(Draft) Transition Planning Guidance for ISO 9001:2015

ISO 9001 *Quality management systems – Requirements* is currently being revised.
The revision work has reached the "Draft International Standard" or "DIS" stage. The target for completing this work and publishing a revised edition of the standard is around September 2015.

In order to help users and other organizations prepare for the advent of the revised edition, the International Accreditation Forum (IAF, www.iaf.nu) has prepared the attached Transition Planning Guidance document, with the assistance of ISO/TC 176/SC2/WG23.

Due to the high level of enquiries that ISO is receiving about this revision, it has been agreed to make this draft of the Transition Planning Guidance available now, before it has completed its formal review and approval processes.

If necessary, once the formal review and approval processes have been completed, an amended final version of the Transition Planning Guidance will be made available on both the IAF's web site, and on ISO/TC 176/SC2's web site: www.iso.org/tc176/sc02/public (where a number of other informative documents concerning the revision may also be found).

Draft 1

IAF Informative Document

Transition Planning Guidance
for ISO 9001:2015

Issue X

(IAF ID X:2014)

NOTICE:

This draft document is presently being circulated to IAF Technical Committee members for an initial round of comments, closing 04 August 2014. The contents could change significantly before publication and therefore should not be considered the official position of IAF.

Note 1: The full process for development of IAF documents is described in IAF PR2: General Procedures for the Development of IAF Documents.

Note 2: See also IAF Resolution 2013-15 for the IAF decision regarding the transition period for implementation of the new standard.

Note 3: Any inquiries regarding this draft Document may be addressed to the co-conveners of the TF Transition for ISO 9001, Alex Ezrakhovich at alex@aeconformity.com and Azusa Nakagawa at azusa.nakagawa@jab.or.jp

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The International Accreditation Forum, Inc. (IAF) details criteria for the accreditation of bodies that provide conformity assessment services, and such accreditation facilitates trade and reduces demands for multiple conformity assessment activities.

Accreditation reduces risk for business and its customers by assuring that accredited Conformity Assessment Bodies (CABs) are competent to carry out the work they undertake within their scope of accreditation. Accreditation Bodies (ABs) that are members of IAF and the CABs they accredit are required to comply with appropriate international standards and the applicable IAF application documents for the consistent application of those standards.

ABs that are signatories to the IAF Multilateral Recognition Arrangement (MLA) are evaluated regularly by an appointed team of peers to provide confidence in the operation of their accreditation programs. The structure and scope of the IAF MLA is detailed in IAF PR 4 - Structure of IAF MLA and Endorsed Normative Documents.

The IAF MLA is structured in five levels: Level 1 specifies mandatory criteria that apply to all ABs, ISO/IEC 17011. The combination of a Level 2 activity(ies) and the corresponding Level 3 normative document(s) is called the main scope of the MLA, and the combination of Level 4 (if applicable) and Level 5 relevant normative documents is called a sub-scope of the MLA.

- The main scope of the MLA includes activities e.g. product certification and associated mandatory documents e.g. ISO/IEC 17065. The attestations made by CABs at the main scope level are considered to be equally reliable.
- The sub-scope of the MLA includes conformity assessment requirements e.g. ISO 9001 and scheme specific requirements, where applicable, e.g. ISO TS 22003. The attestations made by CABs at the sub scope level are considered to be equivalent.

The IAF MLA delivers the confidence needed for market acceptance of conformity assessment outcomes. An attestation issued, within the scope of the IAF MLA, by a body that is accredited by an IAF MLA signatory AB can be recognized worldwide, thereby facilitating international trade.

Issue No X
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INTRODUCTION TO IAF INFORMATIVE DOCUMENTS

This IAF Informative Document reflects the consensus of IAF members on this subject and is intended to support the consistent application of requirements. However, being a document for information purposes only, IAF Accreditation Body Members, and the Conformity Assessment Bodies they accredit, are not under any obligation to use or comply with anything in this document.

This transition planning guidance has been prepared by the International Accreditation Forum (IAF) with cooperation with ISO/TC 176/SC 2/WG 23 to provide advice to interested parties on transition arrangements to be considered before implementing ISO 9001:2015.

