

Redline version  
compares Third edition to  
Second edition



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## General requirements for the competence of testing and calibration laboratories

*Exigences générales concernant la compétence des laboratoires  
d'étalonnages et d'essais*

**ITeH STANDARD PREVIEW**  
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This Redline version provides you with a quick and easy way to compare the main changes between this edition of the standard and its previous edition. It doesn't capture all single changes such as punctuation but highlights the modifications providing customers with the most valuable information. Therefore it is important to note that this Redline version is not the official ISO standard and that the users must consult with the clean version of the standard, which is the official standard, for implementation purposes.



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## Foreword

ISO (the International Organization for Standardization) and IEC (the International Electrotechnical Commission) form the specialized system for worldwide 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 fields of technical activity. ISO and IEC technical committees collaborate in fields of mutual interest. Other international is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. 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. ISO and the International Electrotechnical Commission (IEC) develop joint ISO/IEC documents under the management of the ISO Committee on Conformity assessment (ISO/CASCO).

~~International Standards are~~ The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the ~~rules given in~~ editorial rules of the ISO/IEC Directives, Part 2 (see [www.iso.org/directives](http://www.iso.org/directives)).

~~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.~~

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see [www.iso.org/patents](http://www.iso.org/patents)).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

~~ISO/IEC 17025 was prepared by~~ For an explanation on the ISO Committee on ~~voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment (CASCO), as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL:~~ [www.iso.org/iso/foreword.html](http://www.iso.org/iso/foreword.html).

~~It was~~ This document was prepared by the ISO Committee on Conformity Assessment (CASCO) and circulated for voting to the national bodies of both ISO and IEC, and was approved by both organizations.

This ~~second~~ ~~third~~ edition cancels and replaces the ~~first~~ ~~second~~ edition (ISO/IEC 17025:1999/2005), which has been technically revised.

The main changes compared to the previous edition are as follows:

- the risk-based thinking applied in this edition has enabled some reduction in prescriptive requirements and their replacement by performance-based requirements;
- there is greater flexibility than in the previous edition in the requirements for processes, procedures, documented information and organizational responsibilities;
- a definition of “laboratory” has been added (see 3.6).

## Introduction

The first edition (1999) of this International Standard was produced as the result of extensive experience in the implementation of ISO/IEC Guide 25 and EN 45001, both of which it replaced. It contained all of the requirements that testing and calibration laboratories have to meet if they wish to demonstrate that they operate a management system, are technically competent, and are able to generate technically valid results. Laboratories that conform to this document will also operate generally in accordance with the principles of ISO 9001.

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 have been amended or added only when considered necessary in the light of ISO 9001:2000.

Accreditation bodies that recognize the competence of testing and calibration laboratories should use this International Standard as the basis for their accreditation. Clause 4 specifies the requirements for sound management. Clause 5 specifies the requirements for technical competence for the type of tests and/or calibrations the laboratory undertakes.

Growth in the 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. Addressing both risks and opportunities establishes a basis for increasing the effectiveness of the management system, achieving improved results and preventing negative effects. The laboratory is responsible for deciding which risks and opportunities need to be addressed.

The acceptance of testing and calibration results between countries should be facilitated if laboratories comply with this International Standard and if they obtain accreditation from bodies which have entered into mutual recognition agreements with equivalent bodies in other countries using this International Standard.

The use of this International Standard document will facilitate cooperation between laboratories and other bodies, and assist in the exchange of information and experience, and in the harmonization of standards and procedures. The acceptance of results between countries is facilitated if laboratories conform to this document.

In this document, the following verbal forms are used:

- “shall” indicates a requirement;
- “should” indicates a recommendation;
- “may” indicates a permission;
- “can” indicates a possibility or a capability.

Further details can be found in the ISO/IEC Directives, Part 2.

For the purposes of research, users are encouraged to share their views on this document and their priorities for changes to future editions. Click on the link below to take part in the online survey:

[17025\\_ed3\\_usersurvey](#)

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# General requirements for the competence of testing and calibration laboratories

## 1 Scope

~~1.1 This International Standard specifies the general requirements for the competence to carry out tests and/or calibrations, including sampling. It covers testing and calibration performed using standard methods, non-standard methods, and laboratory developed methods.~~

~~1.2 This International Standard is applicable to all organizations performing tests and/or calibrations. These include, for example, first, second and third party laboratories, and laboratories where testing and/or calibration forms part of inspection and product certification.~~

~~This International Standard is applicable to all laboratories regardless of the number of personnel or the extent of the scope of testing and/or calibration activities. When a laboratory does not undertake one or more of the activities covered by this International Standard, such as sampling and the design/development of new methods, the requirements of those clauses do not apply.~~

~~1.3 The notes given provide clarification of the text, examples and guidance. They do not contain requirements and do not form an integral part of this International Standard.~~

~~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.~~

~~1.5 Compliance with regulatory and safety requirements on the operation of laboratories is not covered by this International Standard.~~

~~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. This International Standard 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 should select an accreditation body that operates in accordance with ISO/IEC 17011.~~

This document specifies the general requirements for the competence, impartiality and consistent operation of laboratories.

