

Introduction ISO 9001:2008

Introduction ISO 9001:2008

On November 14, 2008, the International Organization for Standardization (ISO) published ISO 9001:2008, Quality Management Systems.

ISO 9001:2008 has been developed in order to introduce clarifications to the existing requirements of ISO 9001:2000 and to improve compatibility with ISO 14000:2004. ISO 9001:2008 does not introduce additional requirements nor does it change the intent of the ISO 9001:2000 standard.

The key focuses of the ISO 9001:2008 amendment were to enhance the clarity of ISO 9001:2000 and to enhance its compatibility with ISO 14001:2004.

The benefits identified for the ISO 9001:2008 edition fall into the following categories:

- Provides clarity to ISO 9001:2000
- Increases compatibility with ISO 14001
- Maintains consistency with ISO 9000 family of standards
- Improves translatability

The important changes in ISO 9001:2008 are:

Clause		Change
0.2	Process Approach	Wording changed from "identify" to "determine" to emphasize the importance of processes being capable of achieving desired outputs.
1.1	Scope	Some clarification that "product" can also be "intermediate product" and an explanation that statutory and regulatory requirements can be referred to as legal requirements.
4.1	General Requirements	A note has been added that clarifies requirements regarding outsourcing and the types of control that may be applied to such processes.
4.2.1	General Documentation Requirements	Acknowledgement that documentation can also include records, and that the mandatory procedures may be combined in one document or that the requirements of one procedure may be covered in more than one document.
4.2.3	Document Control	Useful clarification that only documents of external origin that affect the quality management system have to be controlled.
5.5.2	Management Representative	Inclusion of a statement that this person must be a member of the organization's own management.

Introduction ISO 9001:2008

6.2.2	Competence, Training & Awareness	Requires organizations to ensure necessary competencies have been achieved
6.3	Infrastructure	Clarification that information systems are included as a part of the company's infrastructure, and therefore the management system
6.4	Work Environment	Some examples shown of what constitutes the Work Environment
7.2.1	Determination of Requirements related to the Product	Explanations of the sorts of post delivery activities should be covered, such as warranties, maintenance, recycling and so on.
7.3.1	Design and Development Planning	Clarification that review, verification and validation have distinct purposes but may be conducted and recorded separately or in any combination as appropriate to the product and the organization.
7.3.3	Design and Development Outputs	Clarifies that product preservation (such as packaging) may be included for production and service provision.
7.5.4	Customer Property	Clarification that intellectual property and personal data are to be considered as customer property.
7.6	Control of Monitoring & Measuring Devices	Clause has been re-titled and the term "devices" has been replaced by "equipment". A note has been added relating to checking the conformity of software used for monitoring and measuring purposes.
8.2.1	Customer Satisfaction	A note has been added showing examples of how customer satisfaction data may be gathered.
8.2.3	Monitoring & Measurement of Processes	A clarification note has been added that methods of monitoring and measuring of processes are determined based on product conformity and the quality management system effectiveness.
8.2.4	Monitoring & Measuring of Product	A clarification has been included, indicating that release of the product means to the customer, not just the next in-process stage.

Validity of certifications to ISO 9001:2000

One year after the publication of ISO 9001:2008 all accredited certifications issued (new certifications or re-certifications) shall be to ISO 9001:2008.

Twenty four months after publication by ISO of ISO 9001:2008, any existing certification issued to ISO 9001:2000 shall not be valid.



Introduction ISO 9001:2008

Organisations that are already certified to ISO 9001:2000 should contact their certification/registration bodies (CB/RB) to agree a programme for analysing the clarifications in ISO 9001:2008 in relation to their individual quality management systems and for upgrading their certificates.

Certified organizations should bear in mind that ISO 9001:2000 certificates have the same status as new ISO 9001:2008 certificates during the co-existence period. (i.e. Your current ISO 9001:2000 certificate will be valid up to 13th November 2010).

Organizations in the process of certification to ISO 9001:2000 should change to using ISO 9001:2008 and apply for certification to it.

New users should start by using ISO 9001:2008.