



Alignment of ISO/IEC 17025:1999 with ISO 9001:2000

Publication of ISO/IEC 17025:2005

Purpose of the amendment to ISO/IEC 17025:1999

The terms of reference of ISO/CASCO Working Group (WG) 25, which was established in 2001, was to align ISO/IEC 17025:1999, *General requirements for the competence of testing and calibration laboratories*, with ISO 9001:2000, *Quality management systems – Requirements*.

After the first WG meetings it became evident that to achieve a full and comprehensive alignment of ISO/IEC 17025 with ISO 9001 it would necessitate the complete reformulation and rewrite of ISO/IEC 17025. Given the fact that ISO/IEC 17025 had only been published in 1999 and that the transition period for accredited laboratories to comply with its new requirements did not expire until 1st January 2003, all stakeholders (laboratories and accreditation bodies) expressed a desire not to undertake a major revision of ISO/IEC 17025:1999 at this time.

As a result it was agreed that the 'alignment' would only include the minimum of changes to ISO/IEC 17025 that were necessary to ensure 17025 and ISO 9001:2000 were compatible. This included decoupling the linkage between the two standards by removing the statement in the Scope that stated laboratories fulfilling the requirements of ISO/IEC 17025 then also automatically fulfilled the requirements of ISO 9001.

This effectively means laboratories may choose to be accredited to ISO/IEC 17025, or be certified to ISO 9001, or both, but the processes of accreditation and certification would be two separate actions. No longer can a laboratory be accredited to ISO/IEC 17025 and claim that this also means they automatically meet the requirements of ISO 9001.

Latest developments and expected publication date

In February 2005 voting on the Final Draft Amendment (FDAM) to ISO/IEC 17025:1999 was completed. 96% of both voting ISO member bodies and IEC national Committees approved the amendment. Work is now underway to make the final edit of the text in the form of a new edition of ISO/IEC 17025 that will include the amended text within it. The standard will be published in May 2005.

The International Laboratory Accreditation Cooperation (ILAC) have set a transition period of 2 years from date of publication of the new edition for accredited laboratories to comply with the 2005 edition requirements.

The new edition to be published this year effectively reverses the sequence of standard revisions leapfrogging with ISO 9001. A systematic review of ISO/IEC 17025:2005 will not be necessary for a further 5 years, by which time an amended ISO 9001 is expected to have been published in 2008 or 2009.

General changes, and changes in the Introduction and Scope

The main changes to ISO/IEC 17025:1999 that have been made in the approved amendment relate to:

- clarifying that meeting the requirements of ISO/IEC 17025 does not also automatically mean that all the requirements of ISO 9001 are met; and
- changes to the management requirements in ISO/IEC 17025 to reflect the content of ISO 9001:2000, especially in terms of a greater emphasis on the responsibilities of top management, the need to demonstrate a commitment to continually improve the



effectiveness of the management system, and to allow for a greater focus on customer satisfaction.

Through out the standard the word 'client' has been replaced by the word 'customer'.

Through out the standard, where reference is being made to the overall management system that governs the operations of a laboratory (that includes the quality, administrative and technical systems), the words "quality management system" has been replaced by "management system".

The Introduction has been changed to state:

"The growth in use of management systems generally has increased the need to ensure that laboratories which form part of larger organizations or offer other services can operate to a quality management system that is seen as compliant with ISO 9001 as well as with this International Standard. Care has been taken, therefore, to incorporate all those requirements of ISO 9001 that are relevant to the scope of testing and calibration services that are covered by the laboratory's management system.

Testing and calibration laboratories that comply with this International Standard will therefore also operate in accordance with ISO 9001.

Conformity of the quality management system within which the laboratory operates to the requirements of ISO 9001 does not of itself demonstrate the competence of the laboratory to produce technically valid data and results. Nor does demonstrated conformity to this International Standard imply conformity of the quality management system within which the laboratory operates to all the requirements of ISO 9001."

In the second paragraph above 'in accordance with' does not equate to complete or actual compliance with the requirements of ISO 9001. This is further reinforced by the second sentence of the third paragraph that states: "Nor does demonstrated conformity to this International Standard imply conformity of the quality management system within which the laboratory operates to all the requirements of ISO 9001."

In the scope of the standard, clause 1.4 has been rewritten to state:

"1.4 This International Standard is for use by laboratories in developing their management system for quality, administrative and technical operations. Laboratory customers, regulatory authorities and accreditation bodies may also use it in confirming or recognizing the competence of laboratories. This International Standard is not intended to be used for the purpose of certification."

This new formulation highlights that ISO/IEC 17025 is directed towards the competence of laboratories, and is not intended to be used for the purpose of certification of laboratories.

