

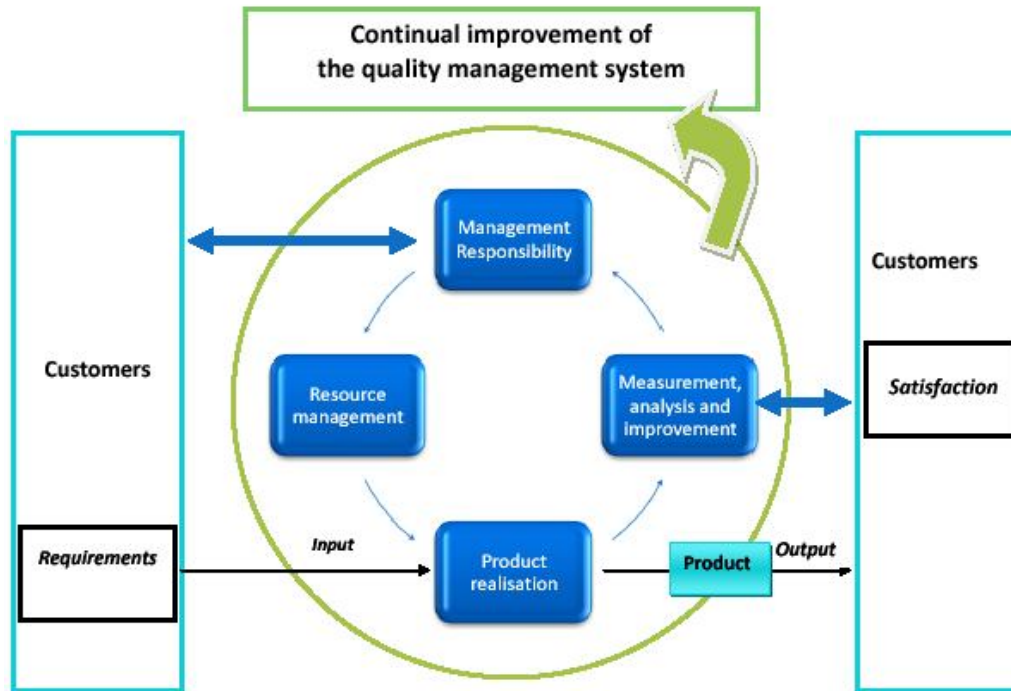
## **International Organisation for Standardization (ISO)**

### **What are ISO 9000 Standards?**

- International quality certification that defines minimum requirements for a company's Quality Management System (QMS). A company's QMS comprises the organization's policies, procedures and other internal requirements that ensure customer requirements are met with consistency resulting in customer satisfaction. This can be applied to any company
- This international Standard specifies requirements for a quality management system where an organisation needs to demonstrate its ability to consistently provide product that meets customer and applicable statutory and regulatory requirements.
- This 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

### **QMS General Requirements**

- Determine the processes needed for the quality management and their application throughout the organization
- Determine the sequence and interaction of these processes
- Determine the criteria and methods needed to ensure both the operation and control of these processes are effective
- Ensure the availability of resources and information necessary to support the operation and monitoring of these processes
- Monitor, measure where applicable and analyze these processes and
- Implement actions necessary to achieve planned results and continual improvement of these processes.



### Who created the standards?

- International Organization for Standardization - Geneva
- ISO tech committee - TC 176 started in 1979 to create QMS standards mainly
  - to eliminate country to country differences
  - to eliminate terminology confusion
  - to increase quality awareness
- This standard was first published in 1987 and subsequently revised in 1994 and 2000.

The third revision of the standard was made in 2008 is referred as ISO 9001:2008

**ISO 9000 series** - provides a framework for quality management and quality assurance

**ISO 14000 series** - provides a similar framework for environmental management

### What is ISO 9001:2008?

- ISO 9001:2008 is an international standard that gives requirements for an organization's Quality Management System ("QMS").
- It is part of a family of standards published by the International Organisation for Standardisation ("ISO") often referred to collectively as the "ISO 9000 series".
- QMS meeting the requirements of ISO 9001:2008, the only standard in the ISO 9000

family that can be used for the purpose of conformity assessment.

