

# ISO 9001:2008

*Introduction*



# What is ISO?

- “ISO” stands for the *International Organization for Standardization*.
- It is a worldwide federation of national standards bodies (ISO member bodies).
- The work of preparing international standards is normally carried out through ISO technical committees.



# What is ISO 9001:2008?

- ISO 9001:2008 is an international standard for quality management systems.
- ISO 9001:2008 aims to give quality assurance of product and to enhance customer satisfaction.

# The ISO 9000 Series of Standards

- ISO 9000:2005
  - Fundamentals and Vocabulary
- ISO 9001:2008
  - Requirements
- ISO 9004:2000
  - Guidelines for Performance Improvements



# Quality Management Principles

- Customer focus
- Leadership
- Involvement of people
- Process approach
- System approach to management
- Continual improvement
- Factual approach to decision making
- Mutually beneficial supplier relationship

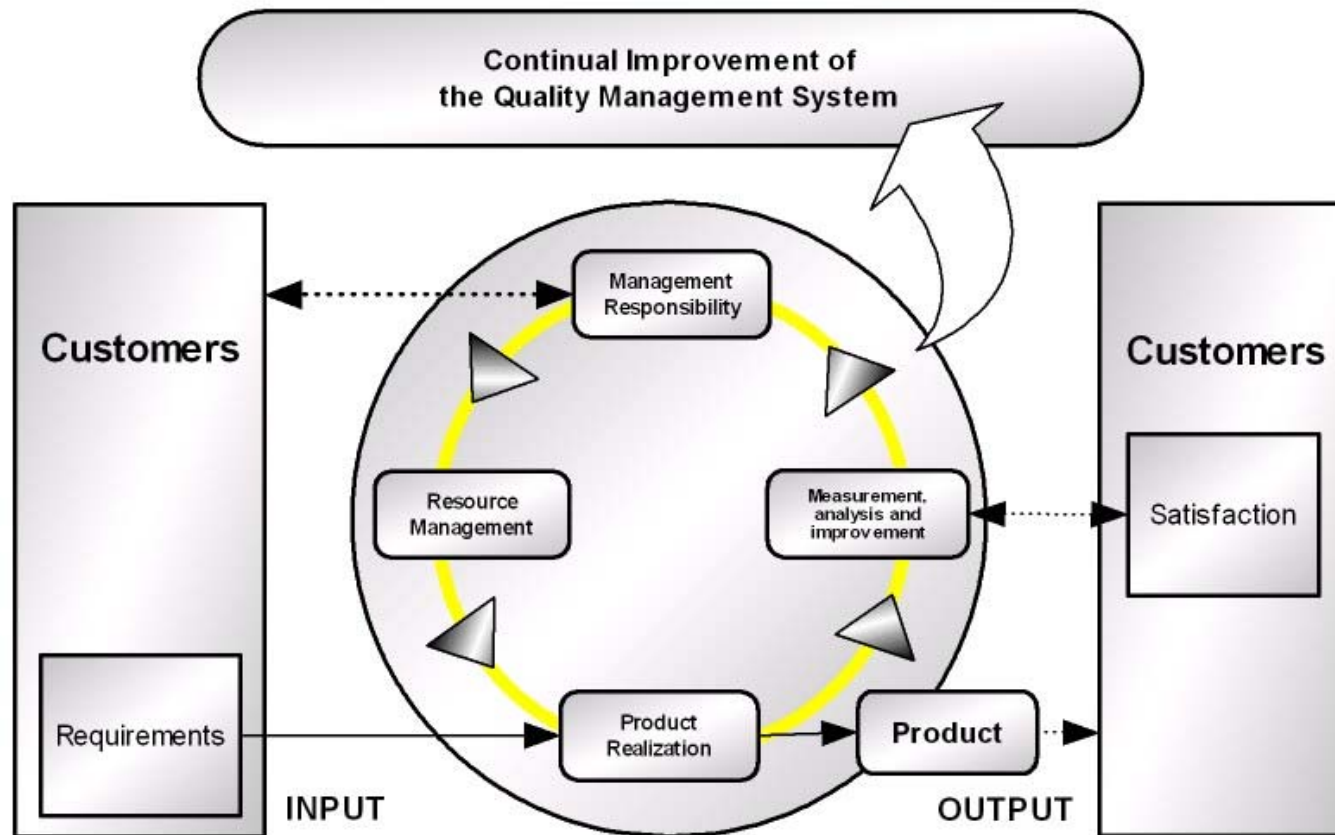


# The Process Approach

- ISO 9001 promotes the adoption of a process approach.
- For an organization to function effectively and efficiently, it has to identify and manage numerous linked activities.
- The application of a system of processes within an organization, together with the identification and interactions and managing of these processes can be referred to as the “process approach”.



# Process-Based Quality Management



# ISO 9001:2008 Requirements

- 1. Scope
  - 1.1 General
  - 1.2 Application
- 2. Normative reference
- 3. Terms and definitions



# Permissible Exclusions

- Organizations may exclude some of the requirements in Section 7 (product realization) for requirements that:
  - Don't apply to the organization
  - Customers' needs make reasonable to exclude
  - Are superseded by regulatory requirements
  - Do not compromise an organization's ability or willingness to meet the demands set by its customers and other parties



## 4 Quality Management System

### ■ 4.1 General requirements

- Document, implement and maintain a quality management system and continually improve its effectiveness.



# 4 Quality Management System

- 4.2 Documentation requirements
  - Documented quality policy and objectives
  - A Quality manual
  - Documented procedures
  - Control of Documents
  - Control of Records

# 4 Quality Management System

ISO 9001:2008 Required Documentation





# 5 Management Responsibility

- 5.1 Management commitment
- 5.2 Customer Focus
- 5.3 Quality Policy
- 5.4 Quality Planning
- 5.5 Responsibility, authority and communication
- 5.6 Management review



