MODULE – 1 PRINCIPLES AND PRACTICE

Syllabus:

Principles and Practice: Definition, basic approach, gurus of TQM, TQM Framework, awareness, defining Quality, historical review, obstacles, benefits of TQM.

Quality Management Systems: Introduction, benefits of ISO registration, ISO 9000 series of standards, ISO 9001 requirements.

Definition:

Total Quality Management (TQM) is an enhancement to the traditional way of doing business.

Total - Makeup of the whole

Quality - Degree of excellence a product or service provides

Management - Act, art, or manner of handling, controlling, directing etc.

TQM is an art of managing the whole to achieve excellence.TQM is defined as both a philosophy and a set of benchmarks that represent the foundation of a continuously improving organization. It is an application of quantitative methods and human resources to improve all the processes within an organization and exceed customer needs at present and in the future. TQM integrates fundamental management techniques, existing improvement efforts and technical tools under a disciplined approach.

Basic Approach:

1. A committed and involved management should provide long-term top-to-bottom organizational support.

2. An unwavering focuses on customers, both internally and externally.

3. Effective involvement and utilization of the entire work force.

4. Continuous improvement of business and production process.

5. Treating suppliers as partners.

6. Establish performance measures for the processes.

1. All employees should participate in a quality program. A quality council should be established to develop a clear vision, set long-term goals and direct the program. Quality goals are included in the business plan. An annual quality improvement program involves input from the entire workforce. Managers participate in quality improvement teams and also act as coaches to other teams. TQM is a continual activity and should be entrenched in the culture. It means that it is not just a one-shot program. TQM should be communicated to all people.

2. The key to an effective TQM program is its focus on customers. An excellent place to start is by satisfying internal customers. One should always listen to the "voice of the customer" and emphasize on design quality and defect prevention. Do it right the first time and every time because customer satisfaction is the most important consideration.

3. TQM is an organization wide challenge that is everyone's responsibility. All personnel should be trained in TQM, statistical process control (SPC) and other appropriate quality improvement skills to effectively participate in project teams. Including internal customers and, for that matter, internal suppliers on project teams are an excellent approach. Those affected by the plan should be involved in its development and implementation. They understand the process better than anyone else. Changing behaviour is the goal. People should come to work not only to do their jobs but also to think about how to improve their jobs. People should be empowered at the lowest possible level to perform processes in an optimum manner.

4. There should be a continual striving to improve all business and production processes. Quality improvement projects such as on-time delivery, order entry efficiency, billing error rate, customer satisfaction, cycle time, scrap reduction and supplier management are good areas to begin. Technical techniques such as SPC, benchmarking, quality function development, ISO 9000 and designed experiments are excellent for problem solving.

5. A partnering relationship rather than an adversarial one should be developed. Both parties have as much to gain or lose based on the success or failure of a product or service. The focus should be on quality and life-cycle costs rather than on price. Suppliers should be few in number so that true partnering can occur.

6. Performance measures such as uptime, percentage of nonconforming, absenteeism and customer satisfaction should be determined for each functional area. These measures should be posted for everyone to see. Quantitative data are necessary to measure the continuous quality improvement activity.

New and Old Cultures Quality Element	Previous State	TQM
Definition	Product-orientated	Customer-oriented
Priorities	Second to service and cost	First among equals of service and cost
Decisions	Short-term	Long-term
Emphasis	Detection	Prevention
Errors	Operations	System
Responsibility	Quality control	Everyone
Problem Solving	Managers	Teams
Procurement	Price	Life-cycle costs, partnership
Manager's Role	Plan, assign, control	Delegate, coach facilitate and
enforce	and mentor	

New and old cultures

Gurus of TQM:

Shewhart: Walter A. Shewhart worked as professional in western electric and bell telephone laboratories. He developed control chart theory with control limits. He wrote a book *Economic Control of Quality of Manufactured Product* on basic principles of quality control. He developed PDSA (Plan-Do-Study-Act) cycle for learning improvement.

Ronald fisher: Fisher is not known as a quality guru. However, he created a solid foundation of statistical methods such as, design of experiments (DOE) and analysis of variance (ANOVA) in the 1930s. DOE is one of the most powerful tools used by many organizations in problem solving and process improvement. Analysis is widely known after being included in his be Statistical Methods for Research Workers. Fisher also published *The Design of Experiments* in 1935 and *Statistical Tables* in 1947.

