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Implementation Guidance for ISO 9001:2015

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IMPLEMENTATION GUIDANCE FOR ISO 9001:2015

1. INTRODUCTION

This Implementation Guidance has been developed to assist users in understanding the issues that need to be considered during the co-existence period between ISO 9001:2008 and ISO 9001:2015.

A wide diffusion of this implementation guidance is recommended, in particular the comparison table between ISO 9001:2008 and ISO 9001:2015 matrix showing the correlation between the clauses of these international standards can be found on the www.iso.org/tc176/sc02/public website.

The revision of ISO 9001:2015 introduces a new 10 clause structure, many new requirements and many terms. Users will need to take into consideration that changes may be necessary to their QMS.

2. BACKGROUND TO THE ISO 9001:2015 REVISION PROCESS

In order to assist organizations to have a full understanding of the new ISO 9001:2015, it may be useful to have an insight on the revision process, how this revision reflects the inputs received from users of the standard, and the consideration given to benefits and impacts during its development.

Prior to the commencement of a revision (or amendment) to a management system standard, a “Justification Study” is prepared to present a case for the proposed project which outlines details of the data and inputs used to support its arguments. In relation to the development of ISO 9001:2015 user needs were identified from the following:

- ISO Annex SL provides a common structure, text, terms and definitions for management system standards.
- the results of a formal “Systematic Review” on ISO 9001:2008 that was performed by the members of ISO/TC 176/SC2
- feedback from the ISO/TC 176/SC2 Working Group on Interpretations
- an extensive worldwide “User Feedback Survey” on ISO 9001 was performed by ISO/TC 176/SC 2

The Justification Study identified the need for a revision to:

- adapt to a changing world
- enhance an organization's ability to satisfy its customers
- provide a consistent foundation for the future
- reflect the increasingly complex environments in which organizations operate
- ensure the new standard reflects the needs of all relevant interested parties
- align with other management systems

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The key focuses of the ISO 9001:2015 revision were to enhance clarity and compatibility with other management system standards.

The benefits identified for the ISO 9001:2015 edition:

- Provides clarity
- Enhanced leadership involvement in the management system
- Risk-based thinking
- Simplified language, common structure and terms
- Aligning QMS policy and objectives with the strategy of the organization

3. USER GROUPS

3.1 Individual organizations using ISO 9001 (including industry associations)

a) Current Users of ISO 9001:2008

This user group is defined as having completed or being in the process of implementing ISO 9001:2008, regardless of whether they are certified or not, or whether they intend to be certified or not.

b) New Users

A New User is defined as an organisation that is either beginning to use ISO 9001:2008 or ISO 9001:2015 for the first time or is a potential user of the standard in the future.

c) Users of Industry Sector Schemes based on ISO 9001:2015

These user groups are defined as those using quality management system programs based on ISO 9001:2015 that include additional requirements, that either can be certified or accredited under the guidance of a particular Industry Sector Scheme (e.g. ISO/TS 16949 *Quality systems – Automotive suppliers*).

3.2 Other user groups

These are defined as being:

- a) National Standards Bodies (NSBs)
- b) Accreditation Bodies (ABs)
- c) Certification/Registration Bodies (CB/RBs)
- d) Trainers and Consultants

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4. IMPLEMENTATION GUIDANCE

4.1 Generic guidance

All users groups are strongly advised to note the IAF’s Informative Document ID 9:2015 (see: <http://www.iaf.nu/upFiles/IAFID9Transition9001PublicationVersion.pdf>) for implementation of accredited certification to ISO 9001:2015, which details the agreed implementation plan for accredited certification as follows:

Accredited certification to ISO 9001:2015 shall not be granted until the publication of ISO 9001:2015 as an International Standard.

Certification of conformity to ISO 9001:2015 and/or national equivalents shall only be issued after official publication of ISO 9001:2015 (which should take place before the end of 2015) and after a routine surveillance or re-certification audit against ISO 9001:2015.

Validity of certifications to ISO 9001:2008

ISO 9001:2008 certifications will not be valid after three years from publication of ISO 9001:2015.

The expiry date of certifications to ISO 9001:2008 issued during the transition period needs to correspond to the end of the three year transition period.