This document is applicable to all organizations performing laboratory activities, regardless of the number of personnel.

Laboratory customers, regulatory authorities, organizations and schemes using peer-assessment, accreditation bodies, and others use this document in confirming or recognizing the competence of laboratories.

## 2 Normative references

The following ~~referenced~~ documents are ~~indispensable for the application of~~ referred to in the text in such a way that some or all of their content constitutes requirements 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~~ ISO/IEC Guide 99, ~~International vocabulary of basic and general terms in metrology~~ metrology — Basic and general concepts and associated terms (VIM)<sup>1)</sup>, issued by BIPM, IEC, IFCC, ISO, IUPAC, IUPAP and OIML

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

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

## 3 Terms and definitions

For the purposes of this document, the ~~relevant~~ terms and definitions given in ISO/IEC ~~17000~~ Guide 99 and ISO/IEC 17000 and ~~VIM~~ the following apply.

~~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.~~

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at <https://www.iso.org/obp>

— IEC Electropedia: available at <http://www.electropedia.org/>

### 3.1 impartiality

presence of objectivity

Note 1 to entry: Objectivity means that conflicts of interest do not exist, or are resolved so as not to adversely influence subsequent activities of the *laboratory* (3.6).

Note 2 to entry: Other terms that are useful in conveying the element of impartiality include “freedom from conflict of interests”, “freedom from bias”, “lack of prejudice”, “neutrality”, “fairness”, “open-mindedness”, “even-handedness”, “detachment”, “balance”.

[SOURCE: ISO/IEC 17021-1:2015, 3.2, modified — The words “the certification body” have been replaced by “the laboratory” in Note 1 to entry, and the word “independence” has been deleted from the list in Note 2 to entry.]

### 3.2 complaint

expression of dissatisfaction by any person or organization to a *laboratory* (3.6), relating to the activities or results of that laboratory, where a response is expected

[SOURCE: ISO/IEC 17000:2004, 6.5, modified — The words “other than appeal” have been deleted, and the words “a conformity assessment body or accreditation body, relating to the activities of that body” have been replaced by “a laboratory, relating to the activities or results of that laboratory”.]

1) Also known as JCGM 200.

**3.3****interlaboratory comparison**

organization, performance and evaluation of measurements or tests on the same or similar items by two or more laboratories in accordance with predetermined conditions

[SOURCE: ISO/IEC 17043:2010, 3.4]

**3.4****intralaboratory comparison**

organization, performance and evaluation of measurements or tests on the same or similar items within the same *laboratory* (3.6) in accordance with predetermined conditions

**3.5****proficiency testing**

evaluation of participant performance against pre-established criteria by means of *interlaboratory comparisons* (3.3)

[SOURCE: ISO/IEC 17043:2010, 3.7, modified — Notes to entry have been deleted.]

**3.6****laboratory**

body that performs one or more of the following activities:

- testing;
- calibration;
- sampling, associated with subsequent testing or calibration

Note 1 to entry: In the context of this document, “laboratory activities” refer to the three above-mentioned activities.

**3.7****decision rule**

rule that describes how measurement uncertainty is accounted for when stating conformity with a specified requirement

**3.8****verification**

provision of objective evidence that a given item fulfils specified requirements

EXAMPLE 1 Confirmation that a given reference material as claimed is homogeneous for the quantity value and measurement procedure concerned, down to a measurement portion having a mass of 10 mg.

EXAMPLE 2 Confirmation that performance properties or legal requirements of a measuring system are achieved.

EXAMPLE 3 Confirmation that a target measurement uncertainty can be met.

Note 1 to entry: When applicable, measurement uncertainty should be taken into consideration.

Note 2 to entry: The item may be, for example, a process, measurement procedure, material, compound, or measuring system.

Note 3 to entry: The specified requirements may be, for example, that a manufacturer's specifications are met.

Note 4 to entry: Verification in legal metrology, as defined in VIML, and in conformity assessment in general, pertains to the examination and marking and/or issuing of a verification certificate for a measuring system.

Note 5 to entry: Verification should not be confused with calibration. Not every verification is a *validation* (3.9).

Note 6 to entry: In chemistry, verification of the identity of the entity involved, or of activity, requires a description of the structure or properties of that entity or activity.

