CHAPTER 3 **ISO 9000 & TQM**

3.1 ISO 9000

As the industries started crossing the boundaries between the countries, now they were not to cater to the local or domestic need but to think globally. With this changed scenario in the entire world there was a need for having a single quality assurance model or standard and hence ISO came in to existence. Basically ISO aims at harmonization of standards at the international level with a view to minimize trade and technical barriers.

Till 1950s there were no formal quality systems. It was J.M Juran who conceptualized Quality Control as an element of quality management with the help of his Quality Control Handbook in 1951 after Second World War. Then in 1959 American Department of Defense issued the first national standard, Mil Std 9858 on quality program requirements. This standard worked as foundation of all subsequent quality system standards. Corrective and preventive actions, data analysis, improvement, removal of special cause variation, contract review, work instructions, record keeping, and document control were a part of this standard of 1950s.

With the growth of the arms race in 1960s, US Military came out with many such standards and in 1968 Mil-Q-9858 was used for the NATO Allied Quality Assurance Publications for application to all member countries engaged in joint defense programmes. Numbers of such standards were published by different countries, but almost all were related to defense industry. Canada was the first country to develop and publish quality system standards for commercial use in 1975 in the form of Canadian Standards Association's Z299 series. BSI published BS 5750 in 1979. By 1983 many more countries did the same and came out with standards for quality with minor differences between them.

By 1984 drafted a revision to BS 5750 1979 and in view of the international interest encouraged International Organization of Standardization (ISO) to embark on an International Standard for Quality Systems. More than 26 countries got involved in

the development of the standard and set a new world standard for quality management.

ISO was published in 1987 as a set of six standards, ISO 8402, ISO 900-1, ISO 9001, ISO 9002, ISO 9003 and ISO 9004-1 all were having a strong resemblance to the BS 5750 family of standards.

In 1990s ISO 9000 became very popular in the manufacturing sector in the beginning and then gradually in the service sector as well. From 27,000 certifications by 1993 to 2,74,040 by 1999 is a proof of its acceptance globally. First review of ISO 9000 was done in 1992, which was superficial in nature. The second edition was published in 1994. By that time further 2,00,000 companies got certified.

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.

On December 15, 2000, the revised and improved ISO 9001:2000 was published which replaced the three 1994 versions of ISO 9001, 9002 and 9003. The main change was regarding the structure. It gave five elements instead of the 20 clauses which earlier ISO had. The new model proposed process based quality management system.

3.1.1 Differences between ISO 9001:1994 and ISO 9001:2000 standard

The following table (Table 3.1) throws some light on the major differences between ISO 9001:1994 and ISO 9001:2004 standard:

Table 3. 1 Key differences between 1994 and 2000 standard

ISO 1994 Version	ISO 2000 Version
Aimed at quality assurance	Aimed at customer satisfaction
Required procedures to be established, documented and maintained	Required processes to achieve defined objectives
Focused on correcting errors	Focuses on continual improvement (improving effectiveness)
Management with executive responsibility to define its commitment to quality	Top management to demonstrate its commitment to developing, implementing and improving a system of interrelated processes to enable achieve objectives

The fourth edition of ISO 9001 was released in year 2008, which replaced the ISO 9001:2000. This revision basically was not for much of amendments, but to clarify the points in the text and also to enhance the compatibility with ISO 14001:2004, which is the environmental standard. ISO-survey2010 suggests that there were 11,09,905 certified companies, all over world (178 countries) in year 2010. India was on 8th place amongst top ten countries with 33,250 certifications. [15]

3.1.2 Changes from ISO 9001:2000 to ISO 9001:2008

Following table (Table 3.2) indicates some of the minor changes from ISO 9001:2000 to ISO 9001:2008: [2]