Deming: W. Edwards Deming PhD, in 1950 he taught statistical process control and six importance of quality to the leading CEOs of Japanese industry. He is credited with providing the foundation for the Japanese quality miracle and resurgence as an economic power. Deming is the best-known quality expert to the world. His 14 points provide a theory for management to improve quality, productivity and competitive position. He has authored a number of books including *Out of the Crisis and Quality*, *Productivity* and *Competitive Position* as well as 161 scholarly studies.

Juran: Joseph M Juran, PhD worked at Western Electric from 1924 to 1941. There he was exposed to the concepts of in Shewhart. Juran travelled to Japan in 1954 to teach quality management. He emphasized the necessity for management at all levels to be committed to the quality effort with hands on involvement. He recommended project improvements based on return on investment to

achieve breakthrough results. The Juran Trilogy for managing quality is carried out by the three interrelated processes of planning, control and improvement. In 1951 the first edition of Juran's Quality Control Handbook was published.

Feigenbaum: Armand V. Feigenbaum PhD argues that total quality control is necessary to achieve productivity, Market penetration and competitive advantage. Quality begins by identifying the customer's requirements and ends with product or service in the hands of a satisfied customer. In addition to customer satisfaction some of Feigenbaum quality principles are genuine management involvement, employee involvement first-line supervision and company-wide quality control. In 1951 he authored Total Qualm Control.

Ishikawa: Kaoru Ishikawa, PhD, studied under Deming, Juan and Feigenbaum. He borrowed the total quality control concept and adapted it for the Japanese. In addition, he authored SPC texts in Japanese and in English. Ishikawa is best known for the development of the *cause and effect diagram*, which is sometimes called an Ishikawa diagram. He developed the quality circle concept in Japan, whereby work groups, including their supervisor, were trained in SPC concepts. The groups then met to identify and solve quality problems in their work environment.

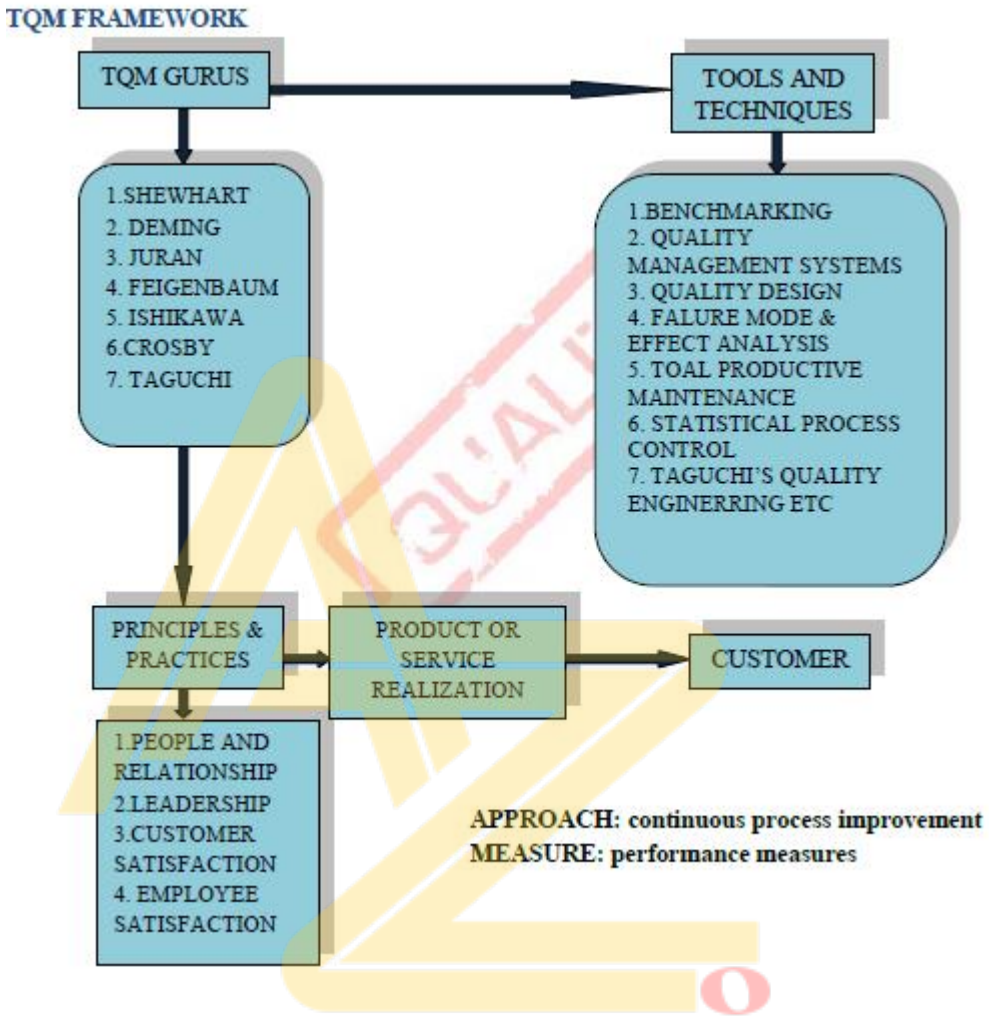
Crosby: Phillip B Crosby authored his first book; *Quality is Free*, in 1979, which was translated into 15 languages. It sold 13 million copies and changed the way management looked at quality. He argued that "doing it right the first time" Is less expensive than the costs of detecting and correcting nonconformities. In 1984, he authored Quality Without Tears, which contained his four absolutes of quality management These absolutes are quality is conformance to requirements, prevention of non-conformance is the objective not appraisal, the performance standard is zero defects not "that's close enough" and the measurement of quality is the cost of non-conformance.

