing the system for production efficiency, one for initial control system of new products and equipment, one for improving the efficiency of administration and are for control of safety, sanitation as working environment.

Stage D - Institutionalizing Stage

By all these activities one would has reached maturity stage. Now is the time for applying for PM award. Also think of challenging level to which you can take this movement.

Expected Questions

1) *Explain the concept of product liability.*
2) *What measures are taken to prevent product failures? Explain.*
3) *What is total productive maintenance? What are its objectives?*
4) *Explain 8 pillars of TPM*
5) *How do you measure TPM? Explain.*

QUALITY BY DESIGN

Quality by Design (QbD): Definition, Key components of QbD,

Role of QbD in Pharmaceutical Industry,

Benefits and Challenges of QbD.

Introduction

- Quality by design is the practice of using a multidisciplinary team to conduct conceptual thinking, product design and production planning all at one time, it is also known as concurrent engineering, simultaneous engineering or parallel engineering.
- Quality by design has recently encouraged changes in management structures.
- The major functions within an organization would complete their task by ‘‘throwingit over the wall’’ to the next department in the sequence and would not be concerned with any internal customer problems that might arise, quality by design or concurrent engineering requires the major functions to be performed at the same time. This system provides for immediate feedback, which prevents problems with quality and productivity from occurring. Fig. 5.3. Shows the flow diagram for both sequential or traditional engineering on the left and quality by design or concurrent engineering on the right.
- When each of the specialists early input to the product definition and specifications, cost is minimized and performance is maximized. Thus, better-quality products are manufactured for less cost with shorter time to market.
- The quality by design or concurrent engineering method combines all these steps into one. The product is designed to be successful at each stage of its life cycle. It is designed correctly the first time, considering all attributes and facets of its life, such as marketability, assembly and service ability, before release to testing and small production.

