FINAL
DRAFT

AMENDMENT

ISO/IEC 17025 FDAM 1

Secretariat: **CASCO**

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2004-12-09

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2005-02-09

General requirements for the competence of testing and calibration laboratories —

AMENDMENT 1

Prescriptions générales concernant la compétence des laboratoires d'étalonnages et d'essais —
AMENDEMENT 1

Please see the administrative notes on page iii

Reference number
ISO/IEC 17025:/FDAM 1:2004(E)

This final draft is submitted to a parallel approval vote in ISO and IEC. Each ISO member body and IEC national committee is requested to take appropriate steps to harmonize the national viewpoint in order to cast the same “yes” or “no” vote to both ISO and IEC.

Positive votes shall not be accompanied by comments.

Negative votes shall be accompanied by the relevant technical reasons.

Foreword

ISO (the International Organization for Standardization) and IEC (the International Electrotechnical Commission) form the specialized system for wordwide standardization. National bodies that are members of ISO or IEC participate in the development of International Standards through technical committees established by the respective organization to deal with particular fieds of technical activity. ISO and IEC technical committees collaborate in fields of mutual interest. Other international organizations, governmental and non-governmental, in liaison with ISO and IEC, also take part in the work. In the field of conformity assessment the ISO Committee on conformity assessment (CASCO) is responsible for the development of International Standards and Guides.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent right. ISO shall not be held responsible for identifying any or all such patent rights.

Amendment 1 to ISO/IEC 17025:1999 was prepared by the ISO Committee on conformity assessment (CASCO).

General requirements for the competence of testing and calibration laboratories —

AMENDMENT 1

Page iv, Foreword

Add the following sentence to the end of the first paragraph:

> "In the field of conformity assessment, the ISO Committee on conformity assessment (CASCO) is responsible for the development of International Standards and Guides."

Replace "Part 3" with "Part 2" in the second paragraph.

Replace the third paragraph with the following:

> "Draft International Standards are circulated to the national bodies for voting. Publication as an International Standard requires approval by at least 75 % of the national bodies casting a vote."

Replace the sixth paragraph with the following:

> "This second edition of ISO/IEC 17025 cancels and replaces the first edition (ISO/IEC 17025:1999)."

Page v, Introduction

Replace the first sentence with the following:

> "The first edition of this International Standard (1999) was produced as the result of extensive experience in the implementation of ISO/IEC Guide 25 and EN 45001, both of which it replaced."

Replace the words "quality system" with the words "management system".

After the first paragraph add the following paragraph:

> "The first edition referred to ISO 9001:1994 and ISO 9002:1994. These standards have been superseded by ISO 9001:2000 which made an alignment of ISO/IEC 17025 necessary. In this second edition, clauses are amended or added only when considered necessary in the light of ISO 9001:2000."

Replace the third paragraph with the following:

> "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."

In the fourth paragraph, delete the words "or ISO 9002".

Replace the fifth paragraph with the following:

"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."

Page 1, subclause 1.4

Replace subclause 1.4 with the following:

"**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 as the basis for certification of laboratories.

NOTE 1 The term 'management system' in this International Standard means the quality, administrative and technical systems that govern the operations of a laboratory.

NOTE 2 Certification of a management system is sometimes also called registration."

Page 1, subclause 1.6

Replace subclause 1.6 with the following:

"**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.

NOTE 1 It might be necessary to explain or interpret certain requirements in this International Standard to ensure that the requirements are applied in a consistent manner. Guidance for establishing applications for specific fields, especially for accreditation bodies (see ISO/IEC 17011) is given in Annex B.

NOTE 2 If a laboratory wishes accreditation for part or all of its testing and calibration activities, it is advised to select an accreditation body that operates in accordance with ISO/IEC 17011."

Page 1, Normative references

Replace this clause with the following:

"The following referenced documents are 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.

ISO/IEC 17000, *Conformity assessment — Vocabulary and general principles*

VIM, *International vocabulary of basic and general terms in metrology*, issued by BIPM, IEC, IFCC, ISO, IUPAC, IUPAP and OIML

NOTE Further related standards, guides, etc. on subjects included in this International Standard are given in the Bibliography."