Taguchi: Genichi Taguchi, PhD, developed his loss function concept that combines cost, target and variation into one metric. Because the loss function is reactive, he developed the signal to noise ratio as a proactive equivalent. The cornerstone of Taguchi's philosophy is the robust design of parameters and tolerances. It is built on the simplification and use of traditional design of experiments.

TQM Framework:

Figure shows the framework for a TQM system. It starts with the knowledge provided by quality gurus- Shewhart, Deming, Juran, Feigenbaum, Ishikawa, Crosby and Taguchi. They contributed to the development of principles and practices and the tools and techniques. These tools

and techniques as well as principles and practices are used for improving product service realization. Ultimate aim is satisfy customer needs with continuous process improvement by performance measures of the product or service.



TQM Framework

Awareness:

Any organization will not start TQM until it is aware of the fact that the quality of product or service should be improved. Awareness comes when an organization loses market share or realizes that quality and productivity go hand-in-hand. It also occurs if TQM is mandated by a customer or if management realizes that TQM is a better way to run a business and compete in domestic and world markets.

Automation and other productivity enhancements might not help a corporation if it is unable to market its products or services because of their poor quality. Until recently, corporations have not

recognized the importance of quality. However, a new attitude has emerged--quality first among the equals of cost and service. To sum it up, a customer wants value.

Quality and productivity are not mutually exclusive. An improvement in quality can lead directly to increased productivity and other benefits. Table illustrates this concept. In the table, the improved quality results in a 5.6% improvement in productivity, capacity and profit. Many quality improvement projects are achieved with the same workforce, same overhead and no investment in new equipment. The prevention of product, service and process problems is a more desirable objective than taking corrective action after the product is manufactured or a service rendered.

TQM does not occur overnight. There are no quick remedies. It takes a long time to build an appropriate emphasis and technique into culture. Overemphasis on short-term results and profits should be set aside and long-term planning and constancy should be allowed to prevail.

Gain in Productivity with Improved Quality

Item	Before improvement 10% nonconforming	After improvement 5% non-conforming
Relative total cost for 20 units	1.00	1.00
Conforming units	18	19
Relative cost for nonconforming units	0.10	0.05
Productivity increase		(100) (1/18)=5.6%
Capability increase		(100) (1/18)=5.6%
Profit increase		(100) (1/18)=5.6%

Gain in productivity with improved quality

Defining Quality:

Quality can be quantified as follows most definitions given to quality refer to ‘fitness for use’ or ‘conformance to requirements’.

