

Chapter 2

ISO 9001:2008 QMS

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Introduction

Everyone wants to achieve profits. Profits can come by more sales with some profit margin and also by cutting down costs. While good quality can lead to more sales, yet the poor processes can increase the cost to achieve that quality level thereby reducing profits. Cost cutting is possible through better processes while ensuring quality output. Quality cannot be compromised at any cost as it dents the company image and paves the path for demise of company. Many techniques for improving the processes are available to modern managers. ISO 9001 is one such technique, widely accepted across the world being an international standard and is applicable to all types of industries, business and organizations. Latest version of this standard is ISO 9001:2008. In today's scenario, many organizations decide to buy products/services (including Telecom solutions) only from ISO 9001 certified suppliers. Therefore ISO 9001 certification for BSNL is a must.

Learning Objectives

After this session, participants will be able to:

- (a) Explain what is ISO 9001 standard and its benefits
- (b) Define Quality and understand ISO quality principles
- (c) Describe the process approach and its linkage to quality
- (d) ISO 9001 implementation and concept of Non-conformity
- (e) Explain the main sections of ISO 9001 standard
- (f) Understand BSNL approach to ISO 9001 certification

What is ISO 9001 standard

ISO stands for international organization for standardization. Across the world page A4 is of same size, size 40 of a shirt is expected to be of same size irrespective of the place of purchase. All such things require adherence to certain standards by the manufacturers. ISO headquartered at Geneva defines standard for almost all the items being sold in the market. In fact, ISO in Greek means equal. ISO has come up with product standards as well as process standards. In India Bureau of Indian Standards (BIS) defines the product standards [ISI mark], which are based on international standard. The process standard of ISO for ensuring quality is called as ISO 9001. At present 2008 version is in effect

commonly known as ISO 9001:2008. This standard helps the organizations to develop, establish, implement and maintain a quality management system capable of delivering consistent quality output with focus on continual improvements.

Benefits of obtaining ISO 9000 certification

Implementing a quality management system brings internal benefits to most Organizations, as well as opening up opportunities vis-à-vis the outside world.

Internal benefits to the company include:

- improved customer focus and process orientation within the company;
- improved management commitment and decision-making;
- better working conditions for employees;
- increased motivation of employees;
- reduced cost of internal failures (lower rates of rework, rejection, etc.) and external failures (fewer customer returns, replacements, etc.); and last but not least,
- continual improvement of the quality management system.

The following *external benefits* are generated:

- customers are more confident that they will receive products conforming to their requirements, which in turn results in higher customer satisfaction;
- an improved image of the company;
- more aggressive publicity, as customers can be informed of the benefits of their doing business with a company that manages the quality of its outputs;
- more confidence that the company's products meet relevant regulatory requirements;
- better objective evidence to defend product liability charges if such are brought by customers.

Quality:

Quality is not absolute, unique, static and by chance. It must be defined, be measurable, achievable and link to customer satisfaction. As per ISO standard, "quality is defined as the 'degree to which, a set of inherent characteristic fulfils requirements of a process, product or system". There are eight quality management principles on which the quality management system standards of the ISO 9000 series are based. The eight quality management principles, Quality management systems Fundamentals and vocabulary are

defined in ISO 9000, and in ISO 9004, Quality management systems Guidelines for performance improvements are detailed.

Principle 1 Customer focus

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

- 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.
- Ensuring a balanced approach between satisfying customers and other interested parties (such as owners, employees, suppliers, financiers etc.).

Principle 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. Key benefits are:

- 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.

Principle 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. Key benefits are:

- 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.

Principle 4 Process approach

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

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

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

Principle 5 System approach to management

Identifying, understanding and managing interrelated processes as a system contributes to the organization's effectiveness and efficiency in achieving its objectives. Key benefits are:

- 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.

Principle 6 Continual improvement

Continual improvement of the organization's overall performance should be a permanent objective of the organization. Key benefits are:

- 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.