Table 3. 2 Changes from ISO 9001:2000 to ISO 9001:2008

Area	ISO 9001:2008
Outsourced Processes	Process approach including outsourced processes
Management Representative	Must be a member of the organization
Infrastructure	It has added information systems to Buildings, workspaces, equipment, software, utilities and support services like transportation and communication o the infrastructural requirements
Work environment	Clarified meaning of conducive working environment , it relates to working conditions which include physical and environmental conditions

Customer requirements	Clarifies the meaning of specific delivery and post delivery. It includes warranty provisions, contractual obligations and supplementary services
Design and development planning	Plan and perform product design and development review, verification and validation activities separately or in combination
Customer satisfaction	A note is added specifying that customer satisfaction can be monitored and measured with the help of customer satisfaction and opinion surveys
Internal Audit Records	Explicitly stating a requirement that a record of internal audit activities and results must be maintained
Process monitoring and measurement	An additional note to stipulate the impact of each process on the overall effectiveness of the quality management system and the impact it has on the ability to meet product requirements must be measured
Release of product	It is made clear that the products are released for delivery to customers and records must indicate who released the products for delivery to customers
Monitoring and measuring equipment	The term device is replaced by equipment to make it unambiguous.

Actually ISO is not an acronym of International Organization for Standardization. In fact, the term 'ISO' is derived from the Greek isos, meaning 'equal'. The name ISO is used around the world to denote the organization, thus avoiding the plethora of acronyms resulting from the translation of 'International Organization for Standardization' into the different national languages of member countries, e.g. IOS in English, OIN in French (from Organization Internationale de Normalization). For all the countries, the short form of the Organization's name is ISO. [16]

The aim of International Standardization is to facilitate trade, exchange and technology transfer through:

- Enhancement of product quality and reliability at a reasonable price
- Improvement of health, safety and environmental protection and reduction of waste
- Greater compatibility and inter-operability of goods and services

- Simplification for improved usability
- Reduction in the number of models and thereby reduction of costs
- Increased efficiency of distribution and ease of maintenance

It is but obvious that users have more confidence in the products and services that conform to International Standards. Assurance of conformity can be provided by manufacturers' declarations, or by audits carried out by independent bodies.

3.1.3 Principles of ISO standards [16]

3.1.3.1 Equal footing

Every participating ISO member institution has the right to take part in the development of any standard which it judges to be important to its country's economy. Irrespective of the size or strength of that economy, each participating member in ISO has one vote. The activities of ISO are carried out in a democratic framework where each country is on an equal footing to influence the direction of ISO's work at the strategic level, as well as the technical content of its individual standards.

3.1.3.2 Voluntary

ISO standards are voluntary. As a non-governmental organization, ISO has no legal authority to enforce their implementation on any firm. However, while ISO standards are voluntary, they may become a market requirement, as has happened in the case of ISO 9000 quality management systems, or of dimensions of freight containers and bankcards.

3.1.3.3 Market-driven

ISO develops only those standards for which there is a market requirement. Experts on loan from the industrial, technical and business sections, which have asked for the standards, carry out the work and subsequently put them to use. Others with relevant knowledge, such as representatives of

government agencies, consumer organizations, academia and testing laboratories may join these experts.

3.1.3.4 Consensus

Even if ISO standards are voluntary – the fact that they are developed in response to market demands, and are based on consensus among the. ISO takes account of both evolving technology and evolving interests by requiring a review of its standards at least every five years to decide whether they should be maintained, updated or withdrawn. In this way, ISO standards retain their position as the state of the art, as agreed by an international cross section of experts in the field.

3.1.3.5 Worldwide

ISO standards are technical agreements, which provide the framework for compatible technology worldwide. Developing technical consensus on this international scale is a major operation carried out by number of ISO technical groups consisting of technical committees, subcommittees and working groups with thousands of experts who participate annually to develop ISO standards.

3.1.4 How ISO standards benefit society [3] [16]

ISO standards have played important role in providing benefits to the various strata of the society. The benefits, which can accrue to the different strata, are given in the following paragraphs:

For business, the widespread adoption of International Standards means that suppliers can base the development of their products and services can base the development of their sectors. This in turn, means that businesses using International Standards are increasingly free to compete on many markets around the world.

