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Conformity assessment — General requirements for the competence of proficiency testing providers

IMPORTANT — Please use this updated version dated 2023-01-17, and discard any previous version of this FDIS. Changes have been made in 3.3, 4.2.1, 6.2.4, 7.3.2.4, 7.3.2.5 and 7.3.2.6.

This draft is submitted to a parallel vote in ISO and in IEC.

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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 organizations, governmental and non-governmental, in liaison with ISO and IEC, also take part in the work.

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 document 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 or www.iec.ch/members_experts/refdocs).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO and IEC 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) or the IEC list of patent declarations received (see https://patents.iec.ch).

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

For an explanation of 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 www.iso.org/iso/foreword.html. In the IEC, see www.iec.ch/understanding-standards.

This document was prepared by the ISO Committee on Conformity Assessment (CASCO).

This second edition cancels and replaces the first edition (ISO/IEC 17043:2010), which has been technically revised.

The main changes are as follows:

— harmonization with ISO/IEC 17025:2017, including technical requirements and structure;

— harmonization with ISO 13528:2022 in terms of terminology;

— incorporation of requirements from ISO/CASCO PROC 33;

— inclusion of the requirement that testing activities, calibration activities and PT item production conform to the relevant requirements of appropriate ISO conformity assessment standards;

— deletion of Annex C and revision of Annexes A and B.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html and www.iec.ch/national-committees.

Introduction

Proficiency testing (PT) is widely recognized as an essential tool for demonstrating the competence of conformity assessment bodies. PT can provide evidence of competence and it can be an indicator of an underlying or emerging problem. This document is intended to promote confidence in the operations of PT providers. It contains requirements for PT providers to enable them to demonstrate that they operate competently and can generate valid evaluations of participant performance.

PT involves the use of interlaboratory comparisons for the evaluation of laboratory performance. The definition of "interlaboratory comparison" (see 3.4) broadens the use of both the terms "laboratories" and "measurements and tests" for the purposes of this document to include all types of conformity assessment bodies and their activities, respectively. The term "method" as used in this document can be considered synonymous with the term "measurement procedure" as defined in ISO/IEC Guide 99.

There are many different purposes for interlaboratory comparisons, which can be addressed by PT schemes, including but not limited to:

a) evaluation of the performance of laboratories for specific measurements, tests, calibrations, examinations, inspections or sampling;

b) identification of problems in laboratories that, for example, can be related to measurement or test methods, effectiveness of training and supervision of personnel, or calibration of equipment;

c) establishment of the effectiveness of measurement or test methods and the comparability of measurement and test results;

d) provision of additional confidence to users of measurement and test results;

e) identification of differences in measurement and test results;

f) education of participating laboratories based on the outcomes of such comparisons;

g) validation of measurement uncertainty claims.

For the following types of interlaboratory comparisons, the term PT does not usually apply because laboratory competence must be established in advance, in order to ensure the validity of measurements or tests as well as the metrological traceability of assigned values:

h) evaluation of the performance characteristics of a measurement or test method (often described as collaborative trials);

i) assignment of values to reference materials;

j) support for statements of the equivalence of measurements of National Metrology Institutes (NMIs), or their Designated Institutes (DIs) through "key and supplementary comparisons", conducted on behalf of the International Bureau of Weights and Measures (BIPM) and associated Regional Metrology Organizations (RMOs).

It is recognized that interlaboratory comparisons for purposes h), i) and j) can contribute to independent demonstrations of laboratory competence. The requirements of this document can be applied to many of the technical planning and operational activities for these interlaboratory comparisons.

This document also requires PT providers to plan and implement actions to address risks and opportunities, based on their experience. Addressing both risks and opportunities establishes a basis for increasing the effectiveness of the management system, achieving improved results and preventing negative events. The PT provider is responsible for deciding which risks and opportunities to address.

The need for ongoing confidence in laboratory performance is essential not only for laboratories and their customers but also for other interested parties, such as regulators, accreditation bodies and other organizations that specify requirements for laboratories. Most of the requirements in this document apply to those evolving areas, especially regarding management, planning and design, personnel,

assuring validity of results and performance evaluations, confidentiality and other aspects, as appropriate.

This document intended to provide a consistent basis for all interested parties to determine the competence of organizations that provide PT.

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.

Conformity assessment — General requirements for the competence of proficiency testing providers

1 Scope

This document specifies general requirements for the competence and impartiality of proficiency testing (PT) providers and consistent operation of all proficiency testing schemes. This document can be used as a basis for specific technical requirements for particular fields of application.

Users of proficiency testing schemes, regulatory authorities, organizations and schemes using peer-assessment, accreditation bodies and others can use these requirements in confirming or recognizing the competence of proficiency testing providers.