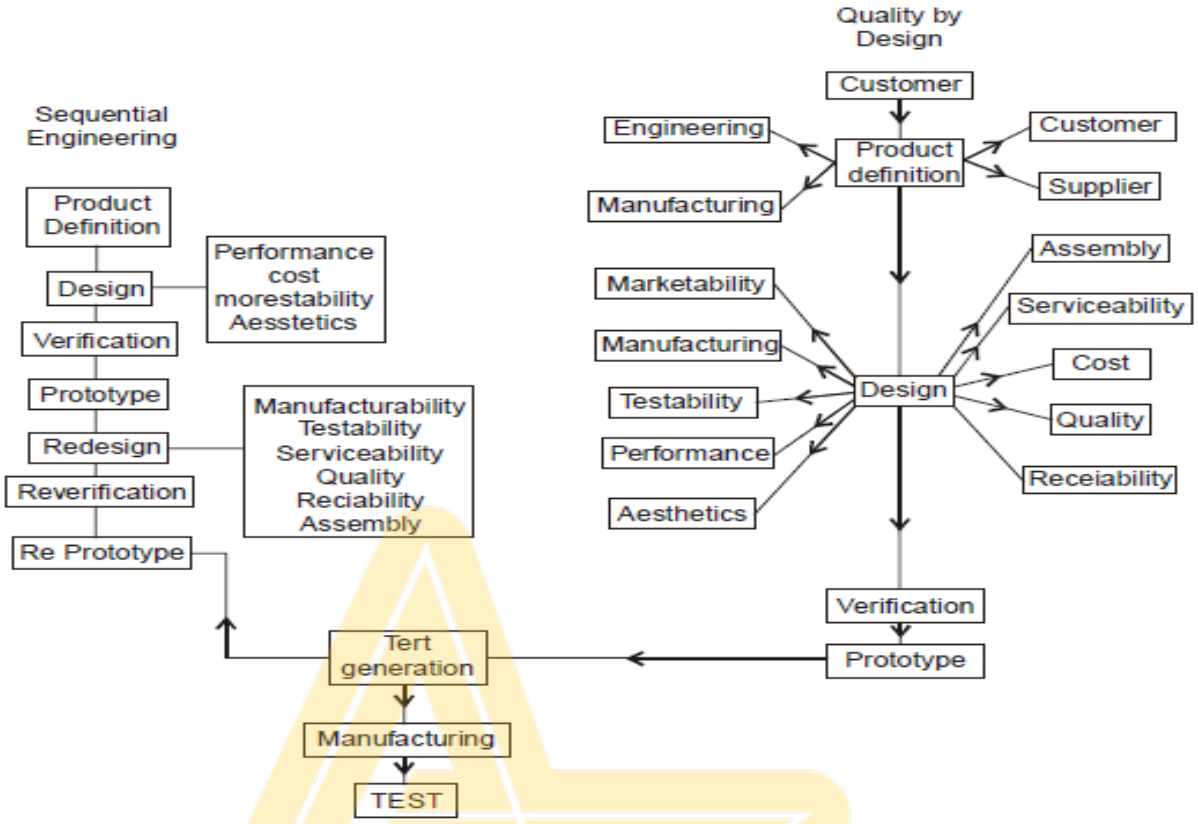
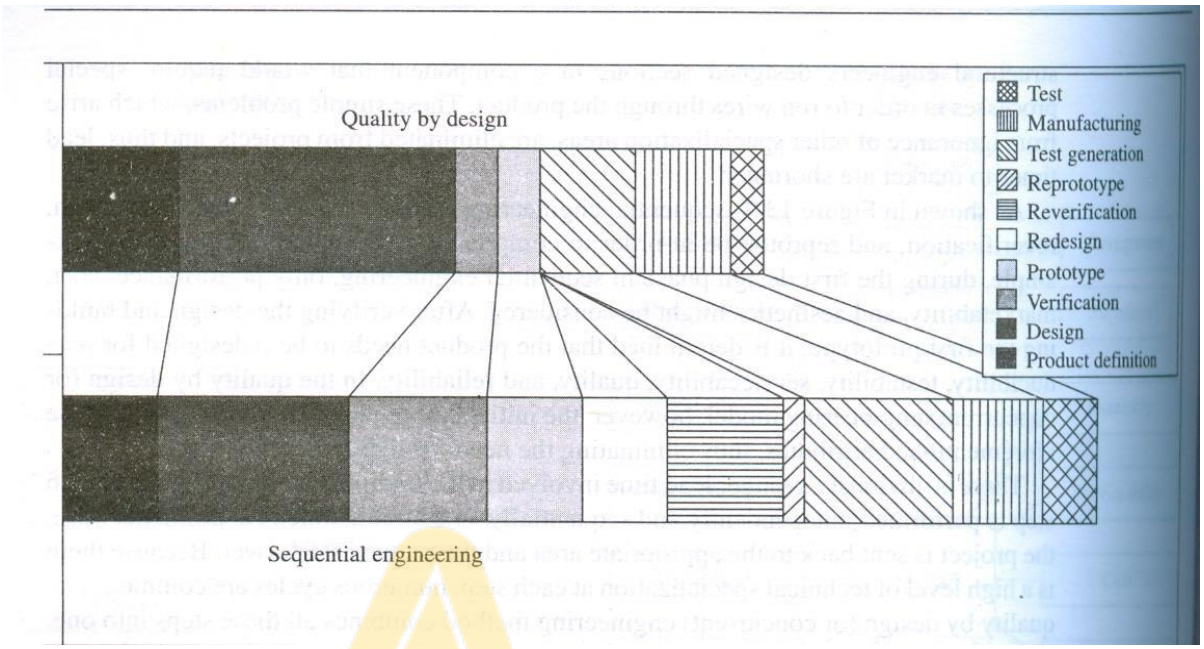


Fig. 5.3. Product development flow diagram. **Source: Shoji shiba, et.al., A new American TQM, four revolutions of Management,productivity press, 1990.**

Rationale for Implementation of Quality by Design.

- The amount of time required in the quality by design model for product-definitionand specifications can be significantly greater than that required in the sequential engineeringmodel.
- By using quality by design, the product is designed within production capabilities inorder for statistical process control to be effective.
- Producing products well within process capabilities will cause a chain reaction of customer satisfaction.
- Customer's returns will decreases and rework costs will also decrease.