Scope clause 1.6 has also been changed to state:

"1.6 If testing and calibration laboratories comply with the requirements of this International Standard they will operate a quality management system for their testing and calibration activities that also meets the principles of ISO 9001. Annex A provides nominal cross-references between this International Standard and ISO 9001. ISO/IEC 17025 covers technical competence requirements that are not covered by ISO 9001."

So while a laboratory cannot claim they meet all the requirements of ISO 9001:2000 by being accredited to ISO/IEC 17025, they do meet the principles of ISO 9001. The use of the word



'principles' is used in a normal dictionary meaning of the term, and does not necessarily equate to the specific principles for quality management as articulated in ISO 9000:2000.

Changes to the management requirements

In relation to requirements for laboratory management, there are new requirements that require top management to ensure that appropriate communication processes are established within the laboratory for implementation of the management system, and that communication takes place regarding the effectiveness of the management system.

In relation to requirements for the management system of the laboratory there is clarification that:

- the objectives set within the management system must be reviewed during the management review process; and
- that there must be a demonstrated commitment to continually improve the effectiveness of the management system.

A new clause on improvement has been added as 4.10 Improvement. It states:

"The laboratory shall continually improve the effectiveness of its management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review."

In clause 4.7 related to Service to the customer, the laboratory must be willing to cooperate with customers to clarify their expectations, and shall seek feedback from its customers to improve its management system, and the provision of testing and calibration services.

Changes in the Technical Requirements

The only significant changes in Clause 5 Technical Requirements relate to continual improvement. Clause 5.2.2 is supplemented to include *"the effectiveness of the training actions taken shall be evaluated."*; and a new requirement has been added to 5.9 Assuring the quality of test and calibration results that states:

"5.9.2 Quality control data shall be analysed and, where they are found to be outside pre-defined criteria, planned action shall be taken to correct the problem and to prevent incorrect results from being reported."

Annex A that shows the nominal cross-references between clauses in ISO 9001 and ISO/IEC 17025 has been updated.

Use of the new ISO/IEC 17025:2005

As noted accredited laboratories have 2 years after the publication date of ISO/IEC 17025:2005 in which to comply with the requirements of the new edition of the standard.

At present there are contrasting views amongst accreditors and laboratories as to whether reference to 'the principles of ISO 9001' should be included on accreditation statements, or in the scope of accreditations. Some accreditors believe that reference to the principles of ISO 9001 should not be permitted, however some laboratories and accreditors believe this should be permitted, especially when the test and calibration services provided by the laboratory need to feed into a supply chain that is only familiar with ISO 9001.

This issue was discussed at the IAF/ILAC/ISO JWG meeting in November 2004. The result of these discussions were included in a communiqué after the meeting and on this point it was stated:



"The JWG reviewed the current debate over whether ISO/IEC 17025 accreditation statements should permit wording that referred to that fact that a laboratory accredited to ISO/IEC 17025 also met the principles of ISO 9001:2000.

This issue has arisen due to the current amendment to ISO/IEC 17025:1999 to ensure compatibility between that standard and ISO 9001:2000. Currently ISO/IEC 17025 makes a statement in the introduction to the effect that laboratories meeting the requirements of ISO/IEC 17025:1999 also meet the requirements of ISO 9001:1994 and ISO 9002:1994. ISO 9001:1994 and ISO 9002:1994 were withdrawn when ISO 9001:2000 was published.

In the amendment to the wording of ISO/IEC 17025 it has been changed to remove this linkage. Wording in the Final Draft Amendment to ISO/IEC 17025:1999 states laboratories fulfilling the requirements of ISO/IEC 17025 also meet the principles of ISO 9001:2000, but not the actual requirements.

Some laboratory accreditation bodies and their laboratory clients wish to maintain their ability to include a phrase to this effect on their accreditation statements.

The JWG discussions on this issue were not conclusive, and the matter has now been returned to the ILAC community for its further deliberation. JWG members undertook to produce an information statement explaining the use of ISO/IEC 17025 in laboratory accreditation and its relationship with ISO 9001:2000. This statement will be based on the existing IAF-ILAC-ISO [Communiqué on the objectives and roles of accreditation and certification of laboratories](#) that was published in 2002."

The information statement referred to in the Communiqué is currently in preparation between ILAC and ISO/CASCO, and will be confirmed at the next IAF-ILAC-ISO JWG meeting in June 2005.

Conclusions for Laboratories

There are no essential changes in the technical requirements. New is the explicit requirement for a continual improvement of the management system. Also there are new requirements for internal communication about the management system and for communications with the customer. It can be concluded that laboratories that already have described and controlled their processes within the laboratory - as already required in the current edition ISO/IEC 17025 - will have only minor adjustments to make to their existing procedures to ensure that the new orientations in the management requirements are fulfilled.