

## **ISO 9001: 2000**

### **Quality management systems - Requirements**

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#### **What is ISO?**

The International Organization for Standardization (ISO) was established in 1947

Currently, it is an association of approximately 149 National Standards Bodies, which each represent their own country.

ISO employs a system of Technical Committees, Sub-committees and Working Groups to develop International Standards.

Besides the National Standards Bodies, ISO permits other international organizations that develop standards to participate in its work, by accepting them as Liaison members.

ISO works in accordance with an agreed set of rules of procedure, the ISO/ IEC Directives, which also include requirements on the presentation of standards.

#### **What is ISO 9000?**

The ISO 9000 standards are a collection of formal International Standards, Technical Specifications, Technical Reports, Handbooks and web based documents on Quality Management and Quality Assurance.

There are approximately 25 documents in the collection altogether, with new or revised documents being developed on an ongoing basis.

#### **What is ISO 9001: 2000?**

It is the 2<sup>nd</sup> revision of Quality Management System Requirement Standard from International Organization for Standards.

It is a replacement for previous ISO 9001/ 9002/ 9003 standards of 1994.

It has introduced considerable conceptual changes.

It is applicable to all types of organisations with possible permissible omissions of certain requirements.

**Why?**

ISO 9001:2000 specifies requirements for a quality management system where an organization:

- Needs to demonstrate its ability to consistently provide product that meets customer and applicable regulatory requirements
- Aims to enhance customer satisfaction through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to customer and applicable regulatory requirements.

**When?**

Any time is the right time to start whether the organization has just started operations; has started production/ or, service delivery; has been successfully running for a long time; is facing quality problems & customer dissatisfaction or, is in any other phase.

Since the standard relies on continual improvement, ISO 9001 can be implemented in any phase of organization lifecycle.

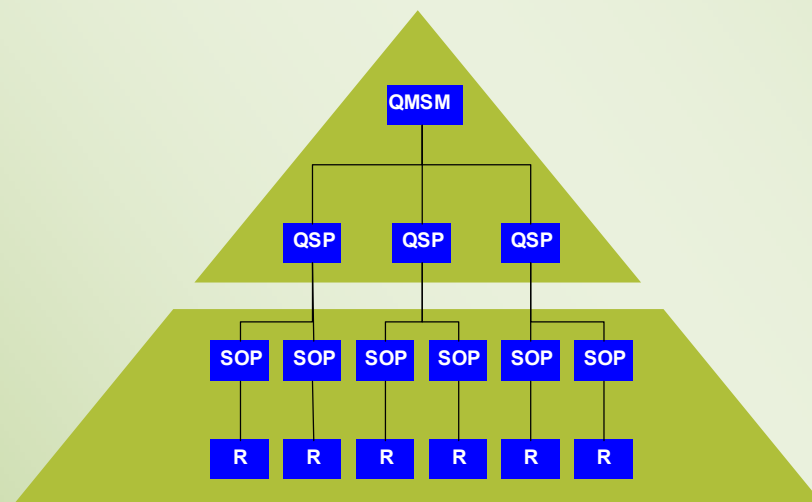
However, its benefits are best realized when it is ingrained during the process formalization phase.

**How?**

Given below is a systematic approach to build a Quality Management System (QMS) based on ISO 9001: 2000.

1. The first step is to sensitise the stake holders of desirability of QMS based on ISO 9001: 2000. This is best achieved through a training sessions/ presentations. It helps to build a commitment to the quality management approach enshrined in ISO 9001: 2000 standard.
2. The scope of activities to be included in QMS is decided. This is normally a strategic decision based on organisation's requirements & business environment.
3. The next step is to appoint a management representative. The responsibilities of management representative are:

- a. To ensure that the Quality system is established, maintained, and implemented.
  - b. To provide formal feedback to management periodically & make recommendations for QMS improvements.
  - c. To promote the importance of customer requirements
4. The organizational structure & responsibilities are defined for those personnel who are involved in the business processes covered under QMS scope.
  5. A gap analysis is carried out to map the status of exiting systems & procedures against the requirements of the standard.
  6. A time bound plan is prepared to cover the development of QMS. This includes development of Quality Policy, Quality Objectives, procedures, systems & measurement metrics.
  7. Next step is to prepare the Quality System Manual. It is recommended that personnel are trained to write their own procedures. These personnel prepare the draft procedures which are compiled as draft Quality System Manual. The system normally has three level of documentation.



8. The system is implemented on a trial basis. It helps to understand the problems in implementation and in gaining acceptance by all concerned.
9. Internal auditors are trained & they conduct an internal audit of the system.
10. Inputs from previous steps are used to improve the system. These improvements are incorporate in QMS.

11. Now is the time to go in for certification through a third party audit by an accredited agency.
12. The system is continually improved through the improvement cycle of audit, improvement & review.



### **Benefits**

It provides a pro-active approach to meet QMS objectives and more importantly their related corporate business and/or financial objectives

The feedback system ensures a basis of resource allocation that optimises the organisation business performance.

Cross functional approach helps improve the morale of stakeholders.

It ensures continual improvement in the customer satisfaction through product/ service quality & delivery.