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Concurrent engineering implementation assessment: A case study in an Indonesian manufacturing company

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Abstract

Concurrent Engineering or Simultaneous Engineering has been utilized by companies since 1980s as an approach to design a new product in integrative manner. It replaces traditional product development method which is a serial process with little coordination between different functions and lack of product life cycle perspectives. Concurrent Engineering (CE) offers opportunity for creating new products in short time while maintaining the highest quality at lowest cost which is considered to answer today's market demand. While benefit of CE is promising, implementing CE is not easy. There are a vast amount research that uncover difficulties during CE implementation. However, study of CE implementation in Indonesian company is only a few. One of them is conducted in 1998 at company X, one Indonesian high technology industry. Thus, this research aims to re-evaluate progress of CE implementation in company X today. In this research, CE implementation achievement level in company X is assessed by using Simultaneous Engineering Gap Analysis (SEGAPAN) and Analytical Hierarchical Process (AHP) . The result shows that management's role, cultural change, and the cross functional team are three factors that have the least level of CE implementatation compliance. In other words, these three factors are the most difficult barrier to implement CE successfully in company X. Next, Five Whys method is utilized to investigate the root cause of these impediments and some recommendations are proposed to reduce or to eliminate these CE implementation impediments accordingly.

Expected Questions

1. What is quality by design? How is it different from sequential engineering?
2. Why do we need to implement quality by design?
3. What are the potential benefits of Quality by Design?
4. What are the barriers and misconceptions about Quality by Design?

Environmental Management System

The overall aim of the Environmental Management systems is **to provide protection to the environment** and **to prevent pollution.**

- The success of ISO 9000 along with increased emphasis on Environmental issues were instrumental in ISO's decision to develop Environmental Management Standards.
- In 1991, ISO formed the Strategic Advisory Group on the Environment (SAGE) which led to the formation of Technical Committee (TC) 207 in 1992.
- Mission of TC207 is to develop standards for an Environmental Management System (EMS) which was identified as ISO 14000.
- TC 207 has established six sub-committees

1. Environmental Management System (EMS)
2. Environmental Auditing (EA)
3. Environmental labelling (EL)
4. Environmental Performance Evaluation (EPE)
5. Life-Cycle Assessment (LCA)
6. Terms & Definitions

EMS has two Evaluation Standards. They are

1. Organization Evaluation Standards 2. Product Evaluation Standards

REQUIREMENT OF ISO 14001

There are six elements

1. GENERAL REQUIREMENTS

EMS should include policy, planning implementation & operation, checking & corrective action, management review.

2. ENVIRONMENTAL POLICY (Should be based on mission)

- The policy must be relevant to the organization's nature.
- Management's Commitment (for continual improvement & preventing pollution).

- Should be a framework (for Environmental objectives & Targets).
- Must be Documented, Implemented, & Maintained.

3. PLANNING

- Environmental Aspects
- Legal & other Requirements
- Objectives & Targets
- Environmental Management Programs

4. IMPLEMENTATION & OPERATION

- Structure & Responsibility
- Training, Awareness & Competency
- Communication
- EMS Documentation
- Document Control
- Operational Control
- Emergency Preparedness & Response

5. CHECKING & CORRECTIVE ACTION

- Monitoring & Measuring
- Nonconformance& Corrective & Preventive action
- Records
- EMS Audit

6. MANAGENMENT REVIEW

- Review of objectives & targets
- Review of Environmental performance against legal & other requirement
- Effectiveness of EMS elements
- Evaluation of the continuation of the policy

BENEFITS OF ENVIRONMENTAL MANAGEMENT SYSTEM:

1. GLOBAL BENEFITS

- Facilitate trade & remove trade barrier
- Improve environmental performance of planet earth
- Build consensus that there is a need for environmental management and a common terminology for EMS

2. ORGANIZATIONAL BENEFITS

- Assuring customers of a commitment to environmental management
- Meeting customer requirement
- Improve public relation
- Increase investor satisfaction
- Market share increase
- Conserving input material & energy
- Better industry/government relation

- Low cost insurance, easy attainment of permits & authorization

Quality Management Systems

Introduction

The central need for reliable products in the Second World War defence procurement focused on tight specifications and consistency in product. Not surprisingly, therefore, post-war developments saw the quality drive being governed by different industries with different systems of standards.