For customers, the worldwide compatibility of technology, which is achieved when products and services are based on International Standards, brings them an

increasingly wide choice of offers, and they also benefit from the effects of competition among suppliers.

For governments, International Standards provide the technological and scientific bases underpinning health, safety and environmental legislation.

For trade officials negotiating the emergence of regional and global markets, International Standards create “a level playing field” for all competitors on those markets. The existence of divergent national or regional standards can create technical barriers to trade, even when there is political agreement to do away with restrictive import quotas and the like. International Standards are the technical means by which political trade agreements can be put into practice.

For developing countries, International standards that represent International consensus on the state of the art constitute an important source of technological know-how. By defining the characteristics that product will be expected to meet on export markets, International Standards give developing countries a basis for making the right decisions when investing there scarce resources and thus avoid squandering them.

For consumers, conformity of products and services to International Standards provides assurance to quality, safety and reliability.

For everyone, International Standards can contribute to the quality of life in general by ensuring that the transport, machinery and tools we use are safe.

For the planet we inhabit, International Standards on air, water and soil quality, and on emissions of gases and radiation, can contribute to efforts to preserve the environment.

3.1.5 Role of ISO quality standards

The standard was primarily intended for situations where customers and suppliers were in a contractual relationship. It was not intended for use when there was no contractual relationship. Even in contractual situations, demonstration of capability is often only necessary when the customer cannot verify the quality of

the products or service after delivery. It is clear that customers need confidence in the quality of products supplied and would require some evidence that addressed the need. ISO 9000 was a neat solution to this problem as it embodied most of the requirements needed to obtain an assurance of quality. Any additional requirement could be put into contract.

ISO 9000:2000 is a series of three International Standards for Quality Management Systems. They specify requirements and recommendations from the design and assessment of management systems. ISO 9000 is not a product standard. The purpose of the standards is to assist organizations of all types to implement and operate effective quality management systems. It is not their purpose to fuel the certification, consulting, training and publishing industries.

3.1.6 The ISO 9000 family of Standards [15]

3.1.6.1 ISO 9000 Quality Management Systems- Fundamentals and Vocabulary

The purpose of ISO 9000 is to provide an appreciation of the fundamental principles of QMS and an explanation of terminology used in the standard. Although they are not requirements, the context and interpretation of the requirements will not be understood without the appreciation of the concepts that underpin the requirements.

3.1.6.2 ISO 9001 Quality Management Systems- Requirements

The purpose of ISO 9001 is to provide requirements which if met will enable organizations to demonstrate they have the capability to consistently provide the product that meets customer and applicable regulatory requirements. These standards can be used in contractual situations. The organizations can use ISO 9001 as a model to design their management system provided they also use ISO 9000 and ISO 9004.

3.1.6.3 ISO 9004 Quality Management Systems- Guidelines for performance improvements

The purpose is to provide guidance for improving the efficiency, effectiveness and overall performance of the organization. The standard should be used as guidance in designing, operating and improving a management system.

3.1.7 Model of a Process based Quality Management System

The ISO 9000:2000 family of standard is based on a process model-a model that is intended to represent a process- based QMS. As seen from the model, there are no processes or systems between the needs of the interested parties and satisfying them other than are shown in the ellipse i.e. the management system. There are no other systems shown like financial management system, environmental management system- in fact only one system. However to confuse matters it refers to this system as a quality management system rather than the management system.

