Introduction to ISO 9001:2015 Quality management systems - Requirements

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What are the main ISO 9000 standards?

- **ISO 9000:2005 Quality management systems – Fundamentals and vocabulary.**

  Covers the basics of what quality management systems are and also contains the core language of the ISO 9000 series of standards. A guidance document used for reference to understand terms and vocabulary related to quality management systems.

- ***ISO 9001:2015 Quality management systems – Requirements***

  This is the only ISO 9000 standard for which certification can be gained.

  Intended for use in any organization regardless of size, type or product including service. It provides a number of Quality Management System requirements which an organization needs to fulfil to achieve customer satisfaction. It includes a requirement for the continual improvement.

- **ISO 9004:2000 Quality management systems - Guidelines for performance improvements.** Covers continual improvement. This gives you advice on what you could do to enhance a mature system. This standard very specifically states that it is not intended as a guide to implementation.

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What is the history of ISO 9001?

ISO 9001:2015 Quality management systems – Requirements is the Fifth edition and was published 15th September 2015.

There are terminology changes in ISO 9001:2015; Top management now referred to as top management products now referred to products and services; exclusions are removed; management representative is not used; documentation, quality manual, documented procedures, records are referred to as documented information; work environment as environment for the operation of processes; monitoring and measuring equipment as monitoring and measuring resources; purchased product as externally provided products and services and a supplier as an external provider

Risk-based thinking is required in this edition and enabled some reduction in the prescribed requirements. There is greater flexibility in the requirements for processes, documented information and organizational responsibilities. The standard now requires a business to assess risks and opportunities and take appropriate actions.

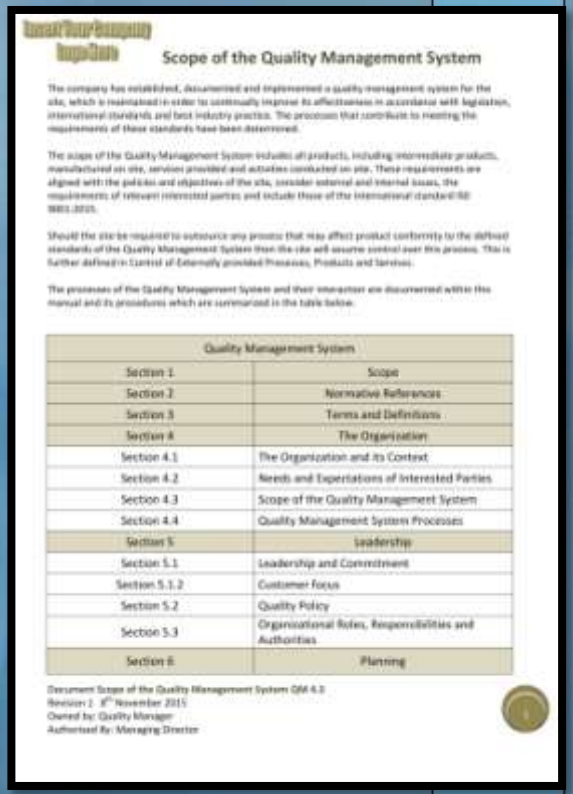
Whereas ISO 9001:2008 used specific terminology such as “documented procedures” and “quality manual”, this edition defines requirements to “maintain documented information”. The term “records” is now expressed as a requirement to “retain documented information”.

ISO 9001:2015 also addresses the need to determine and manage the knowledge maintained by the organization.

What are the ISO 9001:2015 Quality Management System requirements?

The ISO 9001:2015 Standard consists of the following sections:

Section 1: Scope
Section 2: Normative Reference
Section 3: Terms and definitions
Section 4: Context of the Organization
Section 5: Leadership
Section 6: Planning
Section 7: Support
Section 8: Operation
Section 9: Performance Evaluation
Section 10: Improvement

