



# New editions of ISO 9001 and ISO 9004

## Advice for users on implementing ISO 9001:2008

*When this issue of ISO Management Systems was going to press, a new edition of ISO 9001, the world's most widely used quality management system standard, was expected to be published in the October-November 2008 time frame. This article provides advice on implementing ISO 9001:2008 developed by a product support and communication group within ISO/TC 176, the ISO technical committee responsible for the ISO 9000 family.*



by **Rafael A. de Arrascaeta F.**

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ISO's rules for the development of standards require their periodic review to decide if they need revising, maintaining or withdrawing. Compared to the 2000 revision of ISO 9001, ISO 9001:2008 – the fourth edition of the standard – represents fine-tuning, rather than a thorough overhaul. It introduces clarifications to the existing requirements in ISO 9001:2000, based on user experience over the last eight years, and changes that are intended to improve further compatibility with the ISO 14001:2004 standard for environmental management systems.

The new edition of ISO 9001 does not introduce additional requirements, nor does it

change the intent of the ISO 9001:2000 standard.

No new requirements have been introduced in the new edition, but in order to obtain the maximum benefit from the clarifications in ISO 9001:2008, the users of the 2000 edition must consider whether the clarifications have an impact on their current interpretation of ISO 9001:2000. If that is the case, some modifications to the implementation of their quality management system (QMS) based on ISO 9001:2000 may be necessary.

As with the preceding editions, certification is not a requirement of ISO 9001:2008. Organizations are free to implement

the standard for the internal and external benefits that it brings to them and to their clients. However, it is recognized that hundreds of thousands of ISO 9001 user organizations have chosen to have their QMS independently certified as conforming to the requirements of ISO 9001.

Since ISO 9001:2008 does not introduce additional requirements, certification to ISO 9001:2008 does not represent an “upgrade” in qualitative terms. Therefore, ISO 9001:2000 certificates should be afforded the same status during their period of validity as ISO 9001:2008 certificates.



### The ISO 9001:2008 user community

The ISO 9001:2008 user community comprises four categories.

#### Current users of ISO 9001:2000

Current users include organizations that have completed ISO 9001:2000 implementation programmes, or are in the final stages of doing so. They may or may not be certified and may or may not intend to seek certification.

#### New users

New users are organizations that are starting to use ISO 9001 for the first time, or have planned to implement the standard.

#### Users of industry sector schemes, based on ISO 9001:2000

This group is made up of those organizations operating QMS within the context of sector-specific schemes based on ISO 9001:2000, with additional requirements, e.g. ISO/TS 16949:2002, *Quality systems – Automotive suppliers – Particular requirements for the application of ISO 9001:2000*.

#### Other user groups

- national standards bodies (NSBs)
- accreditation bodies (ABs)
- certification/registration bodies (CB/RBs)
- trainers and consultants.