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 17000, *Conformity assessment — Vocabulary and general principles*

ISO/IEC 17025:2017, *General requirements for the competence of testing and calibration laboratories*

ISO 17034, *General requirements for the competence of reference material producers*

ISO/IEC Guide 99, *International vocabulary of metrology — Basic and general concepts and associated terms (VIM)*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO/IEC 17000 and ISO/IEC Guide 99 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 https://www.electropedia.org/

3.1
assigned value
value attributed to a particular property or characteristic of a *proficiency testing item* (3.8)

[SOURCE: ISO 13528:2022, 3.3, modified — The words "or characteristic" have been added and the word “test” has been replaced with “testing”.]

3.2
consensus value
value derived from a collection of results in an *interlaboratory comparison* (3.4)

Note 1 to entry: The phrase “consensus value” is typically used to describe estimates of location and dispersion derived from *participant* (3.6) results in a round of a *proficiency testing scheme* (3.11), but may also be used to refer to values derived from results of a specified subset of such results or, for example, from a number of expert laboratories.

[SOURCE: ISO 13528:2022, 3.11.]

3.3
customer
client
organization or individual for which a *proficiency testing scheme* (3.11) is provided through a contractual arrangement

Note 1 to entry: The term “client” is an alternative term for “customer” used in parts of this document and these terms are regarded as having the same definition.

3.4
interlaboratory comparison
design, performance and evaluation of measurements or tests on the same or similar items by two or more laboratories in accordance with predetermined conditions

Note 1 to entry: The term “laboratories” is used in this document to cover all organizations that provide information on items based on experimental observation, including measurement, testing, calibration, examination, sampling and inspection.

Note 2 to entry: The term “measurements or tests” is used throughout this document to apply to any activities undertaken by the proficiency testing *participants* (3.6) that are subject to the *proficiency testing* (3.7), whether quantitative, qualitative or interpretative, unless otherwise qualified.

Note 3 to entry: Interlaboratory comparisons that involve measurements convey more insight regarding performance when measurement uncertainty is considered.

[SOURCE: ISO 13528:2022, 3.1, modified — The word “organization” has been replaced with “design” and the Notes to the entry have been added.]

3.5
outlier
member of a set of values which is inconsistent with other members of that set

Note 1 to entry: An outlier can arise by chance from the expected population, originate from a different population, or be the result of an incorrect recording or other gross error.

Note 2 to entry: Many *proficiency testing schemes* (3.11) use the term outlier to designate a result that generates an action signal. This is not the intended use of the term. While outliers will usually generate action signals, it is possible to have action signals from results that are not outliers.

[SOURCE: ISO 13528:2022, 3.12, modified — The word “blunder” has been replaced with “gross error” in Note 1 to entry.]

3.6
participant
person or organization that undertakes activities related to *proficiency testing* (3.7) and submits their results for performance evaluation by the *proficiency testing provider* (3.9)

3.7
proficiency testing
PT
evaluation of *participant* (3.6) performance against pre-established criteria by means of *interlaboratory comparisons* (3.4)

Note 1 to entry: Further information regarding the design of various *proficiency testing schemes* (3.11) is provided in Annex A.

3.8
proficiency testing item
PT item
sample, product, artefact, reference material, piece of equipment, measurement standard, object, image, data set or other information used for *proficiency testing* (3.7)

3.9
proficiency testing provider
PT provider
organization which takes responsibility for all activities in the development and operation of a *proficiency testing scheme* (3.11)

3.10
proficiency testing round
PT round
single complete sequence of *proficiency testing* (3.7), including the evaluation and reporting of the performance of *participants* (3.6)

3.11
proficiency testing scheme
PT scheme
proficiency testing (3.7) designed and operated in one or more *proficiency testing rounds* (3.10) for a specified area of measurement, testing, calibration, examination, sampling or inspection

Note 1 to entry: A proficiency testing scheme can cover a particular type of activity or a number of activity types within the same area.

3.12
standard deviation for proficiency assessment
measure of dispersion used in the evaluation of results of *proficiency testing* (3.7), based on the available information

Note 1 to entry: The standard deviation for proficiency assessment can be interpreted as the population standard deviation of results from a hypothetical population of *participants* (3.6) performing exactly in accordance with requirements.

Note 2 to entry: The standard deviation for proficiency assessment applies only to ratio and interval scale results.

Note 3 to entry: Not all *proficiency testing schemes* (3.11) evaluate performance based on the dispersion of results.

