



**Business
Beam**



1

What is ISO 9001 QMS?

Business Beam

Contents

- What is Quality
- About Quality Management System
- About ISO 9001
- ISO 9001 Certification Process

3

What is Quality?

What is ISO 9001 QMS?

What is Quality?

- The totality of features and characteristics of a product or service that bear on its ability to satisfy stated or implied needs



An Organization's Perspective of Quality

- ❑ ***Internal perspective:***
Products or services made as per customers requirements
- ❑ ***External perspective:***
Staying in business by understanding and optimizing the whole system of value exchange



Significance of Quality

Can be summarized as



“Quality is the result of a carefully constructed cultural environment. It has to be the fabric of the organization, not part of the fabric”.

Philip B. Crosby

7

About Quality Management System

What is ISO 9001 QMS?

What is a Management System?

- “A management system is a proven framework for managing and continually improving your organization's policies, procedures and processes.” BSI



- An effective management system defines an organization's...
 - ▣ Goals,
 - Policies & procedures and...
 - ▣ The processes...
 - By which they are maintained and improved
 - ▣ It stipulates...
 - Documented processes, Clear-cut responsibilities, Ongoing training, Internal checks for compliance, A way to correct noncompliance, Management reviews and Continual improvement
 - ▣ The critical aspect of a management system is that...
 - All elements work cohesively toward the stated objectives



- A set of coordinated activities to direct and control an organization in order to continually improve the effectiveness and efficiency of its performance
- Collective policies, plans, practices and supporting infrastructure by which an organization aims to reduce and eventually eliminate nonconformance to specifications, standards and customer expectations

Objectives of QMS

11

- To satisfy customers through a quality product
- To gain self confidence – we get what we planned
- To achieve competitiveness in both the local and overseas markets
- To use as a blueprint for efforts to improve the quality system of the organization



Pillars of QMS

12

- ❑ Management Support
- ❑ Documented Procedures
- ❑ Internal Audit
- ❑ Corrective/Preventive action



Goals of QMS



- ❑ To ensure compliance with company and industry standards
- ❑ Defining the processes to result in the production of quality products and services, rather than in detecting defective products or services after they have been produced

Benefits of QMS

14

- Provides a framework for...
 - ▣ Existing quality functions and processes
 - ▣ Consistency across the organization
 - ▣ Improved customer relations
 - ▣ Consistent approach to complying with customer & internal quality requirements
 - ▣ Accountability
 - ▣ Continual improvement
 - ▣ Operational effectiveness



Benefits of QMS

15



- ❑ Provides a structured framework to all existing processes
- ❑ Identifies the sequence of all processes
- ❑ Documents all processes to avoid personal dependencies
- ❑ Documented procedures help to perform consistent operational activities
- ❑ Consistency in processes leads to quality product or services
- ❑ Increased satisfaction level of internal & external customers

16

About ISO 9001

What is ISO 9001 QMS?

- The ISO 9000 family of standards is related to quality management systems and designed to help organizations ensure that they meet the needs of customers and other stakeholders while meeting statutory and regulatory requirements related to the product
- The standards are published by ISO, the International Organization for Standardization, and available through National standards bodies.

ISO 9000 Family

- ❑ ISO 9000:2005 Fundamentals and vocabulary
- ❑ ISO 9001:2008 Quality Management Systems requirements
- ❑ ISO 9004:2009 Guidelines for performance improvements
- ❑ ISO 19011:2002 Audit of management system

Some Facts about ISO 9001:2008



19

- Originated in 1987
- Certificates issued worldwide:
 - '03 – 497,919 companies in 149 countries
 - '06 – 897,866 companies in 170 countries
 - '09 – Over 1.2 Million companies in 178 countries