Q = P / E

Q= quality P = performance E = expectations

The Oxford American Dictionary defines quality as “a degree or level of excellence.”

Each approach to defining quality has strengths in terms of generalizability, ease of measurement and utility. Thus, the “quality as conformance to standards” approach is more relevant in a manufacturing environment than in a high-contact personal service industry and is of great value in emphasizing efficiency and productivity. “Quality as excellence” is seen as particularly valuable as a motivational device in the general call to arms in a quality management campaign.

The 9 dimensions of quality:

Performance

The basic operating characteristic of a product is performance. For example, how well a car handles or its gas mileage.

Features

Features are the “extra” items added to the basic features, such as stereo CD or a leather interior in a car.

Reliability

Reliability is the probability that a product will operate properly within an expected time frame, e.g., a TV without repair for about 7 years.

Conformance

Conformance is the degree to which a product meets pre-established standards.

Durability

Durability tells how long a product lasts, i.e. its life span before replacement.

Serviceability

Serviceability is the ease of getting repairs, the speed of repairs, and the courtesy and competence of the repair person.

Aesthetics

Aesthetics tells how a product looks, feels, sounds, smells or tastes.

Response

Human – to – human interface, such as the courtesy of the dealer

Reputation

Past performance and other intangibles, such as being ranked first

Historical Review:

History of quality control is as old as industry itself. The concept of specialization of worker is introduced during industrial revolution which leads to the decline of workmanship. In fact because productivity improved there was a decrease in cost, which resulted in lower customer expectations. As products became more complicated and jobs more specialized, it became necessary to inspect products after manufacture.

In 1924 W.A. Shewhart of bell telephone laboratories developed a statistical chart for the control of product variables. This chart is considered to be the beginning of statistical quality control. Later in the same decade. H. F. Dodge and H. G Romig, both of Bell Telephone Laboratories, developed the area of acceptance sampling as a substitute for 100% inspection. Recognition of the value of statistical quality control became apparent by 1942. Unfortunately U.S. managers failed to recognize its value.

In 1946 the *American Society for Quality Control* was formed. Recently, the name was changed to American Society for Quality (ASQ). This organization, through its publications, conferences, and training sessions, has promoted the use of quality for all types of production and service. In 1950, W. Edwards Deming who learned statistical quality control from Shewhart gave a series of lectures on statistical methods to Japanese engineers and on quality responsibility to the CEOs of the largest organizations in Japan. Joseph M Juran made his first trip to Japan in 1954 and further emphasized management's responsibility to achieve quality. Using these concepts the Japanese set the quality standards for the rest of the world to follow.

In 1960 The first quality control circles were formed for the purpose of quality improvement. Simple statistical techniques were learned and applied by Japanese workers. By the late 1970s and early 1980s, U.S., managers were making frequent trips to Japan to learn about the Japanese miracle. A quality renaissance began to occur in U.S. products and services, and by the middle of 1980 the concepts of TQM were being publicized. In the late 1980s the automotive industry began to emphasize statistical process control (SPC). Other industries and the Department of Defence also

implemented SPC. The Malcolm Baldrige National Quality Award was established and became the means to measure TQM.

Taguchi introduced his concepts of parameter and tolerance design and brought about a resurgence of design of experiments (DOE) as a valuable quality improvement tool. Emphasis on quality continued in the auto industry in the 1990s when the Saturn automobile ranked first in customer satisfaction (1996) In addition. ISO 9000 became the worldwide model for a quality management system: ISO 14000 was approved as the worldwide model for environmental management systems. The new millennium brought about increased emphasis on worldwide quality and the Internet.

OBSTACLES:

Many organizations, especially small ones with a niche, feel comfortable with their current state. They are satisfied with the amount of work being performed, the profits realized and the perception that the customers are satisfied. Organizations with this culture see little need for TQM until they begin to lose market share. Once an organization embarks on TQM, it faces some obstacles to its successful implementation. Some of the obstacles are as follows:

1. Lack of Management Commitment

In order to make an organizational effort successful, there should be substantial management commitment of management time and organizational resources. The purpose should be clearly and continuously communicated to all personnel. Management should consistently apply the principles of TQM. In a survey, out of 188 quality professionals, 66% reported that management's compensation is not linked to quality goals such as failure costs, customer complaints and cycle time reduction.