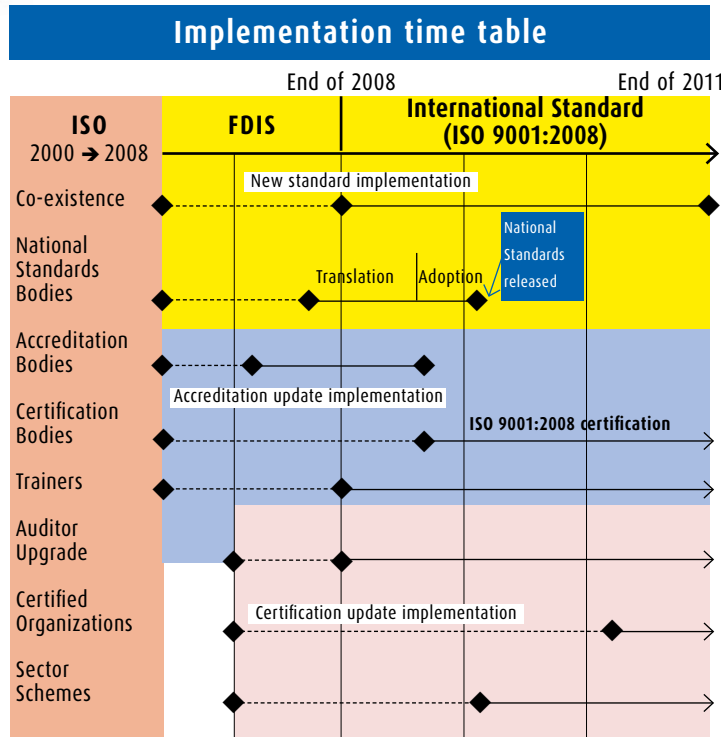


Figure 1 - ISO 9001:2008 implementation timetable

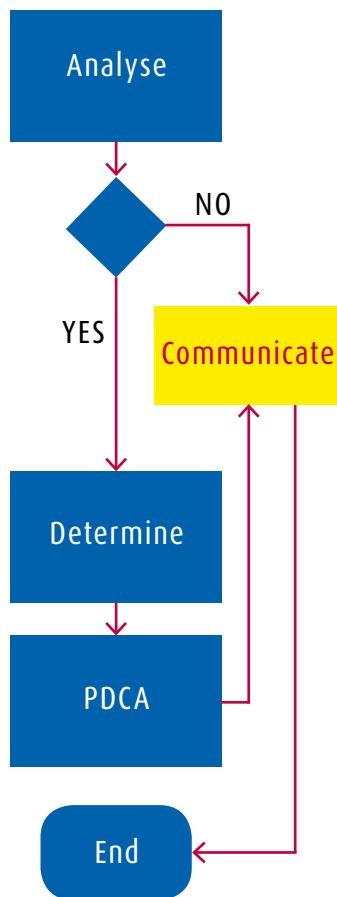


Figure 2 - ISO 9001:2008 implementation flowchart.

### General guidance for ISO 9001:2008 implementation

Figure 1 shows the implementation timetable for ISO 9001:2008, applicable to the various user groups.

To obtain the benefit of the clarifications introduced in ISO 9001:2008, the following generic recommendations are applicable to all user groups. They should be read in conjunction with the flowchart in Figure 2.

1. Get acquainted with the content of the new edition of the standard. Identify the changes and clarifications.
2. Analyze whether your interpretation of ISO 9001:2000 needs to be modified in the light of the clarifications provided in ISO 9001:2008 version.

3. If not, communicate to both internal and external parties the conclusion and results of implementation of ISO 9001:2008.
4. If yes, determine the impact of the clarifications of the new version on your current QMS based on ISO 9001:2000 and plan the necessary actions.
5. Plan-Do-Check-Act the necessary actions. Keep in mind the timeframe provided in Figure 1. The necessary arrangements will vary according to the user group category. Review the specific recommendations are provided in this article.

### Specific guidance for ISO 9001:2008 implementation

The following specific recommendations complement the generic ones provided to all user groups.

#### Current users

Organizations already certified to ISO 9001:2000 are recommended to contact their CB/RB to discuss the timeframe for analyzing the clarifications provided in the new edition and migrating their current certificates.

Certified organizations must keep in mind that ISO 9001:2000 certificates have the same status as new ISO 9001:2008 certificates during the co-existence period. Organizations in the process of certification to ISO 9001:2000 are recommended to apply certification to ISO

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## SPECIAL REPORT

As indicated at the beginning of this article, ISO's rules for the development of standards require their periodic review to decide if they need revising, maintaining or withdrawing. The decision to revise ISO 9001 and the extent of the revision results from a structured process involving multiple inputs, including from users of the standard, and consideration given to the likely benefits and impacts.

Prior to the decision to revise the standard, a justification study was carried out in line with the requirements of ISO/ Guide 72:2001: *Guidelines for the justification and development of management system standards*.

ISO 9001 user needs were identified from the following sources:

- The results of the "systematic review" of ISO 9001:2000 carried out amongst ISO/TC 176 members on ISO 9001:2000 in 2003-2004.
- The feedback from the ISO/TC 176 interpretations process.
- The extensive worldwide ISO/TC 176/SC 2/WG 18 ISO 9001 and ISO 9004 user feedback survey and similar national surveys.

The justification study identified the need for a review and at the same time, required "the impact on the users to be



### Insight into the revision of ISO 9001:2008

limited, and also that changes will only be introduced where there are clear benefits to users".

A summary of process and inputs follows.

#### Rationale for updating ISO 9001

- ISO's standards' development rules require periodic review to keep standards up to date. Must be initiated within a maximum of five years after publication of the standard.
- User inputs:
  - global user questionnaire/survey;
  - market justification study;
  - suggestions arising from the ISO/TC 176 interpretations process;
  - opportunities for increased compatibility with ISO 14001.

#### Current trends:

- to keep up with recent developments in management system practices.

#### Key inputs for the new edition

- ISO/TC 176 approved interpretations:
  - important source of input for ISO 9001:2008;
  - 37 official ISO/TC 176 interpretations, see [www.tc176.org/Interpre.asp](http://www.tc176.org/Interpre.asp);
  - some interpretation requests indicate need for clarification of ISO 9001.
- Systematic reviews conducted on ISO 9001:2000 and ISO 9004:2000.
- Web-based user feedback survey conducted by ISO/TC 176/SC 2.

- responses from 941 users in 63 countries;
- 1 477 individual comments;
- comments from all four ISO 9001:2000 product categories (hardware, software, processed materials and services) well represented, as were small, medium-sized and large organizations;
- of those organizations that specified how long they had been certified, 264 had been for 10 years or more, 424 for four to 10 years and 250 for up to three years;
- approximately 80% of respondents were satisfied with ISO 9001:2000.