### **Objectives ISO 9001:2008**

To provide a set of requirements that, if they are effectively implemented, will provide the customer with confidence that supplier can consistently provide goods and services that:

- Meet needs and expectations and
- Comply with applicable regulations

### **Clauses in ISO**

There are 8 Clauses

- 1. Scope**
- 2. Normative reference:** Document to be referred
- 3. Terms and definition**
- 4. Quality Management System:** General requirement, documentation (general, quality manual, control of documents and control of records)
- 5. Management responsibility:** Management commitment, Customer focus, quality policy, planning, responsibility, authority and communication, Management review,
- 6. Resource management:** Provisions for resources, Human resources, infrastructure, work environment
- 7. Product realization:** Planning of product realization, customer related processes, Design and development, purchasing, production and service provisions, control of monitoring and measuring equipment
- 8. Measurement, analysis and improvement:** General, Monitoring & measurement, control of non-conforming product, analysis of data, Improvement (continual improvement, corrective action and preventive action)

### **Applicability of Clauses**

- General clauses – 1-3 Common Clauses – 4- 8
- Sometimes clause 7 or a part of clause 7 can be exempted but not other clauses

### **ISO 9001:2008 is an Quality Management Practice**

Recognizes “quality management systems” QMS. The nine aspects of QMS are:

1. Quality policy
2. Procedures and instructions

3. Document control
4. Calibration of equipment and instruments
5. Internal quality audits
6. Training
7. Corrective actions for problems
8. Recognize when a product or process is non-conforming
9. Keep records

### **ISO 9001:2008 - Requirements**

- top management commitment to quality
- its customer focus
- adequacy of its resources
- employee competence
- process management (for production, service delivery and relevant administrative and support processes)
- quality planning
- product design
- review of incoming orders
- purchasing, monitoring and measurement of its processes and products
- calibration of measuring equipment
- processes to resolve customer complaints
- corrective/preventive actions
- to drive continual improvement of the QMS.
- to monitor customer perceptions about the quality of the goods and services it provides.

### **Why adopt ISO?**

- To comply with customers who require ISO certification
- To sell in the international market
- To compete in domestic markets
- To improve the quality system
- To minimize repetitive auditing by similar and different customers
- To improve subcontractors' performance

## **ISO Registration**

- To receive an ISO 9000 certification a company must put the required QMS processes and controls in place, monitor performance of its processes and demonstrate continual improvement.
- Most companies hire an experienced consulting firm to assist with these preparations.
- Once the QMS is in place, a registrar (or certification body) is hired to audit the company's compliance with ISO 9000 requirements.
- If discrepancies are found during the audit, they must be corrected before the ISO 9000 certificate is issued.
- The ISO 9000 certification must be maintained through regular audits (bi- annual or annual) conducted by the selected registrar.

## **Ten Steps to ISO Registration**

1. Set the registration objective
2. Select the appropriate standard
3. Develop and implement the quality system
4. Select a third-party registrar and apply
5. Perform self-analysis audit
6. Submit quality manual for approval
7. Pre-assessment by registrar
8. Take corrective actions
9. Final assessment by registrar
10. Registration

## **ISO 14001:2015**

ISO 14001 is an internationally agreed standard that sets out the requirements for an environmental management system. It helps organizations improve their environmental performance through more efficient use of resources and reduction of waste, gaining a competitive advantage and the trust of stakeholders.

### **What is an environmental management system?**

- An environmental management system helps organizations identify, manage, monitor and control their environmental issues in a “holistic” manner.
- Other ISO standards that look at different types of management systems, such as ISO 9001 for quality management and ISO 45001 for occupational health and safety, all use a High-Level Structure.
- This means that ISO 14001 can be integrated easily into any existing ISO management system. ISO 14001 is suitable for organizations of all types and sizes, be they private, not-for-profit or governmental.
- It requires that an organization considers all environmental issues relevant to its operations, such as air pollution, water and sewage issues, waste management, soil contamination, climate change mitigation and adaptation, and resource use and efficiency.
- Like all ISO management system standards, ISO 14001 includes the need for continual improvement of an organization’s systems and approach to environmental concerns.
- The standard has recently been revised, with key improvements such as the increased prominence of environmental management within the organization’s strategic planning processes, greater input from leadership and a stronger commitment to proactive initiatives that boost environmental performance.

### **What benefits will it bring to my business or organization?**

There are many reasons why an organization should take a strategic approach to improving its environmental performance. Users of the standard have reported that ISO 14001 helps:

- Demonstrate compliance with current and future statutory and regulatory requirements
- Increase leadership involvement and engagement of employees
- Improve company reputation and the confidence of stakeholders through strategic communication

Achieve strategic business aims by incorporating environmental issues into business management

- Provide a competitive and financial advantage through improved efficiencies and reduced costs
- Encourage better environmental performance of suppliers by integrating them into the organization's business systems