3.1.8 CLAUSES OF ISO: Process based model [15]

3.1.8.1 Quality Management System

The cycle commences with the Organization's purpose from which are developed objectives. In planning to meet these objectives the processes are identified and their sequence and interaction determined. Once the relationship between processes is known, the criteria and methods for effective operation and control can be developed and documented. The processes are described in terms that enable their effective communication and a suitable way of doing this would be compile the process descriptions into a quality manual that not only references the associated procedures and records but also shows how the processes interact. Before implementation the processes need to be resourced and the information necessary to operate and control them deployed and brought under document control. Once operational the processes need to be monitored to ensure they are functioning as planned. Measurements taken to verify that the processes are delivering the required output and actions taken to achieve the planned results.

The data obtained from monitoring and measurement that is captured on controlled records needs to be analyzed and opportunities for continual improvement identified and the agreed actions implemented.

The system should not be perceived as a set of documents but as a means to achieve the organization's objectives.

3.1.8.2 Management Responsibility

The cycle commences with a Vision- a statement of what we want to be or do, and then a Focus on customers for it is the customer that will decide whether or not the organization survives. It is only when you know what your market is, who your customers will be and where they will be that you can define the Purpose or Mission of the organization. From the purpose or mission you can devise a Vision (where you want to get to- what you want to become) and from the mission come the Policies or Values that will guide you on your journey. These policies help frame the Objectives, the milestones on route towards your destination. The policies won't work unless there is Commitment so that everyone pulls in the same direction. Plans have to be made to achieve the objectives and these plans need to identify and lay out the Processes that will be employed to deliver the results- for all work is a process and without work nothing will be achieved. The plans also need to identify the Responsibility and Authority of those who will be engaged in the endeavor. As a consequence, it is essential that effective channels of Internal Communication is established to ensure that everyone understands what they are required to achieve and how they are performing. No journey should be undertaken without a means of knowing where you are, how far you have to go, what obstacles are likely to lie in the path ahead or what forces will influence your success. It is therefore necessary to collate the facts on current performance and predictions of what lies ahead so that a Management Review can take place to determine what action is required to keep the organization on course or whether any changes are necessary to the course or the capability of the organization in order to fulfill the purpose and mission.

3.1.8.3 Resource Management

Whatever the resource, it firstly has to be planned, then acquired, deployed, maintained and eventually disposed of. The standard does not address financial resources specifically but clearly they are required to implement and maintain the management system.

Purchasing is not addressed under resource management but under product realization. Note that there are no clauses that address resource disposal. This is probably because the standard only focuses on intended product, whereas, ISO 14001 would address resource disposal and unintended product.

Although still a relatively short set of requirement in ISO 9001, they are among the most important, for without adequate resources no organization will fulfill its purpose and mission. We have discovered that we cannot exclude any of the organization's resources at all either directly or indirectly affect our ability to satisfy the needs and expectations of the interested parties.

3.1.8.4 Product Realization

Product realization is also a series of processes that have interfaces with resource management processes and which embody measurement, analysis and improvement processes.

The cycle commences by scanning the environment to gain an understanding of customer needs and expectations. In doing so we need to communicate with customers and determine the requirements of customers, of regulators and of the organization relative to the product or service to be supplied. This will undoubtedly involve more customer communication and once requirements have been determined we need to review the requirements to ensure they are understood and confirm we have the capability to achieve them. If we have identified a need for new products and services, we would then need to plan product realization and in doing so use preventive action methods to ensure the success of the project and

take care of any customer property on loan to us. We would undertake product design and development and in doing so we would probably need to identify product, purchase materials, components and services, build prototypes using the process of production provision and validate new processes. After design validation we would release product information into the market to attract customers and undertake more customer-communication. As customers enquire about our offerings we would once more determine the requirements in order to match customer needs with product offerings and our ability to supply.

Now faced with real customers demanding our products, we would review the requirements and confirm we had the capability to supply a product that matched their needs before entering into a commitment to supply. We would then proceed to plan product realization once again and undertake production or service provision. During production or service delivery we would maintain traceability of the product if applicable, perform measurement and monitoring and control the measuring and monitoring devices. We would monitor and measure processes and monitor and measure products at each stage of the process. If we found variations we would undertake the control of non-conforming product and analyze data to facilitate corrective action.