ISO 9000

- The International Organization for Standardization (ISO) was founded in 1946. It is headquartered in Geneva, Switzerland. Its mandate is to promote the development of international standards to facilitate the exchange of goods and standards worldwide.
- The purpose of ISO is to facilitate global consensus agreements on international quality standards. It has resulted in a system for certifying suppliers to make sure they meet internationally accepted standards for quality management.
- It is a non-government organization. ISO has as its members the national standards organizations for more than 130 countries.
- During the 1970s it was generally acknowledged that the word quality had different meanings within and among industries and countries and around the world.
- The ISO 9000 series of quality-management standards, guidelines and technical reports was first published in 1987 and it is reviewed at least every five years.
- In the United States, the American National Institute/American Society publishes the national standards for Quality (ANSI/ASQ) as the ANSI/ASQ Q9000 series.
- Its purpose is to unify quality terms and definitions used by industrialized nations and use those terms to demonstrate a supplier's capability of controlling its processes.
- In very simplified terms, the standards require an organization to say what it is doing to ensure quality, then do what it says and finally document or prove that it has done what it said.
- The objective of quality management is to quickly produce safe products with low costs to achieve customer satisfaction.

ISO 9000 Series of Standards

- The ISO 9000 series of standards is generic in scope. By design, the series can be tailored to fit any organization's needs, whether it is large or small, a manufacturer or a service organization.

- It can be applied to construction, engineering, health care, legal and other professional services as well as the manufacturing of anything from nuts and bolts to spacecraft.

A. The ISO 9000 series was most recently revised and updated in 2000.

1. ISO 9000:2000: Quality Management Systems-Fundamentals and Vocabulary, is the starting point for understanding the standards. It defines the fundamental terms and definitions used in the ISO 9000 family of standards, guidelines and technical reports.

2. ISO 9001:2000: Quality Management Systems-Requirements, is the standard a company uses to assess its ability to meet customer and applicable regulatory requirements in order to achieve customer satisfaction.

3. ISO 9004:2000: Quality Management Systems-Guidelines for performance improvements, provides detailed guidance to a company for the continual improvement of its quality-management system in order to achieve and sustain customer satisfaction.

4. ISO 9001, 9002 and 9003 standards have been consolidated into the single revised ISO 9001:2000 standard.

5. The ISO 9001:2000 standard replaces the ISO 9001:1994, ISO 9002:1994 and ISO 9003:1994 standards. Although an organization can continue to be certified to these standards until December 2003, if they so choose.

Forms of ISO certification (TYPES OF QUALITY AUDIT)

- If a manufacturer wants to purchase from a non-certified supplier, the manufacturer should visit the supplier and examine its processes, past performances, workers' credentials and so on to verify that the supplier can meet the required quality levels and performance schedule.
- It is easier, cheaper, quicker and legally safer to select an already certified supplier.

There are three forms of certification which are as follows:

1. First party-- A firm audits itself against ISO 9000 standards.
2. Second party-- A customer audits its supplier.
3. Third party-- A "qualified" national or international standards or certifying agency serves as auditor.

- Certification involves getting the proper documents, initiating the required procedures and practices, and conducting internal audits (first party certification).
- This can be followed by a second- or third-party audit as desired.
- In a two-party system, a customer would audit the quality system of a supplier for acceptability resulting in costly multiple audits.

- The best certification of a firm is through a third party.
- A third-party company called a registrar is the only authorized entity that can award ISO 9000 certification.
- Registrars are accredited by an authoritative national body and are contracted by companies for a fee to evaluate their quality-management system to see if it meets the ISO 9000 standards.
- A quality system certification involves the assessment and periodic surveillance audit of the adequacy of a supplier's quality system by a registrar.
- When a supplier's system conforms to the registrar's interpretation of the standard, the registrar issues a certification to that effect to the supplier.
- This certification ensures customers or potential customers that a supplier has a quality system in place and it is being monitored.
- Once passed by the third-party audit, a firm is certified and may be registered and recorded as having achieved ISO 9000 status and it becomes part of a registry of certified companies recognized throughout the world.