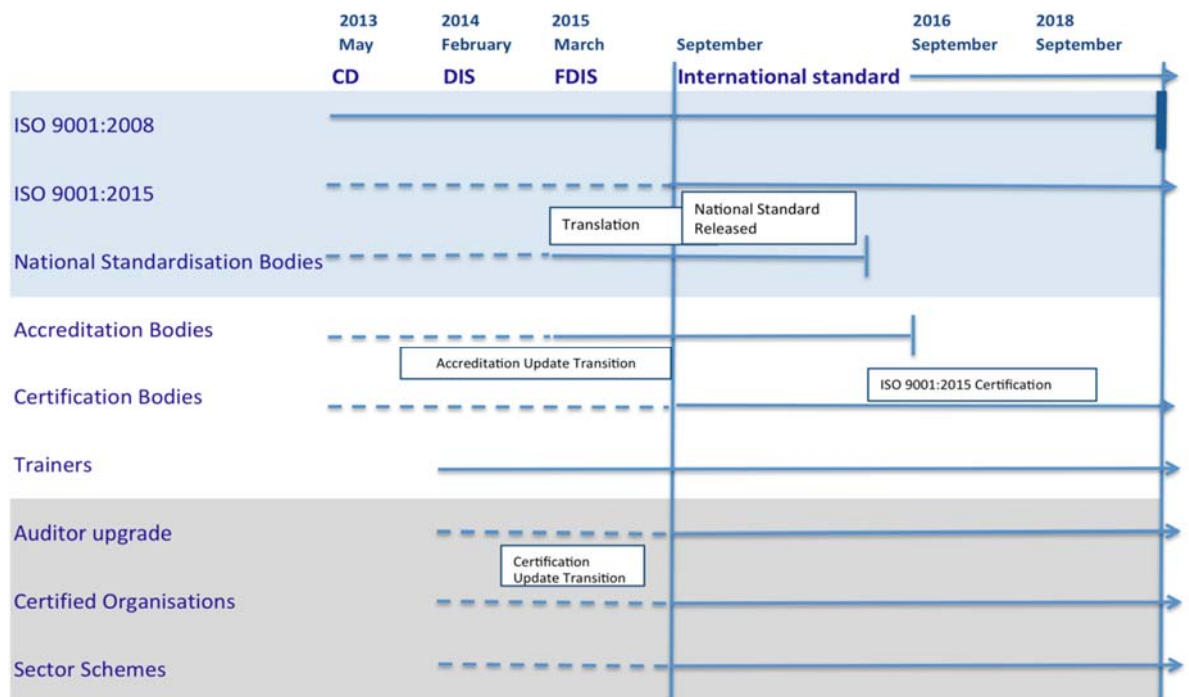
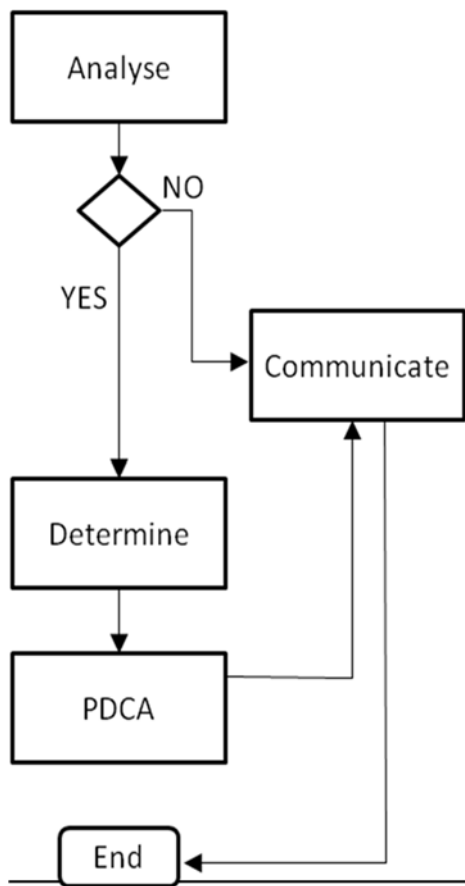


Figure 1 - Implementation timetable for ISO 9001:2015, for all user groups

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To benefit from the changes introduced into ISO 9001:2015, users (from all user groups) should note the recommendations given in the table below. Recommendations for specific user groups are given in section 4.2 further down.



To get acquainted with the new edition of the standard use the following resources:

- Annex A (informative) – New structure, concepts and terminology

Support material found at

www.iso.org/tc176/sc02/public:

- ISO 9001:2015 Change Summary
- Correlation matrices between ISO 9001:2008 and ISO 9001:2015, which provides a before and after view of the clauses
- Risk Based Thinking
- Process Approach

Determine the impact of the changes of the new version on your current use of ISO 9001 and plan any necessary remedial actions.