2. Inability to Change Organizational Culture

Changing an organization's culture is difficult and requires lot of time. Individuals resist change as they become accustomed to doing a particular process and it becomes the preferred way. Management should understand and utilize the basic concepts of change which are as follows:

i) People change when they want to and to meet their own needs.

ii) Never expect anyone to engage in behaviour that serves an organization's values unless adequate reason (way) has been given.

iii) For change to be accepted, people should be moved from a state of fear to trust.

It is difficult for individuals to change their way of doing things. It is much more difficult for an organization to make cultural changes. Impediments to a cultural change are ineffective communication and emphasis on short-term results. Organizations that spend more time in planning for the cultural aspects of implementing a TQM program will improve their chances of success.

3. Improper Planning

All constituents of an organization should be involved in the development of an implementation plan and any modifications that occur as the plan evolves. Of particular importance is the two-way communication of ideas among all personnel during the development of plan and its implementation. The goal should be to achieve customer satisfaction not to achieve any financial or sales goals.

4. Lack of Continuous Training and Education

Training and education is an on-going process for everyone in an organization. Training and education are the most effective when senior management conducts the training on theprinciples of TQM. Informal training occurs by communicating the TQM efforts to all personnel on a continual basis. Lack of training in group discussion and communication techniques, quality improvement skills, problem identification and the problem-solving methods was the second most important obstacle.

5. Incompatible Organizational Structure and Isolated Individuals and Departments

Differences between departments and individuals can create implementation problems. The use of multi-functional terms helps to break down long-standing barriers. The process of restructuring in order to make an organization more responsive to customer needs may be desired. Individuals who do not embrace the new philosophy can be required to leave the organization.

6. Ineffective Measurement Techniques and Lack of Access to Data and Results

The key characteristics of an organization should be measured in order to make effective decisions. In order to improve a process, one needs to measure an effect of improvement ideas. Access to data and quick retrieval is necessary to make a process effective.

7. Paying Inadequate Attention to Internal and External Customers

Organizations need to understand the changing needs and expectations of their customers. Effective feedback mechanisms that provide data for decision making are necessary for this understanding. A way to overcome this obstacle is to give the right people a direct access to the customers.

When an organization fails to empower individuals and teams, it cannot hold them responsible for producing results.

8. Inadequate Use of Empowerment and Teamwork

Whenever possible, teams need to have the proper training and, at least in the beginning, a facilitator and the team's recommendations should be followed. Individuals should be empowered to make decisions affecting the efficiency of their process or the satisfaction of their customers.

9. Failure to Improve Continually

However, a lack of continuous improvement of the process, product and/or service will even leave the leader of the pack in the dust. Will Rogers said, "Even if you're on the right track, you'll get run over if you just sit there." Even though Champion Mortage's 1998 business volume increased to 59%, it continues to address culture, staff and services issues.

Benefits of TQM:

- Improved quality
- Employee participation
- Team work
- Working relationships
- Customer satisfaction
- Employee satisfaction
- Productivity
- Communication
- Profitability
- Market share

Quality Management Systems-I

Introduction

The International Organization for Standardization (ISO) was founded in 1946 in Geneva, Switzerland, where it is still based. Its mandate is to promote the development of international standards to facilitate the exchange

of goods and services worldwide. ISO is composed of more than 90 member countries. The United States representative is the American National Standards Institute (ANSI).

The ISO Technical Committee (TC) 176 develops a series of international standards for quality systems which were first published in 1987. The standards (ISO 9000, 9001 and 9004) were intended to be advisory and were developed for use in two-party contractual situations and internal auditing. However, with their adoption by the European Community (EC) and a worldwide emphasis on quality and economic competitiveness, the standards have become universally acceptable.

Most of the countries have adopted the ISO 9000 series as their national standards. Likewise, thousands of organizations throughout the world have quality systems registered to the standard. In the United States, the national standards are published by the American National Institute/American Society for Quality (ANSI/ASQ) as the ANSI/ASQ Q9000 series. Government bodies throughout the world, including the United States, are also using the standards. US government agencies using the series are the Department of Defense (DOD) and the Food and Drug Administration (FDA).