Sector-specific standards

AS 9000 (The Aerospace Standards)

The aerospace industry requires that all elements of production and supply chain operate to levels of quality and performance that assure safe and reliable products. The Americas Aerospace Quality Group (AAQG) in cooperation with many aerospace companies developed specific requirements for quality systems that are to be implemented and maintained by the complete production and supply chain in the manufacture of products used in aviation and space applications.

AS9000/AS9100

AS9100 includes ASQ9001:2000 quality system requirements and specifies additional requirements for the quality system of the aerospace industry.

Examples of common and unique aerospace requirements found in AS9000/AS9100 are as follows:

• Identification and Control of Key Characteristics
• Stamp Control
• Foreign Object Detection (FOD)
• Requirements Flow Down
• Tooling Control
• Customer and Regulatory Agency Involvement and Approval

AS9101A Quality System Assessment

The checklist corresponding to AS9100 Revision A.

AS9102 Aerospace First Article Inspection Requirement

Established the requirements for First Article Inspection. The purpose of First Article Inspection is to provide objective evidence that all engineering design and specification requirements are properly understood, accounted for, verified and documented.

AS9103 Variation Management of Key Characteristics

Established variation management requirements for key characteristics. This standard also specifies general requirements and provides a process to achieve those requirements.

AS9120

This standard includes ISO 9001:2000 quality management system requirements and specifies additional requirements for a quality management system for the aerospace industry applicable to stockiest distributors.

AS9131 Quality Systems Non-Conformance Documentation

This document defines to supplier/subcontractor common information and documentation required to inform customers, when applicable about nonconformity (Customer-provider use).

ISO 9001 Requirements

CLAUSES (ELEMENTS) OF ISO 9000 (During the year 2000)

1. Scope 2. Normative Reference 3. Terms and Definitions
4. Quality Management System (QMS)
    - General Requirements
    - Documentation
5. Management Responsibility
- Management Commitment
- Customer Focus
- Quality Policy
- Planning
- Responsibility, Authority and Communication
- Management Review
6. Resource Management
- Provision of Resources
- Human Resources
- Infrastructure
- Work Environment
7. Product Realization
- Planning of Product Realization

- Customer related processes
- Design and Development
- Purchasing
- Production and Service Provision
- Control of Monitoring and Measuring devices

8. Monitoring and Measurement

- General
- Monitoring and Measurement
- Control of Non-Conforming Product
- Analysis of Data
- Improvement

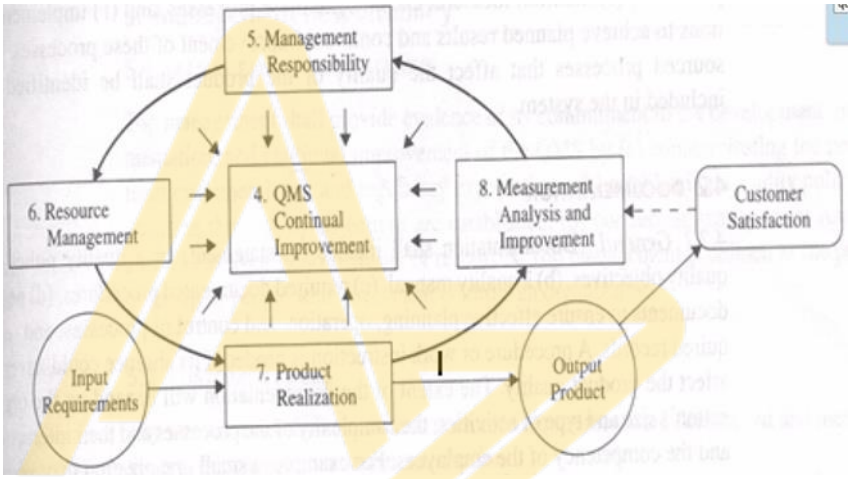

Figure 27.2-- Model of a process-based quality management system

Reasons for implementing ISO Standard

There are various reasons for implementing a quality system that conforms to an ISO standard:

• Customer or marketing are suggesting or demanding compliance to a quality system

• Need for improvements in processes or systems

• Desire for global deployment of products and services

• As more and more organizations become registered, they are requiring their subcontractors or suppliers to be registered, creating a snowball effect

Consequently, in order to maintain or increase market share, many organizations are finding that they should be in conformance with an ISO standard.

