

BSI Communication Day Reynosa 1/30/2009.

Tema:

La Actualización ISO 9001:2008
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AGENDA

- History of the change
- Main changes
- Impact in your certification

The development of ISO 9001:2008

Background to the amendment to ISO 9001

In 2003 the Joint Technical Group on Co-ordination (JTG) between ISO/TC 176/SC2 and ISO/TC 207/SC1 was instructed to plan a parallel revision of ISO 9001 and ISO 14001, to enhance the alignment between the two standards.

With the first major revision of ISO 14001 being expected in 2004, it was felt that their users would not be willing to accept large changes for some time.

Also with ISO 9001 only just having reached the end of the 2003 “Transition period”, it was considered that only very limited changes would be acceptable on it.

Background to the amendment to ISO 9001

It was therefore planned that:

- a limited amendment would be undertaken on ISO 9001, and expected to be completed in 2008
- preliminary co-ordination activity would continue between the two committees until 2008
- a parallel revision of the two standards would commence in 2008, expected to be completed in 2011

Background to the amendment to ISO 9001

ISO/TC 176/SC2 then started:

- A feedback survey from users of ISO 9001:2000
- The formal “systematic review” process in ISO, for the updating of a standard

Results of the User Feedback survey

- Responses from 941 users in 63 countries.
- 1477 individual comments
- All four ISO 9001:2000 product categories (Hardware, Software, Processed Materials and Services) well represented.
- Approx 80 % of respondents were satisfied with the ISO 9001:2000 standard.

Most commented clauses / areas of confusion

813 (55 %) of total 1477 comments related to:

- 4.1 General requirements
- 4.2 Documentation
- 6.2 Human resources
- 7.3 Design and development
- 7.5 Production and Service Provision
- 8.2 Monitoring and Measurement
- 8.5 Improvement

The TC 176 Interpretations process identified the need for improvement/clarification of the following clauses

1.1

7.3

4.1

7.4.1

4.2.3a)

7.5.2

4.2.4

7.6

5.6.3

8.2.4

6.2.2

8.3

7.2.1

8.5.1

The results showed that the national standards bodies agreed that a limited amendment to ISO 9001 should be undertaken.

Design Specification for ISO 9001:2008

Initial objectives of the amendment:

- to provide greater clarity, ease of use, translation
- to address the 37 approved “Interpretations” of ISO 9001
- to improve compatibility with ISO 14001:2004

Design Specification for ISO 9001:2008

- ISO 9001:2000 Process Approach model to be maintained
- The standard to remain generic and be applicable to all sizes and types of organization operating in any sector.
- Compatibility with ISO 14001:2004 to be maintained and if possible enhanced
- Consistency with the revision of ISO 9004:2000 to be maintained
- Changes to be restricted to limit impact on users

- The ISO 9001:2000 Support Package to be used to assist the writers to identify issues needing clarification.
- Ambiguities requiring formally produced interpretations to be addressed
- Changes only introduced where there are clear benefits
- Drafts of the amended standard to be subjected to verification against the design specification, and to validation by users

Consequently

- Proposals to expand the scope of the amendment to ISO 9001

Led to:

- Difficult discussions in ISO/TC 176/SC 2
- Opposition from developing countries and certain sectors with ISO 9001 based standards

Result

No expansion to the scope of the amendment

Amendment achieved

ISO 9001:2008 published on 15 November 2008

ISO 9001:2008 Main Differences

4. Quality Management System

4.1 General Requirements

The new Note below provides an explanation of what is considered an outsourced process.

NOTE 2: An outsourced process is a process that the organization needs for its quality management system and which the organization chooses to have performed by an external party.

ISO 9001:2008 Main Differences

The new Note below identifies the factors influencing the control of an outsourced process.

NOTE 3: Ensuring control over outsourced processes does not absolve the organization of the responsibility of conformity to all customer, statutory, and regulatory requirements. The type and extent of control to be applied to the outsourced process can be influenced by factors such as

a) the potential impact of the outsourced process on the organization's capability to provide

product that conforms to requirements,

b) the degree to which the control for the process is shared;

c) the capability of achieving the necessary control through the application of clause 7.4.

