



IAF Informative Document

Transition Planning Guidance for ISO 9001:2015

Issue 1

(IAF ID 9:2015)

The International Accreditation Forum, Inc. (IAF) facilitates trade and supports regulators by operating a worldwide mutual recognition arrangement among Accreditation Bodies (ABs) in order that the results issued by Conformity Assessment Bodies (CABs) accredited by IAF members are accepted globally.

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 1

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Issue Date: 12 January 2015

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Date: 30 December 2014

Application Date: 12 January 2015

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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 (CABs) they accredit, are not under any obligation to use or comply with anything in this document.

TRANSITION PLANNING GUIDANCE FOR ISO 9001:2015

1. INTRODUCTION

This document provides guidance for the transition from ISO 9001:2008 to ISO 9001:2015 and has been prepared by the International Accreditation Forum (IAF) in 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.

It identifies activities which should be considered by relevant interested parties and increases 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:

- i) The adoption of the HLS as set out in Annex SL of ISO Directives Part 1.
- ii) An explicit requirement for risk-based thinking to support and improve the understanding and application of the process approach.
- iii) Fewer prescribed requirements.
- iv) Less emphasis on documents.
- v) Improved applicability for services.
- vi) A requirement to define the boundaries of the QMS.
- vii) Increased emphasis on organizational context.
- viii) Increased leadership requirements.
- ix) Greater emphasis on achieving desired outcomes to improve customer satisfaction.

Relevant interested parties who will benefit from this guidance include:

- i) Organizations certified and/or using ISO 9001:2008.
- ii) Accreditation Bodies (ABs).
- iii) Certification Bodies (CBs).
- iv) Training bodies and consultants.

2. TRANSITION

The International Accreditation Forum (IAF) and the ISO Committee on Conformity Assessment (CASCO) have agreed to a three year transition period from the publication date of ISO 9001:2015.

IAF Resolution 2013-15 was passed by the IAF General Assembly in Seoul on 23 October 2013 endorsing a 3 year transition period to ISO 9001:2015.

2.1 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.

3. SPECIFIC GUIDANCE FOR INTERESTED PARTIES INVOLVED IN CERTIFICATION AND ACCREDITATION

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 analysis/gap assessment is strongly recommended in order to identify realistic resource and time implications.

3.1 Organizations using ISO 9001:2008

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

- i) Identify organizational gaps which need to be addressed to meet new requirements.
- ii) Develop an implementation plan.
- iii) Provide appropriate training and awareness for all parties that have an impact on the effectiveness of the organisation.
- iv) Update the existing quality management system (QMS) to meet the revised requirements and provide verification of effectiveness.
- v) Where applicable, liaise with their Certification Body for transition arrangements.

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

3.2 Certification Bodies

CBs are recommended to:

- i) Train their auditors and verify the results to ensure the relevant level of competence is demonstrated.
- ii) Communicate regularly with national standards bodies.
- iii) Communicate regularly with ABs.
- iv) Communicate with other CBs to co-ordinate information.
- v) Communicate with existing clients and share guidance on the transition process and arrangements for transition.
- vi) Plan the timing of audit and certification activities for the revised standard.
- vii) Consider the stated transition period and current certification period.
- viii) Plan the timing of certification decisions for upgrading certification documents.
- ix) Encourage current users of ISO 9001:2008 to implement ISO 9001:2015 at an early stage, taking into account any changes that may occur during the DIS stage.
- x) Encourage new users to implement ISO 9001:2015.
- xi) Arrange audit schedules for existing client organizations.

3.3 Accreditation Bodies

ABs are recommended to:

- i) Inform CBs about the transition process using the appropriate guidance as stated in 4.3 and IAF produced documents.
- ii) Plan resources for training and performing assessments to the revised standard.
- iii) Check that criteria used to assess auditor competence are adequate for auditors verifying compliance to the revised standard.
- iv) Train their assessors and verify the result to ensure the relevant level of competence is demonstrated.
- v) Communicate regularly with national standards bodies.
- vi) Communicate regularly with their accredited Certification Bodies.
- vii) Communicate with other Accreditation Bodies to co-ordinate information.
- viii) Plan the timing of assessments and arrange assessment schedules for the revised standard.
- ix) Plan the timing of accreditation decisions for upgrading accreditation certificates.

4. IAF TRANSITION GUIDANCE

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

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 Guidance for Certification Bodies

4.2.1 General

CBs are encouraged to start briefing their clients from the DIS stage and can, if required, start to perform gap analysis between the client system and the DIS.

CBs are to keep track of all evaluation activities during the DIS stage for full verification at the time of the transition audit to ISO 9001:2015.

Accredited certifications to ISO 9001:2015 and/or national equivalents should only be issued once the CB has been accredited to deliver certification to the new standard and after the organization has demonstrated conformance to ISO 9001:2015. The Certification Body should conduct an audit of each client against ISO 9001:2015. Based on the agreement with the certified organizations, CBs can conduct transition activities during a routine surveillance, recertification audit or a special audit. Where transition audits are carried out in conjunction with scheduled surveillance or recertification (i.e. progressive or staged approach), additional time is likely to be required to ensure that all activities are covered for the existing and new standards.

4.2.2 Transition Process

CBs should communicate their transition arrangements to their clients at the earliest opportunity.

It is recommended that this is done at the latter DIS or FDIS stage. CBs are recommended to develop transition plans to address the following:

- i) Training and verification of competence of auditors and other staff.

NOTE: CBs are encouraged to commence training at the DIS stage but additional training may be required to address any differences between the DIS, FDIS and the published standard.

- ii) The CB's arrangements for communicating with its clients.
- iii) The CB's arrangements for auditing conformance to the new standard. For example, will it be a single visit or a staged approach.
- iv) How the CB will ensure clients' ongoing conformance to ISO 9001:2008 through the transition process.
- v) How the CB plans to use the results of any audits conducted against the FDIS.
- vi) Action to be taken in respect of clients that have failed to complete the transition by three years after the publication of ISO 9001:2015. For example, the level of audit necessary for certification to be reinstated.

The following should be ensured:

- i) All issues that require client action for compliance with the new requirements should be clearly identified and raised as documented findings.
- ii) Only when all identified outstanding issues have been appropriately addressed and the effectiveness of the management system demonstrated, can auditors recommend certification to the published ISO 9001:2015 standard.
- iii) Records should be available to demonstrate that all prior transition audit findings have been evaluated for corrective action and compliance before any recommendation for approval to ISO 9001:2015 can be made.
- iv) 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 conformance to ISO 9001:2008.
- v) 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 Guidance 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, noting that there may be some need for additional assessment time. However, additional assessments may be necessary for a CB requesting accreditation within an accelerated timeframe.

ISO 9001:2015 promotes 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.

AB's should, at the earliest opportunity, communicate their transition arrangements and requirements to their accredited CBs. It is recommended that the transition arrangements take account of the following:

- i) Training and verification of competence of assessors and other staff.

NOTE: ABs are encouraged to commence training at the FDIS stage but additional training may be required to address any differences between the FDIS and the published standard.

- ii) 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.
- iii) The AB should develop its transition programmes to make full use of available time, including carrying out as much activity as possible at the FDIS stages in order to enable accreditation for the new standard to be available at the earliest opportunity.
- iv) 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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