- Internal benefits that can be received from developing and implementing a well-documented quality system can far out weigh the external pressures.

- A study of 100 Italian manufacturing firms was undertaken to determine if there was any improvement in performance after registration. Significant improvement was noted in the following areas:
- Internal quality as measured by the percent of scrap, rework and nonconformities at final inspection.
- Production reliability as measured by the number of breakdowns per month, percent of time dedicated to emergencies and percent of downtime per shift
- External quality as measured by product accepted by customers without inspection,claims of nonconforming product and returned product
- Time performance as measured by time to market, on-time delivery and throughput time
- Cost of poor quality as measured by external nonconformities, scrap and rework
- On the negative side, prevention and appraisal costs increased.

IMPLEMENTATION OF QUALITY MANAGEMENT SYSTEM:

1. Top Management Commitment
2. Appoint the Management Representative
3. Awareness
4. Appoint an Implementation Team
5. Training
6. Time Schedule
7. Select Element Owners
8. Review the Present System
9. Write the Documents
10. Install the New System
11. Internal Audit
12. Management Review
13. Pre-assessment
14. Registration

DOCUMENTATION

In every organization, the quality system must be documented properly. The documentation of the system can be seen as a hierarchical format as shown.

1 POLICY
2 PROCEDURES
3 PRACTICES
4 PROOFS

Benefits of ISO Registration

Most of the organizations have found that implementing ISO 9000 systems have benefited them in the

following ways:

- Fewer on-site audits by customers
- Increased market share
- Improved quality, both internally and externally (fewer complaints)
- Improved product and service quality levels from suppliers
- Greater awareness of quality by employees
- A documented formal system
- Reduced operating costs

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Quality Function Deployment

- Ultimately the goal of QFD is to translate often subjective quality criteria into objective ones. That can be quantified and measured and which can then be used to design and manufacture the product.
- It is a complimentary method for determining how and where priorities are to be assigned in product development.
- Quality Function Deployment was developed by Yoji Akao in Japan in 1966.

QFD TEAM:

There are two types of teams namely

1. Team for designing a new product

2. Team for improving an existing product

BENEFITS OF QFD:

1. **Improves Customer satisfaction**

 Creates focus on customer requirements

 Uses competitive information effectively

 Prioritizes resources

 Identifies items that can be acted upon

2. **Reduces Implementation Time**

 Decreases midstream design changes

 Limits post introduction problems

 Avoids future development redundancies

3. **Promotes Team Work**

 Based on consensus

 Creates communication

 Identifies actions

4. **Provides Documentation**

 Documents rationale for design

 Adds structure to the information

 Adapts to changes (a living document)

HOUSE OF QUALITY

The primary planning tool used in QFD is the house of quality. The house of quality converts the voice of the customer into product design characteristics. QFD uses a series of matrix diagrams, also called 'quality tables', resembles connected houses.