Page 2, Terms and definitions

Replace "ISO/IEC Guide 2" with "ISO/IEC 17000".

Replace the Note with the following:

> NOTE General definitions related to quality are given in ISO 9000, whereas ISO/IEC 17000 gives definitions specifically related to certification and laboratory accreditation. Where different definitions are given in ISO 9000, the definitions in ISO/IEC 17000 and VIM are preferred."

Page 2, subclause 4.1.2

Replace the word "client" with the word "customer".

Page 2, subclause 4.1.3

Delete the word "laboratory" the first time it appears.

Page 3, subclause 4.1.5, list item a)

Replace the words in list item a) with the following:

> "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);"

Page 3, subclause 4.1.5, list item c)

Replace the word "clients" with the word "customers".

Page 3, subclause 4.1.5, list item i)

Replace the words "quality system" with the words "management system related to quality".

Page 3, subclause 4.1.5

Add the following list item to the end of the list items:

> "k) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the objectives of the management system."

Page 3, subclause 4.1.6

Add the following subclause:

> "**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."

Page 3, subclause 4.2

Replace the words "Quality system" with the words "Management system".

Page 3, subclause 4.2.1

Replace the words "quality system" with the words "management system".

Page 3, subclause 4.2.2

Replace subclause 4.2.2 with the following:

"**4.2.2** The laboratory's management system policies related to quality, 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. The quality policy statement shall be issued under the authority of top management. It shall include at least the following:"

Page 3, subclause 4.2.2, list item a)

Replace the word "clients" with the word "customers".

Page 3, subclause 4.2.2, list item c)

Replace list item c) with the following:

"c) the purpose of the management system related to quality;"

Page 4, subclause 4.2.2, list item e) and Note

Replace list item e) and Note with the following:

"e) the laboratory management's commitment to comply with this International Standard and to continually improve the effectiveness of the management.

NOTE The quality policy statement should be concise and may include the requirement that tests and/or calibrations shall always be carried out in accordance with stated methods and customers' requirements. When the test and/or calibration laboratory is part of a larger organization, some quality policy elements may be in other documents."

Page 4, subclauses 4.2.3 and 4.2.4

Replace the subclauses 4.2.3 and 4.2.4 with the following:

"**4.2.3** Top management shall provide evidence of commitment to the development and implementation of the management system and continually improving its effectiveness.

4.2.4 Top management shall communicate to the organization the importance of meeting customer as well as statutory and regulatory requirements.

4.2.5 The quality manual shall include or make reference to the supporting procedures including technical procedures. It shall outline the structure of the documentation used in the management system.

4.2.6 The roles and responsibilities of technical management and the quality manager, including their responsibility for ensuring compliance with this International Standard, shall be defined in the quality manual.

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."

Page 4, subclause 4.3.1

Replace the words "quality system" with the words "management system".

Page 4, subclause 4.3.1, Note 2

Replace the cross-reference "4.12" with "4.13".

Page 4, subclause 4.3.2.1

Replace the words "quality system" with the words "management system".

Page 4, subclause 4.3.2.3

Replace the words "Quality system" with the words "Management system".

Page 5, subclause 4.3.3.3

Replace the word "documentation " with the word "document ".

Page 5, subclause 4.4.1, list item c)

Replace the word "clients" with the word "customers".

Page 5, subclause 4.4.1

In the sentence after list item c) replace the word "client" with the word "customer".

Page 5, subclause 4.4.1, Note 1

Replace the word "clients" with the word "customers".

Page 5, subclause 4.4.1, Note 3

Replace the word "client" with the word "customer".

Page 5, subclause 4.4.2

Replace the words "client" and "client's" with the words "customer" and "customer's" respectively.

Page 5, subclause 4.4.2, Note

Replace the words "client" and "client's" with the words "customer" and "customer's" respectively.

Page 5, subclause 4.4.4

Replace the word "client" with the word "customer".

Page 6, subclause 4.5.2 and 4.5.3

Replace the word "client" with the word "customer".

Page 6, subclause 4.6.3, Note

Replace the words "quality system" with the words "management system".