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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*

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## Foreword

ISO (the International Organization for Standardization) 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, also take part in the work. In the field of conformity assessment, ISO and the International Electrotechnical Commission (IEC) develop joint ISO/IEC documents under the management of the ISO Committee on Conformity assessment (ISO/CASCO).

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 editorial rules of the ISO/IEC Directives, Part 2 (see [www.iso.org/directives](http://www.iso.org/directives)).

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.

For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, 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).

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 third edition cancels and replaces the second edition (ISO/IEC 17025:2005), 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

This document has been developed with the objective of promoting confidence in the operation of laboratories. This document contains requirements for laboratories to enable them to demonstrate they operate competently, and are able to generate valid results. Laboratories that conform to this document will also operate generally in accordance with the principles of ISO 9001.

This document requires the laboratory to plan and implement actions to address risks and opportunities. 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 use of this 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](https://standards.iteh.ai/catalog/standards/sist/30679ef7-3744-4e68-8a8d-07e8c2af1c1e/iso-iec-17025-2017) <https://standards.iteh.ai/catalog/standards/sist/30679ef7-3744-4e68-8a8d-07e8c2af1c1e/iso-iec-17025-2017>

# General requirements for the competence of testing and calibration laboratories

## 1 Scope

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 documents are 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 Guide 99, *International vocabulary of metrology — Basic and general concepts and associated terms (VIM)*<sup>1)</sup>

ISO/IEC 17000, *Conformity assessment — Vocabulary and general principles*  
<https://standards.iteh.ai/catalog/standards/sist/30679ef7-3744-4e68-8a8d-07e8c2aflc1e/iso-iec-17025-2017>

## 3 Terms and definitions

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

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.]

1) Also known as JCGM 200.

**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”.]

**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.

## 5 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.

**5.5** The laboratory shall:

- a) define the organization and management structure of the laboratory, its place in any parent organization, and the relationships between management, technical operations and support services;
- b) specify the responsibility, authority and interrelationship of all personnel who manage, perform or verify work affecting the results of laboratory activities;
- c) document its procedures to the extent necessary to ensure the consistent application of its laboratory activities and the validity of the results.

**5.6** The laboratory shall have personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties, including:

- a) implementation, maintenance and improvement of the management system;
- b) identification of deviations from the management system or from the procedures for performing laboratory activities;
- c) initiation of actions to prevent or minimize such deviations;
- d) reporting to laboratory management on the performance of the management system and any need for improvement;
- e) ensuring the effectiveness of laboratory activities.

**5.7** Laboratory management shall ensure that:

- a) communication takes place regarding the effectiveness of the management system and the importance of meeting customers' and other requirements;
- b) the integrity of the management system is maintained when changes to the management system are planned and implemented.

## **6 Resource requirements**

### **6.1 General**

The laboratory shall have available the personnel, facilities, equipment, systems and support services necessary to manage and perform its laboratory activities.

### **6.2 Personnel**

**6.2.1** All personnel of the laboratory, either internal or external, that could influence the laboratory activities shall act impartially, be competent and work in accordance with the laboratory's management system.

**6.2.2** The laboratory shall document the competence requirements for each function influencing the results of laboratory activities, including requirements for education, qualification, training, technical knowledge, skills and experience.

**6.2.3** The laboratory shall ensure that the personnel have the competence to perform laboratory activities for which they are responsible and to evaluate the significance of deviations.

**6.2.4** The management of the laboratory shall communicate to personnel their duties, responsibilities and authorities.

**6.2.5** The laboratory shall have procedure(s) and retain records for:

- a) determining the competence requirements;
- b) selection of personnel;
- c) training of personnel;
- d) supervision of personnel;
- e) authorization of personnel;
- f) monitoring competence of personnel.

**6.2.6** The laboratory shall authorize personnel to perform specific laboratory activities, including but not limited to, the following:

- a) development, modification, verification and validation of methods;
- b) analysis of results, including statements of conformity or opinions and interpretations;
- c) report, review and authorization of results.

### 6.3 Facilities and environmental conditions

**6.3.1** The facilities and environmental conditions shall be suitable for the laboratory activities and shall not adversely affect the validity of results.

**NOTE** Influences that can adversely affect the validity of results can include, but are not limited to, microbial contamination, dust, electromagnetic disturbances, radiation, humidity, electrical supply, temperature, sound and vibration.

**6.3.2** The requirements for facilities and environmental conditions necessary for the performance of the laboratory activities shall be documented.

**6.3.3** The laboratory shall monitor, control and record environmental conditions in accordance with relevant specifications, methods or procedures or where they influence the validity of the results.

**6.3.4** Measures to control facilities shall be implemented, monitored and periodically reviewed and shall include, but not be limited to:

- a) access to and use of areas affecting laboratory activities;
- b) prevention of contamination, interference or adverse influences on laboratory activities;
- c) effective separation between areas with incompatible laboratory activities.

**6.3.5** When the laboratory performs laboratory activities at sites or facilities outside its permanent control, it shall ensure that the requirements related to facilities and environmental conditions of this document are met.

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### 6.4 Equipment

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**6.4.1** The laboratory shall have access to equipment (including, but not limited to, measuring instruments, software, measurement standards, reference materials, reference data, reagents, consumables or auxiliary apparatus) that is required for the correct performance of laboratory activities and that can influence the results.

**NOTE 1** A multitude of names exist for reference materials and certified reference materials, including reference standards, calibration standards, standard reference materials and quality control materials. ISO 17034 contains additional information on reference material producers (RMPs). RMPs that meet the requirements of ISO 17034 are considered to be competent. Reference materials from RMPs meeting the requirements of ISO 17034 are provided with a product information sheet/certificate that specifies, amongst other characteristics, homogeneity and stability for specified properties and, for certified reference materials, specified properties with certified values, their associated measurement uncertainty and metrological traceability.

**NOTE 2** ISO Guide 33 provides guidance on the selection and use of reference materials. ISO Guide 80 provides guidance to produce in-house quality control materials.

**6.4.2** When the laboratory uses equipment outside its permanent control, it shall ensure that the requirements for equipment of this document are met.

**6.4.3** The laboratory shall have a procedure for handling, transport, storage, use and planned maintenance of equipment in order to ensure proper functioning and to prevent contamination or deterioration.

**6.4.4** The laboratory shall verify that equipment conforms to specified requirements before being placed or returned into service.