- ISO 14001:2004.

#### Most commented clauses in need of clarification

- 813 (55%) of total 1 477 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.



### Key strategies for ISO 9001:2008

- Input from ISO/TC 176 approved interpretations.
- ISO 9001:2000 process approach model will be maintained.
- The standard will 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.
- Changes will be restricted to limit impact on users.
- The current scope, purpose, title and field of application of the standard will be unchanged.

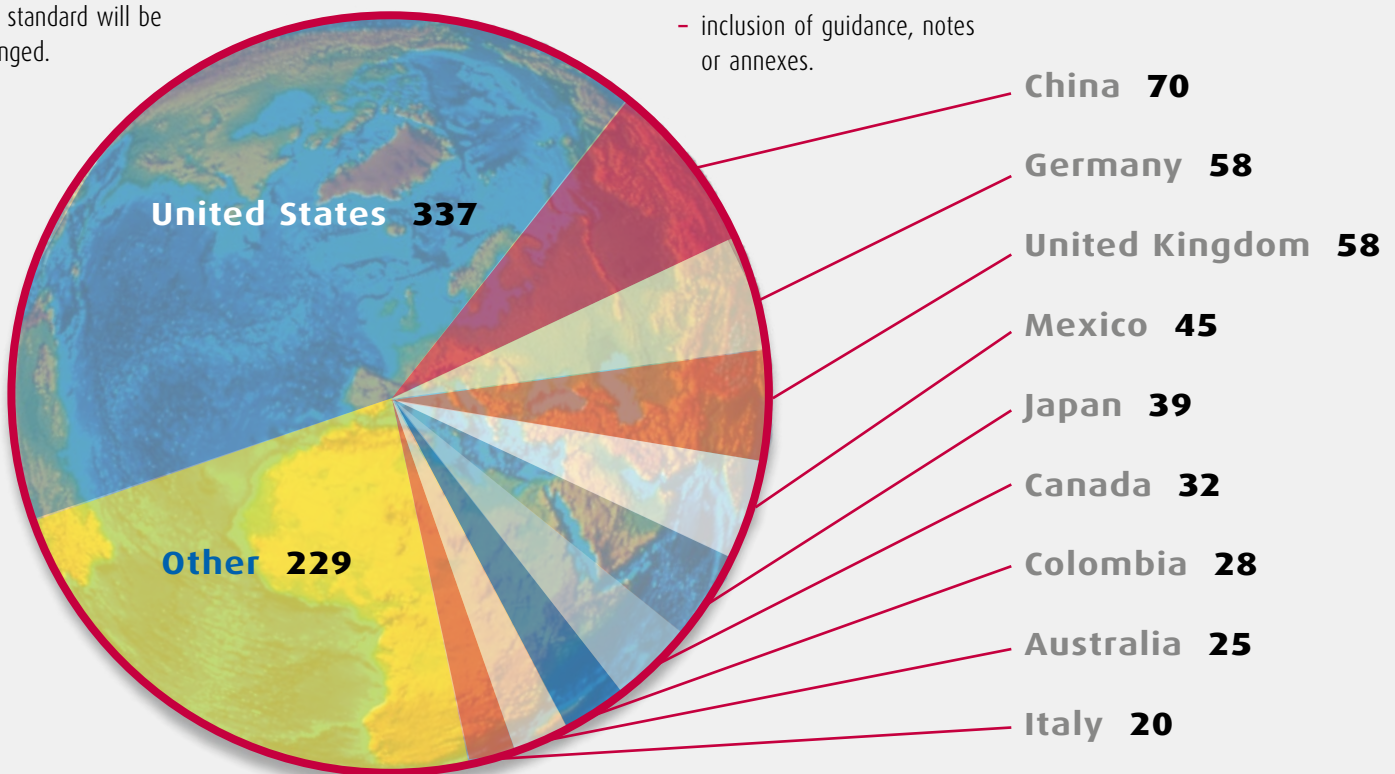
- No new requirements included.
- The eight quality management principles (provided in ISO 9000:2005) will be applied, unchanged.
- Certification to ISO 9001:2008 is not an “upgrade” and organizations that are certified to ISO 9001:2000 should be afforded the same status as those who have already received a new certificate to ISO 9001:2008, for the duration of the migration period, which will be the subject of a future communication by ISO and IAF.

### Compatibility with ISO 14001

- “Compatibility” means that common elements of the standards can be implemented by organizations in a shared manner, in whole or in part, without unnecessary duplication or the imposition of conflicting requirements.
- When maintaining compatibility with ISO 14001:2004 the following do not necessarily represent potential conflicts:
  - different text in common elements or terminology;
  - different numbering of the clauses;
  - different models and structure;
  - inclusion of guidance, notes or annexes.