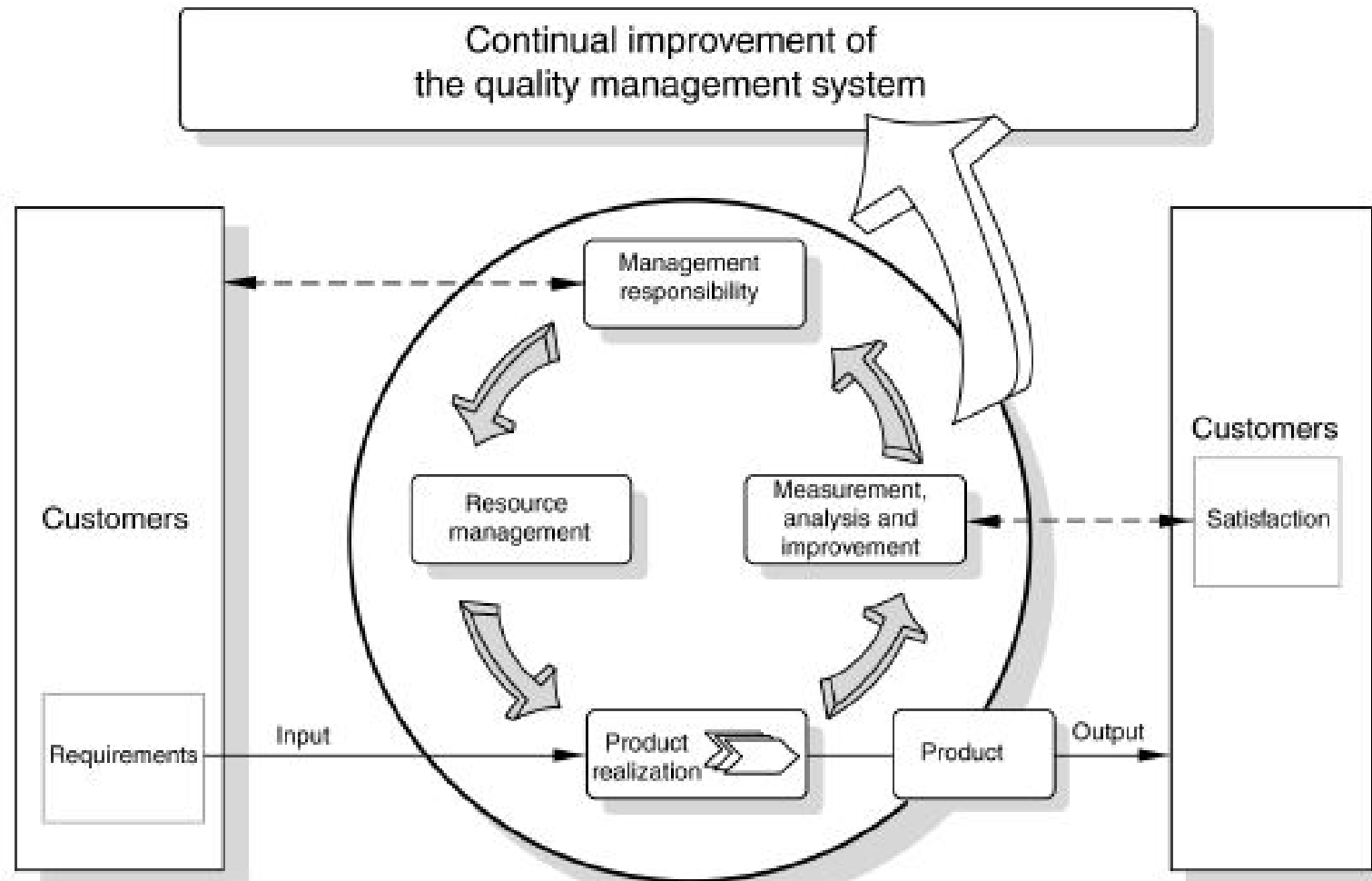
ISO 9001:2008 is based on Eight Quality Management Principles

- Customer focused organization
 - ▣ Understanding customer's needs, striving to exceed their expectations
- Leadership
 - ▣ Establishing direction, unity of purpose, and a supportive work environment
- Involvement of people
 - ▣ Ensuring that all employees at all levels are able to fully use their abilities for the organization's benefit
- Process approach
 - ▣ Recognizing that all work is done through processes, and managing them accordingly