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TRANSITION PLANNING GUIDANCE FOR ISO 9001:2015

1. Introduction

This document provides guidance for the transition from ISO 9001:2008 to ISO 9001:2015.

It identifies activities which should be considered by relevant interested parties and to increase understanding of the context of ISO 9001:2015. The revision introduces significant changes and will be published in September 2015.

The standard is based on Annex SL of the ISO Directives, a high-level structure (HLS) which standardizes sub clause titles, core text, common terms and core definitions to enhance compatibility and alignment with other ISO management system standards.

The main changes in the new version of ISO 9001:2015 are:
- the adoption of the HLS as set out in Annex SL of ISO Directives Part One,
- an explicit requirement for risk-based thinking to support and improve the understanding and application of the process approach,
- fewer prescribed requirements,
- less emphasis on documents,
- improved applicability for services,
- a requirement to define the boundaries of the QMS,
- increased emphasis on organizational context,
- increased leadership requirements,
- greater emphasis on achieving desired outcomes to improve customer satisfaction.

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Relevant interested parties who will benefit from this guidance include:
- organizations using ISO 9001:2008,
- accreditation bodies (ABs),
- certification bodies (CBs),
- training bodies and consultants.

2. Transition

The International Accreditation Forum (IAF) which monitors certifications/accreditations and the ISO Committee on Conformity Assessment (CASCO) have agreed a three year transition period from the publication date of ISO 9001:2015. The transition period will begin in dd September 2015 and end in dd September 2018.

2.1   Validity of certifications to ISO 9001:2008

ISO 9001:2008 certifications will not be valid after the end of September 2018.

From March 2017 all initial certifications under accreditation shall be to ISO 9001:2015.

3. Guidance for transition

For any organisation the degree of change necessary will be dependent upon the maturity and effectiveness of the current management system, organisational structure and practices, therefore an impact assessment is strongly recommended in order to identify realistic resource and time implications.

3.1 Specific guidance for interested parties involved in certification and accreditation

3.1.1 Organizations using ISO 9001:2008

Organizations using ISO 9001:2008 are recommended to take the following actions:

- identify organizational gaps which need to be addressed to meet new requirements,
- develop an implementation plan,
- provide appropriate training and awareness for all parties that have an impact on the effectiveness of the organisation,
- update existing quality management system (QMS) to meet the revised requirements and provide verification of effectiveness,
- where applicable, liaise with your certification body for transition arrangements.

NOTE: users should be aware that at Draft International Standard (DIS) stage technical changes may still occur, therefore it is recommended that, while preparation can be carried out at DIS, significant changes should not be implemented until the Final Draft International Standard (FDIS) is issued and the technical content is finalized.

3.1.2 Accreditation Bodies

ABs are recommended to:
- inform CBs about the transition process using the appropriate guidance and IAF produced documents,
- plan resources for training and performing assessments to the revised standard,
- check that criteria used to assess auditor competence are adequate for auditors verifying compliance to the revised standard.

3.1.3 Certification Bodies

CBs are recommended to:
- train and monitor auditors to ensure relevant level of competence is demonstrated,
- communicate regularly with national standard bodies,
- communicate regularly with ABs,
- communicate with other CBs to co-ordinate information,
- communicate with existing clients and share guidance on the transition process and   arrangements for transition,
- plan the timing of audit and certification activities for the revised standard,
- consider the stated transition period and current certification period,
- plan the timing of certification decisions for upgrading certificates,
- encourage current users of ISO 9001:2008 to implement ISO 9001:2015 at an early stage, taking account of any changes that may occur during the DIS stage,
- encourage new users to implement ISO 9001:2015,
- arrange audit schedules for existing client organizations.

4. IAF Transition Guidance

4.1 Implementation of transition of accredited certification from ISO 9001:2008 to ISO 9001:2015

IAF has agreed an outline implementation plan to ensure a smooth migration of accredited certification to ISO 9001:2015 after consultation with international groupings representing quality management system or auditor certification bodies, and industry users of ISO 9001 certification services.

This document is intended to allow for advanced activity in the planning and adoption of the new requirements, taking into account changes that may still occur during the DIS phase. While planning activities are encouraged during the DIS phase it is recommended that organisations should exercise caution as the DIS may still be subject to further technical changes until the FDIS is published.