Throughout production or service delivery we would seek the preservation of product and take care of customer property. Once we had undertaken all the product verification and preserved the product for delivery, we would ship the product to the customer or complete the service transactions. To complete the cycle customer communication would be initiated once more to obtain feedback on our performance.

3.1.8.5 Measurement, Analysis and Improvement

Measurement, analysis and improvement processes are vital to the achievement of quality. Until we measure using devices of known integrity, we know little about a process or its outcomes. But if we measure using instrument that are unfit for purpose, we will be misled by the results. With the results of valid measurement

we can make a judgment on the basis of facts. The facts will tell us whether we have met the target. Analysis of the facts will tell us whether the target can be met using the same methods or better methods or whether the target is the target to aim for. Measurements without a target value to compare results of measurement are measurements without a purpose. The target value is therefore vital but arbitrary values demotivate personnel. Targets should always be focused on purpose so that through the chain of measures from corporate objectives to component dimensions there is a soundly based relationship between targets, measures, objectives and the purpose of the organization, process or product.

Measurement is a key to performance, for without measurement it is difficult to know how we are performing and where we need to focus our effort to improve performance.

3.1.9 The Eight Principles of Quality Management [3] [17] [18]

Quality management is becoming increasingly important to the leadership and management of all organizations. It is necessary to identify Quality Management as a distinct discipline of management and lay down universally understood and accepted rules for this discipline.

The ISO technical committee working on the ISO 9000 standards had published a document detailing the quality management principles and application guidelines. (This article is based on the said document). The latest revision (version 2008) of ISO 9000 standards are based on these principles.

Definition of Quality Management Principle [17]

"A quality management principle is a comprehensive and fundamental rule / belief, for leading and operating an organization, aimed at continually improving performance over the long term by focusing on customers while addressing the needs of all other stake holders".

The eight principles are:

1. Customer-Focused Organization

2. Leadership

3. Involvement of People

4. Process Approach

5. System Approach to Management

6. Continual Improvement

7. Factual Approach to Decision Making and

8. Mutually Beneficial Supplier Relationships.

Now let us examine the principles in detail.

3.1.9.1 Customer-Focused Organization

"Organizations depend on their customers and therefore should understand current and future customer needs, meet customer requirements and strive to exceed customer expectations".

Steps in application of this principle are:

1. Understand customer needs and expectations for products, delivery, price, dependability, etc.
2. Ensure a balanced approach among customers and other stake holders (owners, people, suppliers, local communities and society at large) needs and expectations.
3. Communicate these needs and expectations throughout the organization.
4. Measure customer satisfaction & act on results, and
5. Manage customer relationships.

Benefits:

- Increased revenue and market share obtained through flexible and fast responses to market opportunities.
- Increased effectiveness in the use of the organization's resources to enhance customer satisfaction.
- Improved customer loyalty leading to repeat business

3.1.9.2 Leadership

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

Steps in application of this principle are:

1. Be proactive and lead by example.
2. Understand and respond to changes in the external environment.
3. Consider the needs of all stake holders including customers, owners, people, suppliers, local communities and society at large.
4. Establish a clear vision of the organization's future.
5. Establish shared values and ethical role models at all levels of the organization.
6. Build trust and eliminate fear.
7. Provide people with the required resources and freedom to act with responsibility and accountability.
8. Inspire, encourage and recognize people's contributions.
9. Promote open and honest communication.
10. Educate, train and coach people.

11. Set challenging goals and targets, and
12. Implement a strategy to achieve these goals and targets.

Benefits:

- People will understand and be motivated towards the organization's goals and objectives.
- Activities are evaluated, aligned and implemented in a unified way.
- Miscommunication between levels of an organization will be minimized.