Principle 7 Factual approach to decision making

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

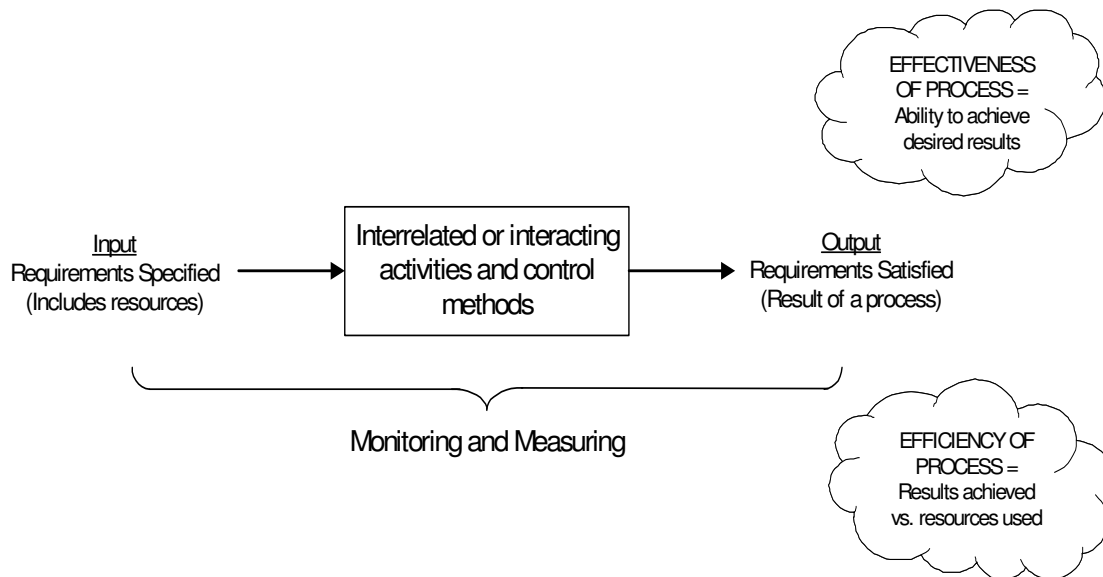
- Informed decisions.
- An increased ability to demonstrate the effectiveness of past decisions through reference to factual records.
- Increased ability to review, challenge and change opinions and decisions.

Principle 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. Key benefits are:

- Increased ability to create value for both parties.
- Flexibility and speed of joint responses to changing market or customer needs and expectations.
- Optimization of costs and resources.

Process: Final product (service) is the outcome of the output from many interacting departments. Each department/section may have many tasks whose output becomes input to other tasks or departments. Process is defined as a discreet part of full work which has defined objective(s), input(s), output(s), activities, and resources. These pprocesses need to be analysed, monitored and/or measured, and improved. Inputs to any process would be specifications/requirements, resources can be men, machine, material etc.



A process approach implies systematically breaking down the whole organisational business into various processes and defining the activities necessary to obtain a desired result in each of these processes. It also includes related factors such as management of resources, methods, and materials, and clear responsibility and accountability for each process and activity. Also the interlink between various processes is to be identified. The key processes are monitored and their results are measured and analysed and. The consequences risks and impacts of these processes on customers, suppliers and other interested parties are suitably evaluated. Key benefits obtained are:

- Effective use of resources and less cost and time.
- Consistent and predictable results.
- Focused and prioritized improvement opportunities.

A methodology widely used for process improvement is PDCA (Plan, Do, Check and Act) This cycle has to be repeated for continual improvements.

ISO 9001:2008 Implementation

- Prepare Documentation (quality manual, processes etc. as per ISO standard)
- Implement it (Impart proper training for its implementation)

- Conduct Internal audits (Need to train internal auditors)
- Remove Non conformities and stabilize system
- Apply for certification
- Get external audit done and obtain certificate (valid for three years)
- Keep conducting regular internal audits
- Face surveillance audits in next three years (five in certificate validity period)
- Go for re-certification audit

Nonconformities

The evidence collected by the auditors is compared with the audit criteria (company's policies and objectives, manuals, procedures, instructions, contracts, regulations etc.) and audit findings including nonconformities, if any, are clarified and reported to the management at the end of the site audit in a formal meeting with the management called "closing meeting". The nonconformities (NCs) are graded by the auditors as "major" or "minor". "Observations" are also noted.

A "major" NC indicates that:

- the company has failed to implement any one part of or the full QMS; or
- any specific department of the company has failed to implement the QMS as applicable to the department; or
- a number of "minor" nonconformities in the same QMS requirements are found.

A "minor" NC means an isolated incident of a failure to comply with a defined process or QMS requirement.

An "observation" indicates that if the situation as found during the audit is not addressed it may lead to an "NC" in future.

Where a major nonconformity is found, the recommendation for certification is deferred until corrective action on the same is verified through a follow-up audit. After obtaining the organization's timetable for corrective action, recommendations for certification are decided by the Lead Auditor (the leader of the audit team), and these recommendations are conveyed to the organization in the closing meeting itself.

