



Summary of changes to the published ISO/IEC 17025:1999 that are incorporated in ISO/IEC WD2 17025

WD2 of the amendment to ISO/IEC 17025:1999 to align the standard with ISO 9001:2000 has been prepared as a result of decisions taken at the ISO/CASCO WG 25 meeting on 2002-12-12 and after further work by the WG 25 drafting group during January, February and March 2003.

General changes

The following changes have taken place through out the document whether the term appears, unless otherwise described.

Current word	New word(s)
quality system	The term quality system has been changed to either management system or quality management system
client	The term client has been changed in customer.
nonconformances and conformance	The term nonconformances has been changed to nonconformities and conformance to conformity
ISO 9001:1994 and ISO 9004:1994	References to ISO 9001:1994 and ISO 9001:1994 have been changed in references to ISO 9001:2000
ISO 8402	References to ISO 8402 have been changed in references to ISO 9000:2000
chief executive	In 4.2.2 the term top management is introduced as a substitute for chief executive. This term top management is also used in new paragraphs (4.1.6, 4.2.3, 4.2.4 and 4.2.7).

Specific changes

The following table summarises the specific changes not already covered above. Where a new subclause is introduced, the following subclauses have been renumbered in ISO/IEC WD2 17025. This renumbering is included below

Original clause or subclause in the published ISO/IEC 17025:1999	New subclause in WD2
Introduction	New text included to explain the reason for the amendment
1.4	New sentence added to the end of the clause. <i>This international standard is not to be used for the purposes of certification of the quality management system.</i>
1.6 If testing and calibration laboratories comply with the requirements of this International Standard they will operate a quality system for their testing and calibration activities that also meets the requirements of ISO 9001 when they engage in the design/development of new methods, and/or develop test programmes combining standard and non-standard test and calibration methods, and ISO 9002 when they only use standard methods.	Replaced by: <i>1.6 If testing and calibration laboratories comply with the requirements of this International Standard they will operate a management system for their testing and calibration activities that also meets the principles of ISO 9001:2000</i>
2. Normative references The following normative documents contain provisions which, through reference in this text,	Replaced by <i>The following referenced documents are</i>

constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards. ISO 9001 :1994, Quality systems — Model for quality assurance in design, development, production, installation and servicing. ISO 9002 :1994, Quality systems—Model for quality assurance in production, installation and servicing.	<i>indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.</i> <i>ISO 9000:2000, Quality management systems -- Fundamentals and vocabulary</i> <i>ISO 9001:2000, Quality Management Systems - Requirements</i>
4.1.5 The laboratory shall a) have managerial and technical personnel with the authority and resources needed to carry out their duties and to identify the occurrence of departures from the quality system or from the procedures for performing tests and/or calibrations, and to initiate actions to prevent or minimize such departures (see also 5.2) ;	Replaced by: <i>a) have managerial and technical personnel, who irrespective of other responsibilities, have the authority and resources needed to carry out their duties, including the implementation, maintenance and improvement of the management system, and to identify the occurrence of departures from the management system or from the procedures for performing tests and/or calibrations, and to initiate actions to prevent or minimize such departures (see also 5.2);</i>
	New subclause inserted <i>4.1.5 k) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives.</i>
	New subclause inserted <i>4.1.6 Top management shall ensure that appropriate communication processes are established within the laboratory and that communication takes place regarding the effectiveness of the management system.</i>
4.2.2 The laboratory's quality system policies and objectives, shall be defined in a quality manual (however named). The overall objectives shall be documented in a quality policy statement...	Replaced by <i>4.2.2 The laboratory's management system policies, including a quality policy statement, shall be defined in a quality manual (however named). The overall objectives shall be established and reviewed during management review...</i>
	New subclause inserted <i>4.2.3 Top management shall provide evidence of commitment to the continual improvement of the management system.</i>
	New subclause inserted

	<i>4.2.4 Top management shall communicate to the organisation the importance of meeting customer as well as statutory and regulatory requirements</i>
	New subclause inserted <i>4.2.7 Top management shall ensure that the integrity of the management system is maintained when changes to the management system are planned and implemented.</i>
4.7.1 Note 3 Laboratories are encouraged to obtain other feedback, both positive and negative, from their customers (e.g. customer surveys). The feedback should be used to improve the quality system, testing and calibration activities and customer service.	Deleted
	New subclause inserted <i>4.7.2 The laboratory shall obtain feedback, both positive and negative, from its direct customers (e.g. through customer satisfaction surveys). The feedback should be used and analysed to improve the quality management system, testing and calibration activities and customer service.</i>
	New subclause inserted <i>4.10 Improvement The laboratory shall continually improve the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.</i>
	New list item added in 4.15.1 after the 9th entry: <i>recommendations for improvement</i>
	New sentence added at the end of subclause 5.2.2 <i>... The effectiveness of the training actions taken shall be evaluated.</i>
	New list item added as 5.9.1 as <i>f) regular checking of equipment for stability and integrity.</i>
	New subclause added <i>5.9.2 Quality control data shall be analysed and where it is found to be outside pre-defined action criteria, the defined actions shall be taken to correct the problem and to prevent incorrect results from being reported.</i>

Annexes

Annex A has been replaced in its entirety giving a new set of cross references between the new versions of ISO 9001 and 17025. There are no changes to Annex B.



Bibliography

The Bibliography has been updated to reflect revisions and replacements of the documents that were originally listed.