ISO 9001:2008 Main Differences

The first Note for clause 4.2.1 has added :

A single document may include the requirements for one or more procedures. A requirement for a documented procedure may be covered by more than one document.

ISO 9001:2008 Main Differences

5.5.2 Management Representative

Most organizations already appoint a Management Representative that is a member of their own management team. The change below clarifies that requirement.

*Top management shall appoint a member of the **organization's** management who, irrespective of other responsibilities, shall have responsibility and authority that includes:*

Some companies in the past have outsourced the Management Representative role to someone in a different organization, or even to their consultant. This text change may be aimed at that practice.

ISO 9001:2008 Main Differences

6.2 Human Resources

6.2.1 General

Personnel performing work affecting **conformity** to product quality **requirements** shall be competent on the basis of appropriate education, training, skills and experience.

The revision above should not be viewed as a new requirement. Anyone performing, verifying, or managing work within the scope of the quality management system, including supporting services, can affect conformity to product requirements. A new Note has been added to 6.2.1 to explain this point.

ISO 9001:2008 Main Differences

NOTE: Conformity to product requirements can be affected directly or indirectly by personnel performing any task within the quality management system.

6.3 Infrastructure

The only change in 6.3 was to add "information systems" as an example of a supporting service.

c) supporting services (such as transport, or communication, **or information systems**).

ISO 9001:2008 Main Differences

6.4 Work Environment

The only change in 6.4 was to add a Note to explain the term “work environment” by giving examples of work environment conditions for achieving conformity to product requirements.

NOTE: The term "work environment" relates to those conditions under which work is performed including physical, environmental, and other factors (such as noise, temperature, humidity, lighting, or weather).

ISO 9001:2008 Main Differences

7.2 Customer-Related Processes

7.2.1 Determination of Requirements Related to the Product

Organizations may not have considered the breadth of post-delivery activities as described by the new Note below.

NOTE: Post delivery activities include, for example, actions under warranty provisions, contractual obligations such as maintenance services, and supplementary services such as recycling or final disposal.

ISO 9001:2008 Main Differences

7.5.3 Identification and Traceability

By moving the “records” reference to the end of the sentence below, the meaning has expanded from recording the product identification, to keeping any type of record associated with product traceability.

Where traceability is a requirement, the organization shall control and record the unique identification of the product and maintain records (see 4.2.4).

ISO 9001:2008 Main Differences

8.2.1 Customer Satisfaction

A new Note has been added to clause 8.2.1 to provide examples of monitoring customer perceptions.

NOTE: Monitoring customer perception can include obtaining input from sources such as customer satisfaction surveys, customer data on delivered product quality, user opinion surveys, lost business analysis, compliments, warranty claims, dealer reports.

ISO 9001:2008 Main Differences

8.5.2 Corrective Action

f) reviewing *the effectiveness of* the corrective action taken.

8.5.3 Preventive Action

e) reviewing *the effectiveness of* the preventive action taken.

IMPACT IN YOUR CERTIFICATION

ISO-IAF Joint Plan

According to a joint announcement by the ISO (International Organization for Standardization) and the IAF (International Accreditation Forum), the two organizations have agreed to an implementation plan for a smooth migration to ISO 9001:2008.

- 1) Certification of conformity to ISO 9001:2008 will only be issued after publication of ISO 9001:2008 (issued November 15, 2008) and after a routine surveillance audit or re-certification audit against ISO 9001:2008.
- 2) One year after publication of ISO 9001:2008, all certifications issued (new certifications and re-certifications) must be to ISO 9001:2008.

IMPACT IN YOUR CERTIFICATION

- 3) Two years after publication of ISO 9001:2008, existing ISO 9001:2000 certifications will not be valid. This is by November of 2010.

QUESTIONS ?

Keeping informed:

- BSI (www.bsigroup.com)
- ISO web site www.iso.org
- ISO Liaison Member web sites
- ISO/TC176/SC2 website (www.iso.org/tc176/sc2)
- “ISO Management Systems” magazine
- ISO Press releases

Web sites

www.iso.org (general guidance)

www.tc176.org (interpretations)

www.iso.org/tc176/sc2
(ISO 9000 Introduction and Support package)

www.iso.org/tc176/ISO9001AuditingPracticesGroup
(auditing guidance)

Thank you

for your attention