# 6 Resource Management

- 6.1 Provision of resources
- 6.2 Human resources
- 6.3 Infrastructure
- 6.4 Work Environment



# 7 Product Realization

- 7.1 Planning of product realization
  - Quality objectives and requirements for the product,
  - Relevant processes, documents and resources specific to the product,
  - Verification, validation, monitoring, inspection and test activities,
  - Records needed to provide evidence that the realization process and resulting product meet requirements.



# 7 Product Realization

## ■ 7.2 Customer-related processes

- Determination of requirements related to the product
- Review of requirements related to the product
- Customer communication



# 7 Product Realization

- 7.3 Design and development
  - Planning
  - Inputs
  - Outputs
  - Review
  - Verification
  - Validation
  - Control of changes

# 7 Product Realization

## ■ 7.4 Purchasing

- Purchasing process
- Purchasing information
- Verification of purchased product



# 7 Product Realization

- 7.5 Production and service provision
  - Controls
  - Validation
  - Identification and traceability
  - Customer property
  - Preservation of product



# 7 Product Realization

- 7.6 Control of monitoring and measuring equipment
  - Calibrated where necessary
  - Adjusted or readjusted as necessary
  - Identified to enable calibration status to be determined
  - Safeguarded from adjustments that would invalidate the measurement result
  - Be protected from damage or deterioration



# 8 Measurement, Analysis, & Improvement

## ■ 8.1 General

- Plan and implement monitoring, measurement, analysis and improvement process needed to:
  - Demonstrate product conformity
  - Ensure conformity of the quality management system
  - Continually improve the QMS



# 8 Measurement, Analysis, & Improvement

- 8.2 Monitoring and measurement
  - Customer satisfaction
  - Internal audit
  - Processes
  - Product



## 8 Measurement, Analysis, & Improvement

- 8.3 Control of nonconforming product
  - Taking action to eliminate the detected nonconformity
  - Authorizing use, release or acceptance under concession
  - Taking action to preclude original intended use or application



# 8 Measurement, Analysis, & Improvement

- 8.4 Analysis of data
  - Customer satisfaction
  - Conformity to product requirements
  - Characteristics and trends of processes and products including opportunities for preventative action
  - Suppliers



# 8 Measurement, Analysis, & Improvement

- 8.5 Improvement
  - Continual improvement
  - Corrective action
  - Preventive action

# Contact Us

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