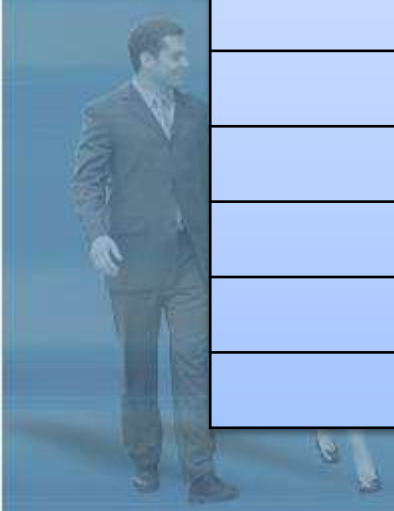


Scope of the Quality Management System

Quality Management System	
Section 1	Scope
Section 2	Normative References
Section 3	Terms and Definitions
Section 4	The Organization
Section 4.1	The Organization and its Context
Section 4.2	Needs and Expectations of Interested Parties
Section 4.3	Scope of the Quality Management System
Section 4.4	Quality Management System Processes
Section 5	Leadership
Section 5.1	Leadership and Commitment
Section 5.1.2	Customer Focus
Section 5.2	Quality Policy
Section 5.3	Organizational Roles, Responsibilities and Authorities
Section 6	Planning

ISO 9001:2015 Quality Management System requirements: Section 9: Performance Evaluation

Section 9	Performance Evaluation
Section 9.1	Monitoring, Measurement, Analysis and Evaluation
Section 9.1.1	General Requirements
Section 9.1.2	Customer Satisfaction
Section 9.1.3	Analysis and Evaluation
Section 9.2	Internal Audit
Section 9.2.1	Internal Audits Scope
Section 9.2.2	Internal Audits Programme
Section 9.3	Management Review
Section 9.3.1	Top Management Review
Section 9.3.2	Management Review Inputs
Section 9.3.3	Management Review Outputs



What are the ISO 9001 Quality Management System document requirements?

ISO 9001:2015 refers to documented information and retained documented information .

Other documentation may be required by an organization in order to manage the processes that are necessary for the effective operation of the quality management system.

This will vary depending on the size of the organization, the kind of activities in which it is involved and their complexity.

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What are the ISO 9001 Quality Management System document requirements?

The references to ‘documented information’ and ‘retained documented information’ are:

4.3 The scope of the organization’s quality management system maintained as documented information.

4.4.2 To the extent necessary, the organization shall:

a) maintain documented information to support the operation of its processes;

b) retain documented information to have confidence that the processes are being carried out as planned.

5.2.2 Communicating the quality policy

The quality policy shall:

a) be maintained as documented information;

6.2.1

maintain documented information on the quality objectives.

What are the ISO 9001 Quality Management System requirements?

The ISO 9001 standard requires that when developing new products, you need to plan the stages of development, with appropriate testing at each stage. You need to test and document whether the product meets design requirements, regulatory requirements and user needs.

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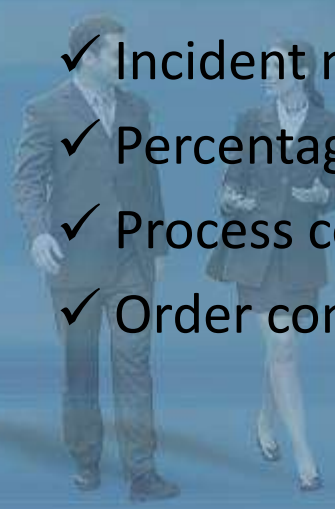
What are the 8 Quality Management Principles?

ISO 9001 Process Approach to Management - How do you measure a process?

Typical factors that are useful to consider when identifying measures of process control and process performance include:

- ✓ Product Conformity with requirements
- ✓ Customer satisfaction
- ✓ Supplier performance
- ✓ On time delivery
- ✓ Lead times
- ✓ Incident numbers and Failure rates
- ✓ Percentage Waste
- ✓ Process costs
- ✓ Order completion



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How will the implementation of the ISO 9001 standard help us?

<u>Improves Efficiency and Streamlines operations:</u>

- Your quality management system focuses on your objectives and operating processes. This encourages you to improve the efficiency of your business, the quality of your products, the service you provide and helps to reduce your waste and customer complaints levels.

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What is the next stage for us?

View the Guide to the process of Implementing an ISO 9001 Compliant Quality Management System