[SOURCE: ISO 13528:2022, 3.4, modified — The words “based on the available information” have been added in the definition; the word “This” has been replaced with “The standard deviation for proficiency assessment” and the word “laboratories” has been replaced with “participants” in Note 1 to entry.]

4 General requirements

4.1 Impartiality

4.1.1 PT activities shall be undertaken impartially.

4.1.2 The PT provider shall be structured and managed so as to safeguard impartiality.

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

4.1.4 The PT provider shall monitor its activities and its relationships to identify threats to its impartiality. This monitoring shall include the relationships of its personnel.

NOTE A relationship can be based on ownership, governance, management, personnel, shared resources, finances, contracts or marketing (including branding). Such relationships do not necessarily present a PT provider with a threat to impartiality.

4.1.5 If a threat to impartiality is identified, its effect shall be eliminated or minimized so that the impartiality is not compromised.

4.1.6 The PT provider shall have top management commitment to impartiality.

4.2 Confidentiality

4.2.1 The PT provider shall be responsible, through legally enforceable agreements, for the management of all information obtained or created during the performance of PT activities. The PT provider shall inform the client in advance of the information it intends to place in the public domain. Except for information that the client makes publicly available, or when agreed between the PT provider and the client, all other information is considered proprietary information and shall be regarded as confidential.

NOTE The terms "proprietary" and "confidential" do not preclude publication for academic and new insights of information purposes, provided that neither clients nor participants can be identified, including by inference.

4.2.2 When the PT provider is required by law or authorized by contractual arrangements to release confidential information, the client concerned shall be notified of the information released, unless prohibited by law.

4.2.3 Information about the participant or customer from a source other than the participant or customer (e.g. complainant or regulator) shall be kept confidential by the PT provider. The identity of the source shall be kept confidential by the PT provider and shall not be shared with the participant or the customer, unless agreed by the source.

4.2.4 Personnel, including any committee members, contractors, personnel of external bodies, or persons acting on the PT provider's behalf, shall keep confidential all information obtained or created during the performance of the PT activities.

4.2.5 The identity of participants in a PT scheme shall be confidential and known only to persons involved in the operation of the PT scheme, unless the participant or the customer waives confidentiality.

5 Structural requirements

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

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

5.2 The PT provider shall identify management that has overall responsibility for the PT activities.

5.3 The PT provider shall define and document the PT schemes for which it conforms with this document. The PT provider shall only claim conformity with this document for those PT schemes.

5.4 The PT provider shall carry out PT activities in such a way so as to meet the requirements of this document and address the requirements of participants, customers, regulatory authorities, and organizations providing recognition. These requirements apply to all PT activities performed in its permanent facilities and any other facility or site.

5.5 The PT provider shall:

a) define its organization and management structure, its place in any parent organization and the relationships between the management, technical operations and support services;

b) specify the responsibility, authority and interrelationships of all personnel who manage, perform or verify work affecting the results of its PT activities;

c) document its procedures to the extent necessary to ensure the consistent application and validity of its PT activities.

5.6 The PT provider 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 while performing the PT activities;

c) initiation of actions to prevent or minimize such deviations;

d) reporting to its management on the performance of the management system and any need for improvement;

e) ensuring the effectiveness of the PT activities.

5.7 The PT provider management shall ensure that:

a) communication takes place regarding the effectiveness of the management system and the importance of meeting the requirements of participants, customers, regulatory authorities and organizations providing recognition;

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

6.1.1 The PT provider shall have access to the personnel, facilities, equipment, systems and support services necessary to manage and perform its PT activities.

6.1.2 Measurements or tests conducted under the responsibility of the PT provider, related to PT item characterization or for assessing homogeneity and stability, shall be conducted in accordance with the relevant requirements of ISO/IEC 17025.

NOTE 1 The relevant requirements are requirements that relate to the validity of the measurement or test results, which can impact the validity of PT activities (e.g. metrological traceability). They are not intended to include management system requirements or other requirements unrelated to the PT activities.

NOTE 2 In the medical area, the relevant requirements of ISO 15189 apply in place of ISO/IEC 17025.

6.1.3 Where the PT item is a material that meets the definition of "reference material", it shall be produced under conditions that meet the relevant requirements of ISO 17034.

NOTE 1 Such materials include reference materials for quality control (e.g. chemical solutions with or without reference values) and reference materials with certified property values (CRMs).

NOTE 2 The relevant requirements are requirements that relate to the validity of operations to produce a reference material that directly impacts the PT activities (e.g. mixing, or handling and storage). They are not intended to include management system requirements or other requirements not directly related to the PT activities (e.g. contents of certificates).

NOTE 3 In the medical area, the relevant requirements of ISO 15194 can apply for CRMs in place of ISO 17034, when applicable.