### Compatibility with sector-specific and other standards

- Sector standards based on ISO 9001:2000, e.g. ISO/TS 16949 (automotive), AS 9100 (aerospace), TL 9000 (telecommunications), ISO/TS 29001 (oil and gas).
- Other management system standards that are based on ISO 9001:2000 and use its structure and text.



Geographical distribution of user survey responses.

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9001:2008, once the new version has been published by ISO.

### New users

New users are invited to start using ISO 9001:2008 as soon as it is published. They will have had the opportunity to become acquainted with the standard through the Final Draft International Standard (FDIS) version, available since July 2008.

### Users of industry sector schemes

Users of industry sector schemes are recommended to contact the organizations responsible for these schemes, of which some examples follow:

- for ISO/TS 16949, contact the International Automotive Task Force (IATF);
- for TL 9000, contact the QuEST Forum;
- for AS 9000, contact the International Aerospace Quality Group (IAQG).

### National standards bodies

NSBs are responsible at national level for widely communicating, in a timely manner, issues regarding the ISO 9001:2008 edition to all interested parties.

ISO/TC 176 recommends that NSB actions should be synchronized with the information flows from ISO and ISO/TC 176 and should coordinate all communication regarding these issues with other national stakeholder, e.g. ABs, CB/RBs, professional quality associations, etc.

If a requirement for translation of the revised standards exists, the translation process should be started as early as possible, using the FDIS version of the standard in order to have the equivalent national adoption of ISO 9001:2008 as soon as possible.

If there are interpretation problems for the national ISO 9001:2008 version interpretation, NSB are recommended to apply for clarification to the "ISO/TC 176 Interpretations Working Group" using the established process.

### Accreditation and certification bodies

When this issue of *ISO Management Systems* was going to press, it was expected that there would be a joint communiqué from ISO and the International Accreditation Forum (IAF) on an implementation timetable for organizations to be certified to the ISO 9001:2008 edition. This was expected to specify a period after which ISO 9001:2000 certificates will no longer be valid.

CBs should remember that certificates of conformity to ISO 9001:2008 and/or its national equivalent adoptions can only be issued after official publication by ISO and its national members.

Accredited certification bodies should ensure that their auditors are aware of the clarifications introduced in ISO 9001:2008 and their implications, prior to conducting audits to the standard.

### Trainers and consultants

All trainers and consultants should be knowledgeable of the clarifications provided in ISO 9001:2008. All training bodies and consultants are recommended to use the generic guidance to determine the need to update training programmes and documentation, or any other changes necessary to the services they provide.

Trainers and consultants are recommended to use ISO/FDIS 9001 in order to update training in readiness for the release of ISO 9001:2008.

### ISO 9001:2008 Implementation Support Package

A task group – ISO/TC 176/SC 2/WG 18/TG1.22 – has been developing an ISO 9001:2008 Implementation Support Package in order to assist all user groups in the analysis of the new edition.

The support package comprises the following documents:

- *ISO 9001:2008 Implementation Plan Guidance*;
- *ISO 9001 2000 vs. 2008 Reference Table*;
- *ISO 9001:2008 Frequently Asked Questions (FAQs)*;
- *Guidance on Sub-clause 1.2 'Application'*;
- *Guidance on the Documentation requirements*;
- *Guidance on the Terminology used in ISO 9001:2008*;
- *Guidance on the Concept and Use of the Process Approach for Management Systems*;

- *Guidance on "Outsourced Processes"*.

It was expected that these documents would be available from early October 2008 on the Web sites of ISO at [www.iso.org/managementstandards](http://www.iso.org/managementstandards) and ISO/TC 176/SC 2 at [www.iso.org/tc176/sc2](http://www.iso.org/tc176/sc2).

### Authentic information

The first contact for authentic information regarding the requirements of ISO 9001:2008 should be directed to the NSB in the reader's country. These are listed with full contact information on the ISO Web site [www.iso.org](http://www.iso.org).

In addition to the ISO members and *ISO Management Systems* magazine, other recommended sources of information are:

- ISO Web site, [www.iso.org](http://www.iso.org), for the Implementation Support Package and other information on general information regarding ISO 9001:2008, as well as the current ISO 9004:2000 revision programme;
- ISO/TC176 Web site, [www.tc176.org](http://www.tc176.org), for more specific information on the work programme of ISO/TC 176;
- The ISO/TC 176/SC 2 Web Site, [www.iso.org/tc176/sc2](http://www.iso.org/tc176/sc2), for detailed information on the ISO 9001/9004 revision programme, updated on a regular basis. •