Evaluation activity undertaken by the CB during the DIS stage cannot be taken into account as part of the formal transition process. Any early evaluation must be re-assessed and fully verified before transition to ISO 9001:2015.

4.2 Requirements for Certification Bodies

CBs are encouraged to start briefing their clients from the DIS stage and can, if required, start to perform preliminary evaluations.

Accredited certification to ISO 9001:2015 and/or national equivalents shall only be issued once the CB has been accredited to deliver certification to the new standard and after an audit of each client against ISO 9001:2015 including the mandatory requirements identified as required to audit prior to transition. This audit can be a routine surveillance, recertification audit or a special audit; that is the decision of the organization in coordination with their CB. Where transition audits are carried out in conjunction with scheduled surveillance or reassessment, additional time is likely to be required to ensure that all activities are covered for the existing and new standards.

Validity of accredited certifications to ISO 9001:2008

Eighteen (18) months after publication of ISO 9001:2015 all accredited new certifications issued (initial certifications) shall be to ISO 9001:2015.
Three years after publication of ISO 9001:2015, any existing accredited certifications issued to ISO 9001:2008 shall not be valid.

Transition Process

IAF member AB shall require its accredited CBs to develop "Transition Implementation Plans" including specific measures to address as a minimum, the following.

1. All CB auditors receive comprehensive training to the requirements of ISO (DIS) 9001:2015. The records of this training should be maintained by the CB.
2. Additional training will be required to address any differences between the DIS, FDIS and final published standard requirements.
3. Audits shall only be conducted following completion of such training; records shall be available to show the content and method for training received and the evaluation methods used to verify auditor competence.
4. Where a progressive or staged approach to transition is undertaken, the client audit files shall show the progress made and the evaluation of each requirement within ISO 9001:2015.
5. All issues that require client action for compliance with the new requirements shall be clearly identified and raised as documented findings.
6. Only when all identified outstanding issues have been addressed (see point 5, above) and the effectiveness of the management system demonstrated, can auditors recommend certification to ISO 9001:2015.

7. Records shall be available to demonstrate that all prior findings have been evaluated for corrective action and compliance before any recommendation for approval to ISO 9001:2015 can be made.

8. The CB should ensure that the evaluation of a client's conformance to the new requirements during the transition phase does not interfere with the client's on-going compliance with ISO 9001:2008. Where evaluation activities have taken place at the FDIS, a review will be undertaken by the Decision Maker to ensure the validity of such activity is taken into account in the decision process.

4.3 Requirements for Accreditation Bodies

Additional visits by ABs to assess solely for the transition to ISO 9001:2015 are not normally required. The implementation should, wherever possible, be verified during normal scheduled activity. However, additional assessments may be necessary for a CB requesting accreditation within an accelerated timeframe.

ISO 9001:2015 mandates the need to demonstrate system effectiveness and the application of risk-based thinking through the process approach. This may result in the need for a variation of auditing techniques, therefore witnessed assessments may be necessary as part of the transition programme.

It is recommended that AB transition arrangements take the following into account.

1. That all AB assessors receive comprehensive training to the requirements ISO 9001:2015. It is recommended that such training should be started at the FDIS stage wherever possible. The records of this training should be maintained by AB.

2. Where training has been carried out based on the FDIS, additional training may be required should there be any differences between the FDIS and final published standard requirements.

3. The AB should develop its transition programmes to make full use of available time including carrying out as much activity as possible at the latter DIS and the FDIS stages in order to enable accreditation for the new standard to be available at the earliest opportunity.

4. The AB should, at the earliest opportunity, communicate its transition arrangements and requirements to accredited CBs.

5. The transition assessment should focus on changes to be implemented by CBs as a result of implementing the new standard: primary consideration should be given to consistent interpretation of the requirements; competence; reporting, and any associated change in audit methodology (see note above regarding witnessed assessments). The assessment will also review the CB's transition arrangements for its certified clients.

End of IAF Informative Document Transition planning guidance for ISO 9001:2015

Further Information:

For further Information on this document or other IAF documents, contact any member of IAF or the IAF Secretariat.

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