In a two-party system, the supplier of a product or service would develop a quality system that conforms to the standards. The customers would then audit the system for acceptability. This two-party system results in both supplier and customer having to participate in multiple audits which can be extremely costly. This practice is replaced by a third-party registration system.

A quality system registration involves the assessment and periodic surveillance audit of the adequacy of a supplier's quality system by a third party, who is a registrar. When a system conforms to the registrar's interpretation of the standard, the registrar issues a certificate of registration to the supplier. This registration ensures customers or potential customers that a supplier has a quality system in place and it is being monitored.

Benefits of ISO Registration

There are various reasons for implementing a quality system that conforms to an ISO standard. The primary reason is that customers are suggesting, or market is demanding, compliance to a quality system. Other reasons include required improvements in processes or systems and a desire for global deployment of products and services. As more and more organizations become registered, they require 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 outweigh 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. Additional examples of benefits after registration are as follows:

1. The American Institute of Certified Public Accountants (AICPA) now has a quality system that works. Also, there was a 4% improvement in gross margins which was the largest improvement in their history.

2. North town Ford automobile dealership in Toronto, Ontario, raised customer satisfaction and loyalty by 20%. It experienced a 55% increase in customers who would recommend the dealership.

3. United Airlines reduced the average engine overhaul cycle time from 120 days to 60 days.

4. Cleveland Center for Joint Reconstruction has experienced lower costs and more control and consistency in the care it provides.

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. 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 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 three standards of the series are described briefly below:

1. ISO 9000:2000

Quality Management Systems (QMS) fundamentals and vocabulary discusses the fundamental concepts related to the QMS and provides the terminology used in the other two standards.

2. ISO 9001:2000

QMS requirements is the standard used for registration by demonstrating conformity of the

QMS to customers, regulator and the organization's own requirements.

3. ISO 9004:2000

QMS guidelines for performance improvement provide guidelines that an organization can use to establish a QMS focused on improving performance.

ISO 9001 Requirements

The standard has following eight clauses:

1. Scope

2. Normative references

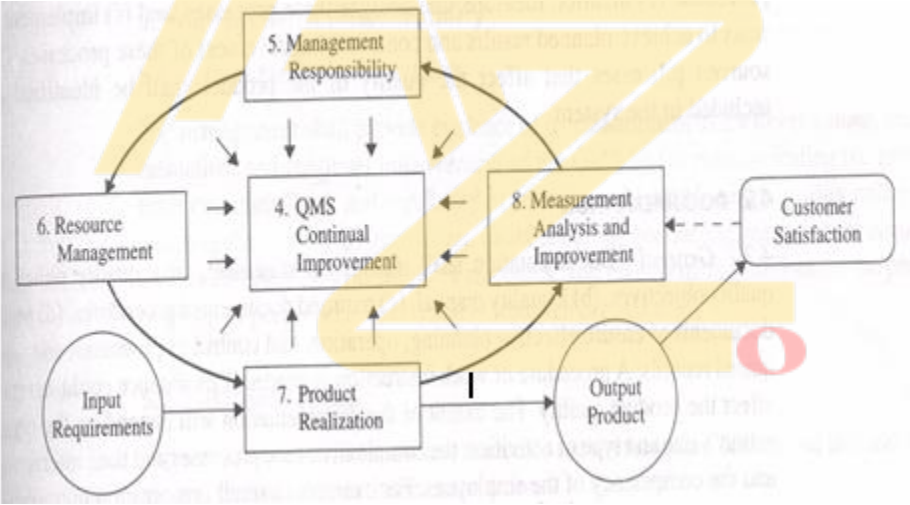
3. Definitions
4. Quality management systems
5. Management responsibility
6. Resource management
7. Product and/or service realization
8. Measurement, analysis and improvement

The first three clauses are for information while the last five are requirements that an organization should meet. The application of a system of process within an organization, together with their identification and interactions and the managing of these processes, is referred to as the process approach. This approach emphasizes the importance of the following:

• Understanding and fulfilling the requirements
• The need to consider processes in terms of value added
• Obtaining results of process performance and effectiveness
• Continual improvement of processes based on objective measure

1. Scope

The purpose of the standard is for the organization to demonstrate its ability to provide a product that meets customer and regulatory requirements and achieves customer satisfaction.