3.1.9.3 Involvement of People

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

Steps in application of this principle are:

1. Accept ownership and responsibility to solve problems.
2. Actively seek opportunities to make improvements, and enhance competencies, knowledge and experience.
3. Freely share knowledge & experience in teams.
4. Focus on the creation of value for customers.
5. Be innovative in furthering the organization's objectives.
6. Improve the way of representing the organization to customers, local communities and society at large.
7. Help people derive satisfaction from their work, and
8. Make people enthusiastic and proud to be part of the organization.

Benefits:

- Motivated, committed and involved people within the organization.
- Innovation and creativity in furthering the organization's objectives.
- People being accountable for their own performance.
- People eager to participate in and contribute to continual improvement.

3.1.9.4 Process Approach

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

Steps in application of this principle are:

1. Define the process to achieve the desired result.
2. Identify and measure the inputs and outputs of the process.
3. Identify the interfaces of the process with the functions of the organization.
4. Evaluate possible risks, consequences and impacts of processes on customers, suppliers and other stake holders of the process.
5. Establish clear responsibility, authority, and accountability for managing the process.
6. Identify internal and external customers, suppliers and other stake holders of the process, and
7. When designing processes, consider process steps, activities, flows, control measures, training needs, equipment, methods, information, materials and other resources to achieve the desired result.

Benefits:

- Lower costs and shorter cycle times through effective use of resources.

- Improved, consistent and predictable results.
- Focused and prioritized improvement opportunities.

3.1.9.5 System Approach to Management

"Identifying, understanding and managing a system of interrelated processes for a given objective improves the organization's effectiveness and efficiency."

Steps in application of this principle are:

1. Define the system by identifying or developing the processes that affect a given objective.
2. Structure the system to achieve the objective in the most efficient way.
3. Understand the interdependencies among the processes of the system.
4. Continually improve the system through measurement and evaluation, and
5. Estimate the resource requirements and establish resource constraints prior to action.

Benefits:

- Integration and alignment of the processes that will best achieve the desired results.
- Ability to focus effort on the key processes.
- Providing confidence to interested parties as to the consistency, effectiveness and efficiency of the organization.

3.1.9.6 Continual Improvement

"Continual improvement should be a permanent objective of the organization."

Steps in application of this principle are:

1. Make continual improvement of products, processes and systems an objective for every individual in the organization.
2. Apply the basic improvement concepts of incremental improvement and breakthrough improvement.
3. Use periodic assessments against established criteria of excellence to identify areas for potential improvement.
4. Continually improve the efficiency and effectiveness of all processes.
5. Promote prevention based activities.
6. Provide every member of the organization with appropriate education and training, on the methods and tools of continual improvement such as the Plan-Do-Check-Act cycle, problem solving, process re-engineering, and process innovation.
7. Establish measures and goals to guide and track improvements, and
8. Recognize improvements.

Benefits:

- Performance advantage through improved organizational capabilities.
- Alignment of improvement activities at all levels to an organization's strategic intent.
- Flexibility to react quickly to opportunities.

3.1.9.7 Factual Approach to Decision Making

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

Steps in application of this principle are:

1. Take measurements and collect data and information relevant to the objective.

2. Ensure that the data and information are sufficiently accurate, reliable and accessible.
3. Analyze the data and information using valid methods.
4. Understand the value of appropriate statistical techniques, and
5. Make decisions and take action based on the results of logical analysis balanced with experience and intuition.

Benefits:

- Informed decisions.
- An increased ability to demonstrate the effectiveness of past decisions through reference to factual records.
- Increased ability to review, challenge and change opinions and decisions.

3.1.9.8 Mutually Beneficial Supplier Relationships

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

Steps in application of this principle are:

1. Identify and select key suppliers.
2. Establish supplier relationships that balance short-term gains with long-term considerations for the organization and society at large.
3. Create clear and open communications.
4. Initiate joint development and improvement of products and processes.
5. Jointly establish a clear understanding of customers' needs.
6. Share information and future plans, and
7. Recognize supplier improvements and achievements.