ISO 9001:2008 is based on Eight Quality Management Principles

- System approach to management
 - ▣ Expands on the previous principle in that achieving any objective requires a system on interrelated processes
- Continual Improvement
 - ▣ As a permanent organizational objective, recognizing and acting on the fact that no process is so good that further improvement is impossible
- Factual approach to decision making
 - ▣ Acknowledging that sound decisions must be based on analysis of factual data and information
- Mutually beneficial supplier relationship
 - ▣ To take advantage of the synergy that can be found in such relationships

QMS Process Model



Required Procedures in ISO9001:2008



23

- Control of Documents
- Control of Records
- Internal Audit
- Control of Non-conforming Product
- Corrective Action
- Preventive Action

- Requirements of the ISO9001:2008 are classified into the following five sections of the standard:
 - 4 . Quality Management System
 - 5 . Management Responsibility
 - 6 . Resource Management
 - 7 . Product Realization
 - 8 . Measurement, Analysis and Improvement

- This section defines the overall requirements by the QMS
- It has following sub sections
 - 4.1 General Requirements
 - 4.2 Documentation Requirements
 - 4.2.1 General
 - 4.2.2 Quality Manual
 - 4.2.3 Control of Documents
 - 4.2.4 Control of Records

- This section outlines the overall management commitment and its responsibilities in order to successfully implement the QMS.
- This section has following sub-sections:
 - 5.1 Management Commitment
 - 5.2 Customer Focus
 - 5.3 Quality Policy
 - 5.4 Planning
 - 5.5 Responsibility, Authority & Communication
 - 5.6 Management Review

- This section is about ensuring that the resources essential to the implementation of strategy and the achievement of the organization's objectives are identified and made available, by the Top Management.
- This section has following sub-sections
 - 6.1 Provision of Resources
 - 6.2 Human Resources
 - 6.3 Infrastructure
 - 6.4 Work Environment

- This section is about effective and efficient operation of realization and support processes and the associated process network so that the organization has the capability of satisfying its interested parties.
- This section has following sub-sections:
 - 7.1 Planning of Product Realization
 - 7.2 Customer-related Processes
 - 7.3 Design and Development
 - 7.4 Purchasing
 - 7.5 Production & Service Provision
 - 7.6 Control of Monitoring & Measuring Devices

Measurement, Analysis and Improvement

- Measurement data are important for making fact-based decisions.
- This section is about ensuring effective and efficient measurement, collection and validation of data to ensure the organization's performance and the satisfaction of interested parties.
- This section has following sub-sections:
 - 8.1 General
 - 8.2 Monitoring & Measurement
 - 8.3 Control of Nonconformity
 - 8.4 Analysis of Data
 - 8.5 Improvement

30

ISO 9001 Certification Process

What is ISO 9001 QMS?

Certification Process

31

- The assessment process for achieving certification consists of a two stage Initial Certification Audit as follows:
- Stage 1 - the purpose of this visit is to confirm the readiness of the organization for full assessment. The assessor will:
 - ▣ Confirm that the quality manual conforms to the requirements of ISO 9001:2008
 - ▣ Confirm its implementation status & the scope of certification
 - ▣ Check legislative compliance
 - ▣ Produce a report that identifies any non-compliance or potential for non-compliance and agree a corrective action plan if required.
 - ▣ Develop an assessment plan and confirm a date for the Stage 2 assessment visit.

- Stage 2 - the purpose of this visit is to confirm that the quality management system fully conforms to the requirements of ISO 9001:2008 in practice. The assessor will:
 - ▣ Undertake sample audits of the processes and activities defined in the scope of assessment
 - ▣ Document how the system complies with the standard
 - ▣ Report any non-compliances or potential for non-compliance
 - ▣ Produce a surveillance plan and confirm a date for the first surveillance visit
 - ▣ If the assessor identifies any major non-conformance, the organization cannot be certified until corrective action is taken and verified.



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33

Thank you!

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