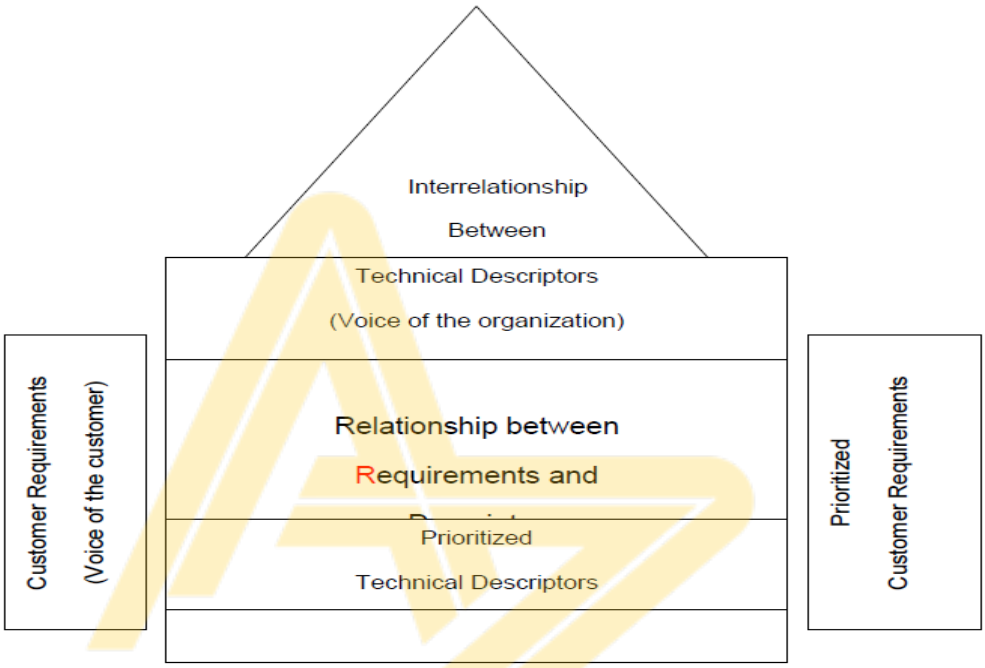


Fig. House of Quality

The Steps in Building a House of Quality are:

1. List Customer Requirements (WHAT's)
2. List Technical Descriptors (HOW's)
3. Develop a Relationship Matrix between WHAT's and HOW's
4. Develop an Inter-relationship Matrix between HOW's
5. Competitive Assessments

a. Customer Competitive Assessments
b. Technical Competitive Assessments

6. Develop Prioritized Customer Requirements
7. Develop Prioritized Technical Descriptors

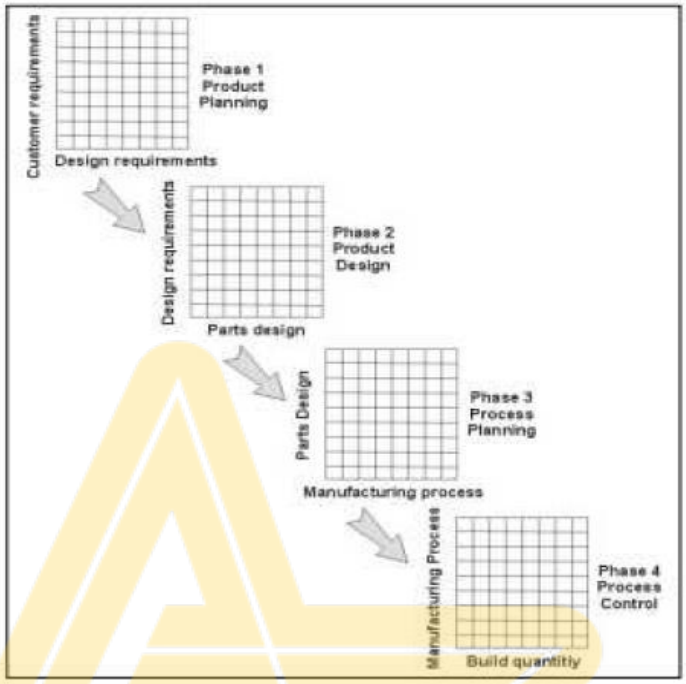
Phase 1, *Product Planning*: Building the House of Quality. Led by the marketing department,

Phase 1, or product planning, is also called The House of Quality.

Phase 1 documents customer requirements, warranty data, competitive opportunities, product measurements,

competing product measures, and the technical ability of the organization to meet each customer requirement.

Getting good data from the customer in Phase 1 is critical to the success of the entire QFD process.



Phase 2, ***Product Design***: This phase 2 is led by the engineering department. Product design requires creativity and innovative team ideas. Product concepts are created during this phase and part specifications are documented. Parts that are determined to be most important to meeting customer needs are then deployed into process planning, or Phase 3.

Phase 3, *Process Planning*: Process planning comes next and is led by manufacturing engineering. During process planning, manufacturing processes are flowcharted and process parameters (or target values) are documented.

Phase 4, *Process Control*: And finally, in production planning, performance indicators are created to monitor the production process, maintenance schedules, and skills training for operators. Also, in this phase decisions are made as to which process poses the most risk and controls are put in place to prevent failures.

Significance of QFD

QFD is a way to assure the design quality while the product is still in the design stage.

- QFD is a planning tool used to fulfil customer expectations.
- QFD focuses on customer expectations or requirements, often referred to as voice of the customer.