Model of a process-based quality management system

This purpose is accomplished by evaluating and continually improving the system rather than the product. The requirements of the standard are intended to be applicable to all types and sizes of organization. Requirement in clause 7, product realization which is not appropriate to an organization, can be excluded.

2. Normative Reference

ISO 9000:2000 Quality Management Systems-- Fundamentals and vocabulary are a normative reference that provides applicable concepts and definitions.

3. Terms and Definitions

For the purposes of this standard, the terms and definitions given in ISO 9000:2000 apply. In addition, the supply chain is defined as follows:

Supplier → Organization → Customer

4. Quality Management System (QMS)

I. General Requirements

The organization should establish, document, implement and maintain a QMS and continually improve its effectiveness. The organization should also do the following

i) Identify needed processes such as management activities, provision of resources, product realization and measurement.

ii) Determine their sequence and interaction.

iii) Determine criteria and methods for effective operation and control of these processes.

iv) Ensure the availability of resources and information necessary to support and monitor these processes.

v) Monitor, measure and analyze these processes.

vi) Implement actions to achieve planned results and continual improvement of these processes.

Outsourced processes that affect the quality of the product should be identified and included in the system.

5. Documentation

a. General Documentation

It should include the following:

• Statements of a quality policy and quality objectives

• A quality manual

• Required documented procedures

• Needed documents to ensure effective planning, operation and control of processes

• Required records

b. Quality Manual

A quality manual should be established and maintained that includes the following:

• All the scope of the QMS with details and justification for any exclusions

• The documented procedures or reference to them

• A description of the interaction among the QMS processes

c. Control of Documents

Documents required by the QMS should be controlled. A documented procedure should be in place to define the control needed to do the following:

• Approve documents prior to use

• Review, update and re-approve as necessary

• Identify the current revision status

• Ensure that current versions are available at the point of use

• Ensure that documents are legible and readily identified

• Identify and distribute documents of external origin

• Provide for the prompt removal of obsolete documents and suitably identify those that may be retained

Documented procedure means that the procedure is established, documented, implemented and maintained.

d. Control of Records

Records should be established and maintained to provide evidence of conformity to requirements and the effective operation of the QMS. They should be legible, readily identifiable and retrievable. A documented procedure should be established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records. Records can be used to document tractability and to provide evidence of verification, preventive action and corrective action.

6. Management Responsibility

I. Management Commitment

Top management should provide evidence of its commitment to the development, implementation and continual improvement of the QMS by doing the following:

• Communicating the need to meet customer, legal and regulatory expectations

• Establishing a quality policy

• Ensuring that quality objectives are established

• Conducting management reviews

• Ensuring the availability of resources

Top management is defined as the person or group of people who directs and controls an organization.

II. Customer Focus

Top management should ensure that customer requirements are determined and met with the aim of enhancing customer satisfaction.

III. Quality Policy

Top management should ensure the following with regard to the quality policy:

i) It is appropriate to the organization's purpose or mission.

ii) It includes a commitment to comply with requirements and continually improve the effectiveness of the QMS.

iii) It provides a framework for establishing and reviewing the quality objectives.

iv) It is communicated and understood within the organization.

v) It is reviewed for continuing stability.

The quality policy gives the overall intention and direction of the organization related to quality.

IV. Planning

a. Quality Objectives

Top management should ensure that quality objectives are established at relevant functions and levels within the organization and include product requirements.

b. Quality Management System Planning

Top management should ensure that the planning of the QMS is accomplished in order to meet the requirements of the QMS as stated in the general requirements as well as the quality objectives.

V. Responsibility, Authority and Communication

a. Responsibility and Authority

Top management should ensure that responsibilities and authorities are defined and communicated within the organization. Responsibilities can be defined in job descriptions, procedures and work instructions.

b. Management Representative

Top management should appoint a member of the management, regardless of his/her other duties, who should have the responsibility and authority including the following:

• Ensuring that processes needed for the QMS system are established, implemented and maintained

• Reporting to top management on the performance of the QMS and any need for improvement

• Ensuring the promotion of awareness of customer requirements throughout the organization.

c. Internal Communication

Top management should ensure that appropriate communication channels are established within the organization and that communication takes place regarding the QMS. Typical communication techniques are management workplace briefing, recognition of achievement, bulletin boards, e-mail and in-house news brochures.