ISO 9001 standard: This standard has eight sections as briefly described below:

1. Scope :

1.1 General : This clause specifies that ISO 9001 QMS is applicable for those organizations which need to demonstrate ability to consistently provide products as per requirements and customer satisfaction through continual improvement and prevention of nonconformity.

1.2 Application : This clause mentions that the ISO 9001 standard is applicable to all organizations irrespective of their type, size or product delivered. Exclusions are permitted provided these do not affect organization ability to meet customer & applicable regulatory requirements. Exclusions are possible only in section 7.

2. Normative Reference : This standard makes a reference to other documents or currently valid international standards viz. ISO 9000 QMS-Fundamentals and vocabulary.

3. Terms & Definitions: This clause specifies that ISO 9001 standard uses the terms and definitions given in ISO 9000.

4. Quality Management System (QMS)

The organization has to identify all processes and their interactions, operate these processes, ensure resource availability, monitor these processes objectively and implement actions to achieve planned results and continual improvement. A documented procedure implies that the procedure is established, documented, implemented and maintained. Extent of QMS documentation depends on organization . The documentation includes various types such as quality manual, quality plan, specifications, guidelines, procedures and records. All the documents required by the QMS are controlled as per documented procedure as regards their approval, review & updation, change / version management, identity & distribution, and ensuring intended use. Procedure has to be defined to identify, store, protect, retrieve, retain (for the period specified)and dispose records.

5. Management responsibility :

The top management has to develop, implement and continually improve the effectiveness of its QMS by meeting requirements, establishing quality policy &

objectives, conducting reviews ensuring resource availability. Management has to define and communicate the responsibilities and authorities for various individuals and groups of the organization. A suitable communication processes within the organisation has to be established. A management representative has to be appointed who will drive and promote the QMS within the organization. Regular management reviews have to be conducted for finding and taking appropriate actions for improvements.

6. **Resource Management :**

Organization's responsibility to determine and provide adequate resources for meeting all the QMS requirements has to be documented to ensure that competent people with suitable education, training, skills and experience should be in charge of important Process affecting the product quality. The records of *Competence, awareness and training* of these people has to be maintained. Organization has to ensure necessary infrastructure like building, workspace, associated utilities, process equipment (hardware and software), support services (eg. transport or communication) and proper work environment as applicable.

7. **Product realization**

This is the most important section of ISO 9001 standard which defines key areas such as Planning of product realization(activities like need analysis, resources requirement, verification, validation, monitoring, inspection and test activities with proper records as objective evidence), *Customer related processes* (customer needs confirmation, capability to fulfill needs, effective communication with customer etc.), *Design & Development*(requirements for Design and development planning, Inputs, Outputs, review, verification, validation and control of changes), *Purchasing, Production & service provision, Control of Monitoring & measuring equipment* etc.

8. **Measurement, analysis and improvement :** This section necessitates the establishment of processes for measurement, analysis and improvement related to Customer satisfaction, Internal audit, Monitoring & measurement of processes & product, Control of non conforming product, Analysis of data, Continual improvement, Corrective action and Preventive action.

ISO 9001 in BSNL

ALTTC was the first unit of BSNL to obtain ISO 9001 certification in 2001. Since then many other training centers, Maintenance regions & project circles, Civil and electrical wings, Telecom Factories have obtained this certificate. In 2007, BSNL corporate office

directed Circles to obtain ISO 9001 certification for all SSAs. Apart from SSAs, circles have also been asked to obtain this certification for customer related sections such as Enterprise Business, CS, Commercial, PG cell etc. Similarly at BSNL Corporate office, initially CS, EB, PG, Commercial and T&C sections have to get ISO 9001 certification.

Various training centers of BSNL are imparting training to BSNL executives for helping field units in obtaining ISO certification. Many Circles and SSAs are in the advanced stage of certification.

Sample Self study Questions

1. ISO 9001 third revision was done in
 - a. 1994
 - b. 2000
 - c. 2008
 - d. None of the above

2. Which is the 5th clause of ISO 9001:2008?
 - a. Management Responsibility
 - b. Management of Resources
 - c. Product Realisation
 - d. None of the above

3. Total mandatory ISO procedures are
 - a. 1
 - b. 3
 - c. 6
 - d. 8

4. Internal Audit is clause _____ of ISO 9001:2008
 - a. 4.1
 - b. 5.2
 - c. 7
 - d. 8.2.2

Subjective Questions

1. What are the principal's of ISO 9001 standard?
2. Write down steps involved in ISO certification.
3. What are all the main clauses of ISO 9001:2008?

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