Use the Plan-Do-Check-Act methodology to manage the implementation.

Note that the actions may need to vary according to your user group (see 4.2 below).

4.2 Guidance for specific user groups

These recommendations complement the generic guidance to all user groups given in section 3.0 above.

4.2.1 Organizations using ISO 9001:2008

a) Current users

Organisations that are already certified to ISO 9001:2008 should contact their certification/registration bodies (CB/RB) to agree a program for analysing the clarifications in ISO 9001:2015 in relation to their individual quality management systems and for upgrading their certificates.

Certified organizations should bear in mind that ISO 9001:2008 certificates have the same status as new ISO 9001:2015 certificates during the co-existence period.

Organizations in the process of certification to ISO 9001:2008 should change to using ISO 9001:2015 and apply for certification to it.

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b) New users

New users should start by using ISO 9001:2015.

c) Industry Sector Schemes

Users of specific sector schemes are recommended to refer to the organization that is responsible that sector scheme', e.g. for:

- ISO/TS 16 949 refer to the IATF (www.iatfglobaloversight.org)
- TL 9000 refer to the QuEST Forum (www.questforum.org)
- AS9100/EN9100 refer to IAQG (www.iaqg.org)

4.2.2 National Standards Bodies

Information regarding the 2015 edition of ISO 9001 should be communicated to standard users, in a timely manner, by the national standards bodies (NSBs). It is recommended that NSB actions be synchronized with the information flows from ISO and ISO/TC 176/SC2.

NSBs are responsible, at a national level, for communicating the issues regarding the changes from ISO 9001:2008 to ISO 9001:2015 to all interested parties and for providing translations of the new edition of the standard in their national languages. It is recommended that they coordinate their communications regarding these issues with other local interested parties (for example: ABs, CB/RBs, professional quality associations, etc.).

Translation Issues - If a requirement for translation of the new standards exists, the translation process should be started as early as possible, in order to provide the equivalent national edition as soon as possible.

An NSB should analyse if there are interpretation problems in the national ISO 9001:2008 version due to former translation problems. In affirmative cases the NSB should carry out an extensive translation of the standard. If interpretation divergences still remain, the NSB is recommended to apply for clarification to the ISO/TC 176/SC2 Interpretations Working Group using the established "Interpretations" process (see: www.iso.org/tc176/sc02/public).

4.2.4 Accreditation Bodies

ABs should refer to the IAF's Informative Document ID 9:2015 for the implementation of accredited certification to ISO 9001:2015 (see 4.1 above).

4.2.5 Certification Bodies

CBs should refer to the IAF's Informative Document ID 9:2015 for the implementation of accredited certification to ISO 9001:2015 (see 4.1 above).

CBs should remember that certificates of conformity to ISO 9001:2015 and/or its national equivalent adoptions can only be issued after the official publication of the amended standard.

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It is important that accredited certification bodies ensure that their auditors are aware of the clarifications introduced in ISO 9001:2015, and their implications, prior to conducting audits to that standard.

4.2.6 Training Bodies and Consultants

All trainers and consultants should be aware of the clarifications in ISO 9001:2015. All training bodies and consultants are recommended to determine the need for updating training programs and documentation, or any other changes necessary, to the services they provide.

5.0 FREQUENTLY ASKED QUESTIONS

While this Implementation Guidance provides recommendations on a number of issues facing the different user groups during the co-existence period, it does not address more general questions about the ISO 9000 standards. Instead ISO/TC 176/SC 2 has prepared a set of frequently asked questions (FAQs) to provide such advice.

It is expected that the FAQs will be updated on a more regular basis than this Implementation Guidance. For the latest version of the FAQs, reference should be made to the open access web site at www.iso.org/tc176/sc02/public.

6.0 AUTHENTICITY OF INFORMATION REGARDING ISO 9001:2015

The first point of contact for information regarding the requirements of ISO 9001:2015 should be your National Standards Body (for a listing of ISO's member National Standards Bodies, see www.iso.org/iso/about/iso_members.htm).

Other recommended sources of information are:

- ISO's web site www.iso.org provides general information regarding the ISO 9001:2015 revision programme (as well as details of its member National Standards Bodies).
- The ISO/TC176/SC2 web site, www.iso.org/tc176/sc02/public provides detailed information on the ISO 9001 revision program and is updated on a regular basis.