[SOURCE: ISO/IEC Guide 99:2007, 2.44]

### 3.9 validation

verification (3.8), where the specified requirements are adequate for an intended use

EXAMPLE A measurement procedure, ordinarily used for the measurement of mass concentration of nitrogen in water, may be validated also for measurement of mass concentration of nitrogen in human serum.

[SOURCE: ISO/IEC Guide 99:2007, 2.45]

## 4 General requirements

### 4.1 Impartiality

4.1.1 Laboratory activities shall be undertaken impartially and structured and managed so as to safeguard impartiality.

4.1.2 The laboratory management shall be committed to impartiality.

4.1.3 The laboratory shall be responsible for the impartiality of its laboratory activities and shall not allow commercial, financial or other pressures to compromise impartiality.

4.1.4 The laboratory shall identify risks to its impartiality on an on-going basis. This shall include those risks that arise from its activities, or from its relationships, or from the relationships of its personnel. However, such relationships do not necessarily present a laboratory with a risk to impartiality.

NOTE A relationship that threatens the impartiality of the laboratory can be based on ownership, governance, management, personnel, shared resources, finances, contracts, marketing (including branding), and payment of a sales commission or other inducement for the referral of new customers, etc.

4.1.5 If a risk to impartiality is identified, the laboratory shall be able to demonstrate how it eliminates or minimizes such risk.

### 4.2 Confidentiality

4.2.1 The laboratory shall be responsible, through legally enforceable commitments, for the management of all information obtained or created during the performance of laboratory activities. The laboratory shall inform the customer in advance, of the information it intends to place in the public domain. Except for information that the customer makes publicly available, or when agreed between the laboratory and the customer (e.g. for the purpose of responding to complaints), all other information is considered proprietary information and shall be regarded as confidential.

4.2.2 When the laboratory is required by law or authorized by contractual arrangements to release confidential information, the customer or individual concerned shall, unless prohibited by law, be notified of the information provided.

4.2.3 Information about the customer obtained from sources other than the customer (e.g. complainant, regulators) shall be confidential between the customer and the laboratory. The provider (source) of this information shall be confidential to the laboratory and shall not be shared with the customer, unless agreed by the source.

4.2.4 Personnel, including any committee members, contractors, personnel of external bodies, or individuals acting on the laboratory's behalf, shall keep confidential all information obtained or created during the performance of laboratory activities, except as required by law.

## 4.5 Management Structural requirements

5.1 The laboratory shall be a legal entity, or a defined part of a legal entity, that is legally responsible for its laboratory activities.

NOTE For the purposes of this document, a governmental laboratory is deemed to be a legal entity on the basis of its governmental status.

5.2 The laboratory shall identify management that has overall responsibility for the laboratory.

5.3 The laboratory shall define and document the range of laboratory activities for which it conforms with this document. The laboratory shall only claim conformity with this document for this range of laboratory activities, which excludes externally provided laboratory activities on an ongoing basis.

5.4 Laboratory activities shall be carried out in such a way as to meet the requirements of this document, the laboratory's customers, regulatory authorities and organizations providing recognition. This shall include laboratory activities performed in all its permanent facilities, at sites away from its permanent facilities, in associated temporary or mobile facilities or at a customer's facility.

### 4.1 Organization

~~4.1.1 The laboratory or the organization of which it is part shall be an entity that can be held legally responsible.~~

~~4.1.2 It is the responsibility of the laboratory to carry out its testing and calibration activities in such a way as to meet the requirements of this International Standard and to satisfy the needs of the customer, the regulatory authorities or organizations providing recognition.~~

~~4.1.3 The management system shall cover work carried out in the laboratory's permanent facilities, at sites away from its permanent facilities, or in associated temporary or mobile facilities.~~

~~4.1.4 If the laboratory is part of an organization performing activities other than testing and/or calibration, the responsibilities of key personnel in the organization that have an involvement or influence on the testing and/or calibration activities of the laboratory shall be defined in order to identify potential conflicts of interest.~~

~~NOTE 1 Where a laboratory is part of a larger organization, the organizational arrangements should be such that departments having conflicting interests, such as production, commercial marketing or financing do not adversely influence the laboratory's compliance with the requirements of this International Standard.~~

~~NOTE 2 If the laboratory wishes to be recognized as a third-party laboratory, it should be able to demonstrate that it is impartial and that it and its personnel are free from any undue commercial, financial and other pressures which might influence their technical judgement. The third party testing or calibration laboratory should not engage in any activities that may endanger the trust in its independence of judgement and integrity in relation to its testing or calibration activities.~~

#### 4.1.5 The laboratory shall

- ~~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);~~
- ~~b) have arrangements to ensure that its management and personnel are free from any undue internal and external commercial, financial and other pressures and influences that may adversely affect the quality of their work;~~