VI. Management Review

a. General

Top management should review the QMS at planned intervals to ensure its continuing suitability, adequacy and effectiveness.

b. Review Input

The input to the review should include information on the following:

• Results of audits

• Customer feedback

• Process performance and product conformity

• Status of corrective and preventative performance

• Follow-up actions from previous management reviews

• Changes that could affect the QMS

• Recommendations for improvement

c. Review Output

The output from the review should include any decisions and actions related to the following:

• Improvement of the effectiveness of the QMS and its processes

• Improvement of the product related to customer requirements

• Resource needs

Top management can use the outputs as inputs to improvement opportunities.

6. Resource Management

I. Provision of Resources

The organization should determine and provide the resources needed to implement and maintain the QMS and continually improve its effectiveness and to enhance customer satisfaction by meeting customer requirements. Resources may be people, infrastructure, work environment, information, suppliers, natural resources and financial resources. Resources can be aligned with quality objectives.

II. Human Resources

a. General

Personnel performing work that affects product quality should be competent on the basis of appropriate education, training, skills and experience.

b. Competence, Awareness and Training

The organization should do the following:

• Determine the necessary competence for personnel performing work affecting product quality

• Provide training or take other actions to satisfy these needs

• Evaluate the effectiveness of the actions taken

• Ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives

• Maintain appropriate records of education, training, skills and experience

III. Infrastructure

The organization should determine, provide and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable, the following:

• Buildings, workspace and associated utilities

• Process equipment (both hardware and software)

• Supporting services (such as transport or communication)

IV. Work Environment

The organization should determine and manage the work environment needed to achieve conformity to product requirements. Creation of a suitable work environment can have a positive influence on employee motivation, satisfaction and performance.

7. Product Realization

I. Planning of Product Realization

The organization should plan and develop the processes needed for product realization. In planning product realization, the organization should determine the following, as appropriate:

• Quality objectives and requirements for the product

• The need to establish processes, documents and provide resources specific to the product

• Required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance

• Records needed to provide evidence that the realization processes and resulting product or service meet requirements.

The output of this planning should be in a form suitable for the organization’s method of operations.

II. Customer-Related Processes

a. Determination of Requirements Related to the Product

b. Review of Requirements Related to the Product

c. Customer Communication

III. Design and Development

a. Design and Development Planning

b. Design and Development Inputs

c. Design and Development Outputs

d. Design and Development Reviews

e. Design and Development Verification

f. Design and Development Validation

g. Control of Design and Development Changes

IV. Purchasing

a. Purchasing Process

h. Purchasing Information

i. Verification of Purchased Product

j. Production and Service Provision

k. VI. Control of Monitoring and Measuring Devices

8. Measurement, Analysis and Improvement

I. General

l. The organization should plan and implement the monitoring, measurement, analysis and improvement processes needed for the following purposes:

m. • To demonstrate conformity of the product

n. • To ensure conformity of the QMS

o. • To continually improve the effectiveness of the QMS

II. Monitoring and Measurement

p. Customer Satisfaction

q. Internal Audit

r. Monitoring and Measurement of Processes

s. Monitoring and Measurement of Product and Service

III. Control of Non-conforming Product

t. The organization should ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. The controls and related

responsibilities and authorities for dealing with nonconforming product should be defined in a document procedure.

IV. Analysis of Data

u. The organization should determine, collect and analyze appropriate data to demonstrate the suitability and effectiveness of the QMS and to evaluate where continual improvement of the effectiveness of the QMS can be made.

V. Improvement

a. Continual Improvement

v. The organization should continually improve the effectiveness of the QMS through the use of the following:

w. • Quality policy

• Quality objectives

• Audit results

• Analysis of data

• Corrective and preventive actions

• Management review

b. Corrective Action

The organization should take action to eliminate the cause of nonconformities in order to prevent recurrence .

c. Preventive Action

The organization should determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence.

c. Preventive Action

The organization should determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence.