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CABPUB/188/CD

2020-10-23

INTERNATIONAL ELECTROTECHNICAL COMMISSION

DRAFT ISO/IEC CONFORMITY ASSESSMENT PUBLICATIONS THROUGH THE IEC CONFORMITY ASSESSMENT BOARD (CAB)

SUBJECT

ISO/IEC CD 17043 Conformity assessment – General requirements for the competence of proficiency testing providers

BACKGROUND

ISO/CASCO WG 57 has prepared the attached CD.

This document has been prepared to provide a consistent basis for all interested parties to determine the competence of organizations that provide proficiency testing. In doing so it replaces ISO/IEC 17043:2010. This document has preserved and updated the principles for the operation of proficiency testing described in the 1st edition of ISO/IEC 17043:2010.

Please note that the CD ballot (Committee Draft (CD) Ballot – ISO/IEC 17043) from ISO/CASCO (who manages the development of this standard) has, exceptionally, included **two separate questions** in their CD.

IEC has preferred to separate these two questions into two separate documents.

This document will treat the normal CD commenting aspects, while a second IEC document, CABPUB/189/Q, will treat the issue of changing the name of the standard (to be aligned with the ISO/IEC 17000 series naming convention).

IEC National Committees are invited to comment on the Committee Draft.

The ballot period set by ISO for ISO/IEC CD 17043 starts on 2020-10-20 with a closing date on 2020-12-15. The IEC commenting period starts on 2020-10-23 and closes on 2020-12-18.

ACTION

National Committees are invited to comment on CABPUB/188/CD no later than **2020-12-18**, using the IEC form **and stating whether their comments are identical to the ones made sent to ISO/CASCO**.

Please note that to facilitate the review, the "grey" text in the CD indicates the ISO/CASCO mandatory wording from the PROC 33, that cannot be modified.

National Committees are strongly encouraged to consult the IECEE, IECQ, IECEx and IECRE communities in their country when developing their national position on this draft.

ISO/IEC CD1 17043-:20XX(E)

ISO CASCO/WG57

Secretariat: ISO CS

Conformity assessment — General requirements for the competence of proficiency testing providers¹

CD1

Warning for WDs and CDs

This document is not an ISO International Standard. It is distributed for review and comment. It is subject to change without notice and may not be referred to as an International Standard.

Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

¹ If ISO/CASCO and IEC Members disapprove to extend the scope of revision to the title, the title as stated in the current version will be retained: Conformity assessment — General requirements for proficiency testing.

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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).

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 <http://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.

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 compared to the previous edition are as follows:

- alignment with ISO/IEC 17025:2017, ISO 13528:2015;
- inclusion of requirement from CAS/PROC/33;
- inclusion of requirement that testing activities, calibration activities and proficiency test item production conform to the relevant requirements of appropriate ISO conformity assessment standards.

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.

Introduction

Interlaboratory comparisons are widely used for a number of purposes and their use is increasing internationally. Typical purposes for interlaboratory comparisons include:

- a) evaluation of the performance of laboratories for specific tests or measurements and monitoring laboratories' continuing performance;
- b) identification of problems in laboratories and initiation of actions for improvement which, for example, may be related to inadequate test or measurement procedures, effectiveness of staff training and supervision, or calibration of equipment;
- c) establishment of the effectiveness and comparability of test or measurement methods;
- d) provision of additional confidence to laboratory customers;
- e) identification of interlaboratory differences;
- f) education of participating laboratories based on the outcomes of such comparisons;
- g) validation of uncertainty claims;
- h) evaluation of the performance characteristics of a measurement method – often described as collaborative trials;
- i) assignment of values to reference materials and assessment of their suitability for use in specific test or measurement procedures; and
- j) support for statements of the equivalence of measurements of National Metrology Institutes through “key comparisons” and supplementary comparisons conducted on behalf of the International Bureau of Weights and Measurement (BIPM) and associated regional metrology organizations.

Proficiency testing involves the use of interlaboratory comparisons for the determination of laboratory performance, as listed in a) to g) above. Proficiency testing does not usually address h), i) and j) because laboratory competence is assumed in these applications, but these applications can be used to provide independent demonstrations of laboratory competence. The requirements of this document can be applied to many of the technical planning and operational activities for h), i) and j).

The need for ongoing confidence in laboratory performance is not only essential for laboratories and their customers but also for other interested parties, such as regulators, laboratory 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 quality, confidentiality, and other aspects, as appropriate.

This document has been prepared to provide a consistent basis for all interested parties to determine the competence of organizations that provide proficiency testing. In doing so it replaces ISO/IEC 17043:2010. This document has preserved and updated the principles for the operation of proficiency testing described in the 1st edition of ISO/IEC 17043:2010. This edition has revised the content of Annexes A to C on typical types of proficiency testing schemes, guidance on appropriate statistical methods, selection and use of proficiency testing schemes by laboratories, accreditation bodies, regulatory bodies, and other interested parties. Revisions in Annex B on statistical methods are

intended to conform to terminology and accepted practices in ISO 13528:XXX, Statistical methods for use in proficiency testing by interlaboratory comparisons.

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: XXXX (to be developed by the Secretariat later)

1 Scope

This document specifies general requirements for the competence and impartiality of proficiency testing 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 17000:2020, *Conformity assessment — Vocabulary and general principles*

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 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](https://www.iso.org/obp)

— IEC Electropedia: available at [http:// www.electropedia .org/](http://www.electropedia.org/)

3.1

assigned value

value attributed to a particular property of a proficiency test item

3.2

coordinator

one or more individuals with responsibility for organizing and managing all of the activities involved in the operation of a proficiency testing scheme

3.3

customer

organization or individual for which a proficiency testing scheme is provided through a contractual arrangement

3.4

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

3.5

outlier

observation in a set of data that appears to be inconsistent with the remainder of that set

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

3.6

participant

laboratory, organization or individual that receives proficiency test items and submits results for review by the proficiency testing provider

Note 1 to entry: In some cases, the participant can be an inspection body.

3.7

proficiency testing

evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons

Note 1 to entry: For the purposes of this document, the term “proficiency testing” is taken in its widest sense and includes, but is not limited to:

- a) quantitative scheme — where the objective is to quantify one or more measurands of the proficiency test item;
- b) qualitative scheme — where the objective is to identify or describe one or more characteristics of the proficiency test item;
- c) sequential scheme — where one or more proficiency test items are distributed sequentially for testing or measurement and returned to the proficiency testing provider at intervals;
- d) simultaneous scheme — where proficiency test items are distributed for concurrent testing or measurement within a defined time period;
- e) single occasion exercise — where proficiency test items are provided on a single occasion;
- f) continuous scheme — where proficiency test items are provided at regular intervals;
- g) sampling — where samples are taken for subsequent analysis; and
- h) data transformation and interpretation — where sets of data or other information are furnished and the information is processed to provide an interpretation (or other outcome).

Note 2 to entry: Some providers of proficiency testing in the medical area use the term “External Quality Assessment (EQA)” for their proficiency testing schemes, or for their broader programmes, or both (see Annex A). The requirements of document cover only those EQA activities that meet the definition of proficiency testing.

3.8

proficiency test item

sample, product, artefact, reference material, piece of equipment, measurement standard, data set or other information used for proficiency testing

3.9

proficiency testing provider (PT provider)

organization which takes responsibility for all tasks in the development and operation of a proficiency testing scheme

3.10

proficiency testing round

single complete sequence of distribution of proficiency test items, and the evaluation and reporting of results to the participants

3.11

proficiency testing scheme

proficiency testing designed and operated in one or more rounds for a specified area of testing, measurement, calibration or inspection

Note 1 to entry: A proficiency testing scheme might cover a particular type of test, calibration, inspection or a number of tests, calibrations or inspections on proficiency test items.

3.12

robust statistical method

robust statistical method that is insensitive to small departures from underlying assumptions surrounding an underlying probabilistic model

3.13

standard deviation for proficiency assessment

measure of dispersion used in the evaluation of results of proficiency testing, based on the available information

Note 1 to entry: The standard deviation applies only to ratio and differential scale results.

Note 2 to entry: Not all proficiency testing schemes evaluate proficiency based on the dispersion of results.

3.14

metrological traceability

property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty

Note 1 to entry: For this definition, a “reference” can be a definition of a measurement unit through its practical realization, or a measurement procedure including the measurement unit for a non-ordinal quantity, or a measurement standard.

Note 2 to entry: Metrological traceability requires an established calibration hierarchy.

Note 3 to entry: Specification of the reference must include the time at which this reference was used in establishing the calibration hierarchy, along with any other relevant metrological information about the reference, such as when the first calibration in the calibration hierarchy was performed.

Note 4 to entry: For measurements with more than one input quantity in the measurement model, each of the input quantity values should itself be metrologically traceable and the calibration hierarchy involved may form a branched structure or a network. The effort involved in establishing metrological traceability for each input quantity value should be commensurate with its relative contribution to the measurement result.

Note 5 to entry: Metrological traceability of a measurement result does not ensure that the measurement uncertainty is adequate for a given purpose or that there is an absence of mistakes.

Note 6 to entry: A comparison between two measurement standards may be viewed as a calibration if the comparison is used to check and, if necessary, correct the quantity value and measurement uncertainty attributed to one of the measurement standards.

Note 7 to entry: The abbreviated term “traceability” is sometimes used to mean “metrological traceability” as well as other concepts, such as “sample traceability” or “document traceability” or “instrument traceability” or “material traceability”, where the history (“trace”) of an item is meant. Therefore, the full term of “metrological traceability” is preferred if there is any risk of confusion.

[ISO/IEC Guide 99:2007, definition 2.41, modified — Note 7 to entry has been deleted.]]

3.15

measurement uncertainty **uncertainty of measurement** **uncertainty**

non-negative parameter characterizing the dispersion of the quantity values being attributed to a measurand, based on the information used

Note 1 to entry: Measurement uncertainty includes components arising from systematic effects, such as components associated with corrections and the assigned quantity values of measurement standards, as well as the definitional uncertainty. Sometimes estimated systematic effects are not corrected for but, instead, associated measurement uncertainty components are incorporated.

Note 2 to entry: The parameter may be, for example, a standard deviation called standard measurement uncertainty (or a specified multiple of it), or the half-width of an interval, having a stated coverage probability.

Note 3 to entry: Measurement uncertainty comprises, in general, many components. Some of these may be evaluated by Type A evaluation of measurement uncertainty from the statistical distribution of the quantity values from series of measurements and can be characterized by standard deviations. The other components, which may be evaluated by Type B evaluation of measurement uncertainty, can also be characterized by standard deviations, evaluated from probability density functions based on experience or other information.

Note 4 to entry: In general, for a given set of information, it is understood that the measurement uncertainty is associated with a stated quantity value attributed to the measurand. A modification of this value results in a modification of the associated uncertainty.

[ISO/IEC Guide 99:2007, definition 2.26]

3.16

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.

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.]

3.17

complaint

expression of dissatisfaction, other than *appeal* (3.18), by any person or organization to a conformity assessment body or an accreditation body, relating to the activities of that body, where a response is expected

[SOURCE: ISO/IEC 17000:2020, 8.7.]

3.18

appeal

request by the person or organization that provides, or that is, the object of conformity assessment to a conformity assessment body or an accreditation body for reconsideration by that body of a decision it has made relating to that object

[SOURCE: ISO/IEC 17000:2020, 8.7.]

4 General requirements

4.1. Impartiality

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

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

4.1.3. The proficiency testing 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 body with a threat to impartiality.

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

4.1.5. The proficiency testing provider shall have top management commitment to impartiality.

4.2. Confidentiality

4.2.1. The proficiency testing provider shall be responsible, through legally enforceable agreements, for the management of all information obtained or created during the performance of proficiency testing. The proficiency testing 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 proficiency testing provider and the all other information is considered proprietary information and shall be regarded as confidential.

4.2.2. When the proficiency testing 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 participant information obtained from sources other than the participant (e.g., complainant or regulators) shall be confidential between the participant and the proficiency testing provider. The source of this information shall be confidential to the proficiency testing provider and shall not be shared with the participant, unless agreed by the source.

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

5 Structural requirements

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

5.2. The proficiency testing provider shall identify management that has overall responsibility for proficiency testing activity.

5.3. The proficiency testing provider shall define and document the range of proficiency testing activities for which it conforms with this document. The proficiency testing provider shall only claim conformity with this document for this range of proficiency testing activities.

5.4. Proficiency testing activities shall be carried out in such a way as to meet the requirements of this document, the proficiency testing participants and customers, regulatory authorities, and organizations providing recognition. This shall include proficiency testing activities performed in all its permanent facilities and at sites away from its permanent facilities.

5.5. The proficiency testing provider shall:

- a) define the organization and management structure of the proficiency testing provider, 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 result of proficiency testing activities;
- c) document its procedures to the extent necessary to ensure the consistent application of its proficiency testing activities.

5.6. The proficiency testing 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 for performing proficiency testing activities;
- c) initiation of actions to prevent or minimize such deviations;
- d) reporting to proficiency testing provider management on performance of the management system and any need for improvement;
- e) ensuring the effectiveness of proficiency testing activities.

5.7. Proficiency testing 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 and customers.
- 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 development and operation of proficiency testing schemes shall be undertaken by proficiency testing providers having resources with the competence to conduct interlaboratory comparisons and have access to expertise for the particular type of proficiency test schemes.

6.1.2 The proficiency testing provider shall have access to the necessary technical expertise and experience in the relevant field of testing, calibration, sampling or inspection, as well as statistics.

6.1.3 The proficiency testing provider shall identify and plan those processes that directly affect the quality of proficiency testing scheme, and the proficiency testing scheme design shall be documented.

NOTE A mechanism (e.g. a management/technical advisory group) can be established to make recommendations on part or all of the production processes, for example, assigning the property values of interest.

6.1.4 Testing and calibration activities shall be conducted in accordance with the relevant requirements of ISO/IEC 17025 or ISO 15189.

6.2. Personnel

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

6.2.2. The proficiency testing provider shall document the competence requirements for each function influencing the results of proficiency testing activity, including requirements for education, qualification, training, technical knowledge, skills and experience.

6.2.3. The proficiency testing provider shall have access to a sufficient number of personnel to perform its proficiency testing activities for which they are responsible and to evaluate the significance of deviations.

6.2.4. The proficiency testing provider shall have a process for managing competence of its personnel.

6.2.5. The proficiency testing provider shall have documented information demonstrating competence of its personnel.

6.2.6. The management of the proficiency testing provider shall communicate to personnel their duties, responsibilities, and authorities.

6.2.7. The proficiency testing provider shall have procedures 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.

6.2.8. The proficiency testing provider shall authorize personnel to perform specific activities within proficiency testing schemes, including but not limited to the following:

- a) select appropriate proficiency test items;
- b) plan proficiency testing schemes;
- c) perform particular types of sampling;
- d) operate specific equipment;
- e) conduct measurements to determine stability and homogeneity, as well as assigned values and associated uncertainties of the measurands of the proficiency test item;
- f) prepare, handle and distribute proficiency test items;
- g) operate the data processing system;
- h) conduct statistical analysis;

- i) evaluate the performance of proficiency testing participants;
- j) give opinions and interpretations; and
- k) authorize the issue of proficiency testing reports.

6.3. Equipment, accommodation and environment

6.3.1. The proficiency testing provider shall ensure that there is appropriate accommodation for the operation of the proficiency testing scheme. This includes facilities and equipment for proficiency test item manufacturing, handling, calibration, testing, storage and despatch, for data processing, for communications, and for retrieval of materials and records.

6.3.2. The proficiency testing provider shall ensure that the environmental conditions do not compromise the proficiency testing scheme or the required quality of operations. Particular care shall be taken when operations are undertaken at sites away from the proficiency testing provider's permanent facilities or are undertaken by external service providers. The technical requirements for accommodation and environmental conditions that can affect the proficiency testing shall be documented.

6.3.3. Access to and use of areas affecting the quality of proficiency testing schemes shall be controlled. The proficiency testing provider shall determine the extent of control based on its particular circumstances.

6.3.4. The proficiency testing provider shall identify environmental conditions that can significantly influence the quality of the proficiency test items and any testing and calibration carried out, including conditions that are required by relevant specifications and measurement procedures. The proficiency testing provider shall control and monitor these conditions, and shall record all relevant monitoring activities. Relevant proficiency testing activities shall be stopped when the environmental conditions jeopardize the quality or the operations of the proficiency testing scheme.

NOTE Conditions can include, for example, biological sterility, dust, electromagnetic disturbances, radiation, humidity, electrical supply, temperature, and sound and vibrations levels, as appropriate to the technical activities concerned

6.3.5. There shall be effective separation between neighbouring areas in which there are incompatible activities. Action shall be taken to prevent cross-contamination.

6.3.6. Measuring system shall be capable of achieving the measurement accuracy and stability required to provide valid results. The PT providers shall use only equipment, service and supplies that comply with specified requirements to ensure the validity of the schemes.

6.4. Externally provided products and services

6.4.1. The proficiency testing provider shall ensure that only suitable externally provided products and services that affect proficiency testing activities are used, when such products and services:

- a) are intended for incorporation into the proficiency testing provider's own activities;
- b) are provided, in part or in full, directly to the participant or other customer by the proficiency testing provider, as received from the external provider;
- c) are used to support the operation of the proficiency testing provider.

6.4.2. Proficiency testing providers shall not engage external service providers for the following activities:

- a) the planning of proficiency testing schemes;
- b) the evaluation of performance;
- c) the authorization of reports.

NOTE This does not preclude the proficiency testing provider utilizing advice or assistance from any advisors, experts or steering group.

6.4.3. The proficiency testing provider shall inform participants, in advance and in writing, of services that are, or may be provided externally.

6.4.4. The proficiency testing provider shall have a procedure and retain records for:

- a) defining, reviewing and approving the proficiency testing provider's requirements for externally provided products and services;
- b) defining the criteria for evaluation, selection, monitoring of performance and re-evaluation of the external provider;
- c) ensuring that externally provided products and services conform to the proficiency testing provider's established requirements, or when applicable, to the relevant requirements of this document, before they are used or directly provided to the customer;
- d) taking any actions arising from the evaluations, monitoring of performance and re-evaluations of the external providers.

6.4.5. The proficiency testing provider shall communicate its requirements to external providers for:

- a) the products and services to be provided;
- b) the acceptance criteria;
- c) competence, including any required qualification of the organization or personnel involved;
- d) activities that the proficiency testing provider or its customers intend to perform at the external provider's premises.

6.4.6. The proficiency testing provider shall be responsible to the participants and other customers for the work of externally provided services, except in the case where a regulatory authority specifies which service provider is to be used.

7 Process requirements

7.1 Review of requests, tenders and contracts

7.1.1. The proficiency testing provider shall have a procedure for the review of requests, tenders and contracts. The procedure shall ensure that:

- a) the requirements, including those for test and calibration methods, measuring equipment and proficiency test items to be used, are adequately defined, documented and understood;
- b) the proficiency testing provider has the capability and resources to meet the requirements; and
- c) the proficiency testing scheme is technically appropriate taking into account the needs of the given application or field of application.

NOTE 1 This review is particularly important when a customer requests a proficiency testing scheme to be created for a specific purpose or for a different level or frequency of participation from that normally offered.

NOTE 2 This review can be simplified when the proficiency test scheme is fully described in a catalogue or other notice, and the participant is enrolling for a routine shipment.

7.1.2. Records of such reviews, including any changes, shall be retained. Records shall also be retained of pertinent discussions with a customer relating to the customer's requirements, or the results of the work during the period of execution of the contract.

7.1.3. The review shall cover all aspects of the request, including any externally provided services.

7.1.4. The participants and other customers, as appropriate, shall be informed of any deviation in the contract or agreed proficiency testing scheme design.

7.1.5. If a request or contract is amended after the proficiency testing scheme is underway, the same review process shall be repeated, and any amendments shall be communicated to all affected personnel.

7.2 Planning

7.2.1. The proficiency testing provider shall identify and plan those processes which directly affect the quality of the proficiency testing scheme and shall ensure that they are carried out in accordance with prescribed procedures.

7.2.2. The proficiency testing provider shall document a plan before commencement of the proficiency testing scheme that addresses the objectives, purpose and basic design of the proficiency testing scheme, including the following information and, where appropriate, reasons for its selection or exclusion:

- a) the name and address of the proficiency testing provider;
- b) the name, address and affiliation of the coordinator and other personnel involved in the design and operation of the proficiency testing scheme;
- c) the activities to be provided by external organizations and the names and addresses of the organizations involved in the operation of the proficiency testing scheme;
- d) criteria to be met for participation;
- e) the number and type of expected participants in the proficiency testing scheme;
- f) selection of the measurand(s) or characteristic(s) of interest, including information on what the participants are to identify, measure, or test for in the specific proficiency testing round;
- g) a description of the range of values or characteristics, or both, to be expected for the proficiency test items;
- h) the potential major sources of errors involved in the area of proficiency testing offered;
- i) requirements for the production, quality control, storage and distribution of proficiency test items;
- j) reasonable precautions to prevent collusion between participants or falsification of results, and procedures to be employed if collusion or falsification of results is suspected;
- k) a description of the information which is to be supplied to participants and the time schedule for the various phases of the proficiency testing scheme;
- l) for continuous proficiency testing schemes, the frequency or dates upon which proficiency test items are to be distributed to participants, the deadlines for the return of results by participants and, where appropriate, the dates on which testing or measurement is to be carried out by participants;
- m) any information on methods or procedures which participants need to use to prepare the test material and perform the tests or measurements;
- n) procedures for the test or measurement methods to be used for the homogeneity and stability testing of proficiency test items and, where applicable, to determine their biological viability;
- o) preparation of any standardized reporting formats to be used by participants;
- p) a detailed description of the statistical analysis to be used;
- q) the origin, metrological traceability and measurement uncertainty of any assigned values;
- r) criteria for the evaluation of performance of participants;
- s) a description of the data, interim reports or information to be returned to participants;
- t) a description of the extent to which participant results, and the conclusions that will be based on the outcome of the proficiency testing scheme, are to be made public; and
- u) actions to be taken in the case of lost or damaged proficiency test items.

7.2.3. Technical expertise shall be used, as appropriate, to determine matters such as the following:

- a) planning requirements as listed in 7.2.2;
- b) identification and resolution of any difficulties expected in the preparation and maintenance of homogeneous proficiency test items, or in the provision of a stable assigned value for a proficiency test item;
- c) preparation of detailed instructions for participants;

- d) comments on any technical difficulties or other remarks raised by participants in previous proficiency testing rounds;
- e) provision of advice in evaluating the performance of participants;
- f) comments on the results and performance of participants as a whole and, where appropriate, groups of participants or individual participants;
- g) provision of advice for participants (within limits of confidentiality), either individually or within the report;
- h) responding to feedback from participants; and
- i) planning or participating in technical meetings with participants.

7.3 Preparation of proficiency test items

7.3.1 The proficiency testing provider shall establish and implement procedures to ensure that proficiency test items are prepared in accordance with the plan described in 7.2.

NOTE ISO 17034 or ISO 13485 can be used when reference materials or certified reference materials are used.

7.3.2 The proficiency testing provider shall establish and implement procedures to ensure appropriate acquisition, collection, preparation, handling, storage and, where required, disposal of all proficiency test items. The procedures shall ensure that materials used to manufacture proficiency test items are obtained in accordance with relevant regulatory and ethical requirements.

7.3.3 Proficiency test items should match in terms of matrix, measurands and concentrations, as closely as practicable, the type of items or materials encountered in routine testing or calibration.

7.3.4 In proficiency testing schemes that require participants to prepare or manipulate, or both prepare and manipulate, the proficiency test item and submit it to the proficiency testing provider, the proficiency testing provider shall issue instructions for preparation, packaging and transport of the proficiency test item.

7.4 Homogeneity and stability

7.4.1 Criteria for suitable homogeneity and stability shall be established and shall be based on the risk that inhomogeneity and instability can impact the evaluation of the participants' performance.

NOTE 1 The requirements in this subclause are intended to ensure that every participant receives comparable proficiency test items, and that these proficiency test items remain stable throughout the proficiency testing. Careful planning, manufacture and shipping are necessary to achieve this, and testing is usually needed to confirm it.

NOTE 2 In some cases, it is not feasible for proficiency test items to be subjected to homogeneity and stability testing. Such cases would include, for example, when limited material is available to prepare proficiency testing items.

NOTE 3 In some cases, materials that are not sufficiently homogeneous or stable are the best available; in such cases, they can still be useful as proficiency test items, provided that the uncertainties of the assigned values or the evaluation of results take due account of this (see B.3.1.3 and ISO 13528:2015, Annex B).

NOTE 4 Assessment of homogeneity and stability are further discussed in ISO 17034, ISO Guide 35 and ISO 13528.

7.4.2. The procedures for the assessment of homogeneity and stability shall be documented and conducted, where applicable, in accordance with appropriate statistical designs. Where possible, the proficiency testing provider shall use a representative sample of proficiency test items from the whole batch of test material in order to assess the homogeneity of the material.

NOTE In some cases, the use of a statistically random selection of proficiency test items from the whole batch is more appropriate.

7.4.3 The assessment of homogeneity shall be performed after the proficiency test items have been packaged in the final form unless, for example, stability studies indicate that they should be stored in bulk form.

NOTE Homogeneity can be demonstrated prior to packaging where no influence of packaging is reasonably expected.

7.4.4 Proficiency test items shall be demonstrated to be sufficiently stable to ensure that they will not undergo any significant change throughout the conduct of the proficiency testing, including storage and transport conditions. When this is not possible, the stability shall be quantified and considered as an additional component of the measurement uncertainty associated with the assigned value of the proficiency test item, and/or taken into account in the evaluation criteria.

7.4.5 When proficiency test items from previous rounds are retained for future use, the property values to be determined in the proficiency testing scheme shall be confirmed by the proficiency testing provider prior to distribution.

7.4.6 In circumstances where homogeneity and stability testing is not feasible, the proficiency testing provider shall demonstrate that the procedures used to collect, produce, package and distribute the proficiency test items are sufficient for the purpose of the proficiency testing.

7.5 Statistical design

7.5.1 Statistical designs shall be developed to meet the objectives of the scheme, based on the nature of the data (quantitative or qualitative, including ordinal and categorical), statistical assumptions, the nature of errors, and the expected number of results (see B.3.2.2).

NOTE 1 Statistical design covers the process of planning, collection, analysis and reporting of the proficiency testing scheme data. Statistical designs are often based on stated objectives for the proficiency testing scheme, such as detection of certain types of errors with specified power or determination of assigned values with specified measurement uncertainty.

NOTE 2 Data analysis methods could vary from the very simple (e.g. descriptive statistics) to the complex, using statistical models with probabilistic assumptions or combinations of results for different proficiency test items.

NOTE 3 In cases where the proficiency testing scheme design is mandated by a specification given by, for example, a customer, regulatory authority or accreditation body, the statistical design and data analysis methods can be taken directly from the specification.

NOTE 4 In the absence of reliable information needed to produce a statistical design, a preliminary interlaboratory comparison can be used.

7.5.2 The proficiency testing provider shall document the statistical design and data analysis methods to be used to identify the assigned value and evaluate participant results, and shall provide a description of the reasons for their selection and assumptions upon which they are based. The proficiency testing provider shall be able to demonstrate that statistical assumptions are reasonable and that statistical analyses are carried out in accordance with prescribed procedures.

7.5.3 In designing a statistical analysis, the proficiency testing provider shall give careful consideration to the following:

- a) the accuracy (trueness and precision) as well as the measurement uncertainty required or expected for each measurand or characteristic in the proficiency testing;
- b) the minimum number of participants in the proficiency testing scheme needed to meet the objectives of the statistical design; in cases where there is an insufficient number of participants

to meet these objectives or to produce statistically meaningful analysis of results, the proficiency testing provider shall document, and provide to participants, details of the alternative approaches used to assess participant performance;

- c) the relevance of significant figures to the reported result, including the number of decimal places;
- d) the number of proficiency test items to be tested or measured and the number of repeat tests, calibrations or measurements to be conducted on each proficiency test item or for each determination;
- e) the procedures used to establish the standard deviation for proficiency assessment or other evaluation criteria;
- f) procedures to be used to identify or handle outliers, or both;
- g) where relevant, the procedures for the evaluation of values excluded from statistical analysis; and
- h) where appropriate, the objectives to be met for the design and the frequency of proficiency testing rounds.

7.6 Assigned values

7.6.1 The proficiency testing provider shall document the procedure for determining the assigned values for the measurands or characteristics in a particular proficiency testing scheme. This procedure shall take into account the metrological traceability and measurement uncertainty required to demonstrate that the proficiency testing scheme is fit for its purpose.

7.6.2 Proficiency testing schemes in the area of calibration shall have assigned values with metrological traceability, including measurement uncertainty.

7.6.3 For proficiency testing schemes in areas other than calibration, the relevance, needs and feasibility for metrological traceability and associated measurement uncertainty of the assigned value shall be determined by taking into account specified requirements of participants or other interested parties, or by the design of the proficiency testing scheme.

NOTE The required metrological traceability chain can differ depending on the type of proficiency test item, the measurand or characteristic, and the availability of traceable calibrations and reference materials.

7.6.4. When a consensus value is used as the assigned value (see Annex B), the proficiency testing provider shall document the reason for that selection and shall estimate the uncertainty of the assigned value as described in the plan for the proficiency testing scheme.

7.7 Choice of method or procedure

7.7.1 Participants shall normally be expected to use the test method, calibration or measurement procedure of their choice, which should be consistent with their routine procedures. The proficiency testing provider may instruct participants to use a specified method in accordance with the design of the proficiency testing scheme.

7.7.2 Where participants are permitted to use a method of their choice, the proficiency testing provider shall:

- a) have a policy and follow a procedure regarding comparison of results obtained by different test or measurement methods;
- b) be aware of which different test or measurement methods for any measurand are technically equivalent, and take steps to assess participants' results using these methods accordingly.

7.8 Instructions for participants

7.8.1. The proficiency testing provider shall give participants sufficient prior notice before sending proficiency test items, providing the date on which the proficiency test items are likely to arrive or to be despatched, unless the design of the proficiency testing scheme makes it inappropriate to do so.

7.8.2. The proficiency testing provider shall give detailed documented instructions to all participants. Instructions to participants shall include:

- a) the necessity to treat proficiency test items in the same manner as the majority of routinely tested samples (unless there are particular requirements of the proficiency testing scheme which require departure from this principle);
- b) details of factors which could influence the testing or calibration of the proficiency test items, e.g. the nature of the proficiency test items, conditions of storage, whether the proficiency testing scheme is limited to selected test methods, and the timing of the testing or measurement;
- c) detailed procedure for preparing or conditioning, or both preparing and conditioning, of the proficiency test items before conducting the tests or calibrations;
- d) any appropriate instructions on handling the proficiency test items, including any safety requirements;
- e) any specific environmental conditions for the participant to conduct tests or calibrations, or both, and, if relevant, any requirement for the participants to report relevant environmental conditions during the time of the measurement;
- f) specific and detailed instructions on the manner of recording and reporting test or measurement results and associated uncertainties. If the instructions include reporting of the uncertainty of the reported result or measurement, this shall include the coverage factor and, whenever practicable, the coverage probability;
NOTE This instruction usually includes parameters such as the units of measurement, the number of significant figures or decimal places and reporting basis (e.g. on dry weight, or “as received”).
- g) the latest date for the provider to receive the proficiency testing or measurement results for analysis;
- h) information on the contact details of the proficiency testing provider for enquiries; and
- i) instructions on return of the proficiency test items, when applicable.

7.9 Proficiency test items handling and storage

7.9.1. The proficiency testing provider shall ensure that proficiency test items are appropriately identified and segregated and cannot become contaminated or degraded, from the time of preparation to their distribution to participants.

7.9.2. The proficiency testing provider shall provide secure storage areas or stock rooms, or both, which prevent damage or deterioration of any proficiency test item between preparation and distribution. Appropriate procedures for authorizing despatch to, and receipt from, such areas shall be defined.

7.9.3. When appropriate, the condition of stored or stocked proficiency test items, chemicals and materials shall be assessed at specified intervals during their storage life in order to detect possible deterioration.

7.9.4. Where potentially hazardous proficiency test items, chemicals and materials are used, facilities shall be available to ensure their safe handling, decontamination and disposal.

7.10 Packaging, labelling and distribution of proficiency test items

7.10 The proficiency testing provider shall control packaging and labelling processes to the extent necessary to ensure conformity with relevant national, regional, or international safety and transport requirements.

NOTE The proper distribution of proficiency test items can present severe problems for some types of material, e.g. those which require uninterrupted storage in cold conditions or which should not be exposed to X-rays, shock or vibration. Most types of chemical materials would benefit from air-tight packaging to avoid contamination by atmospheric contaminants, e.g. fuel vapours or engine exhaust gases which can be encountered during transport.

7.11 Data analysis and records

7.11.1 All data processing equipment and software shall be validated in accordance with procedures before being brought into use. Computer system maintenance shall include a back-up process and system recovery plan. The results of such maintenance and operational checks shall be recorded.

NOTE Commercial off-the-shelf software in general use within its designated application range can be considered to be sufficiently validated.

7.11.2. The proficiency testing provider shall specify relevant environmental conditions for the transport of proficiency test items. Where relevant, the proficiency testing provider shall monitor the pertinent environmental conditions of the proficiency test item during transport and assess the impact of environmental influences on the proficiency test item.

7.11.3. In proficiency testing schemes where participants are required to transport the proficiency test items to other participants, documented instructions for this transport shall be supplied.

7.11.4 The proficiency testing provider shall ensure that labels are securely attached to the packaging of individual proficiency test items and are designed to remain legible and intact throughout the proficiency testing round.

7.11.5 The proficiency testing provider shall follow a procedure to enable the confirmation of delivery of the proficiency test items.

7.11.6. Results received from participants shall be recorded and analysed by appropriate methods. Procedures shall be established and implemented to check the validity of data entry, data transfer, statistical analysis, and reporting.

7.11.7. Data analysis shall generate summary statistics and performance statistics, and associated information consistent with the statistical design of the proficiency testing scheme.

7.11.7. The influence of outliers on summary statistics shall be minimized by the use of robust statistical methods or appropriate tests to detect statistical outliers.

7.11.8. The proficiency testing provider shall have documented criteria and procedures for dealing with test results that may be inappropriate for statistical evaluation, e.g. miscalculations, transpositions and other gross errors.

7.11.9 The proficiency testing provider shall have documented criteria and procedures to identify and manage proficiency test items that have been distributed and are subsequently found to be unsuitable for performance evaluation, e.g. because of inhomogeneity, instability, damage or contamination.

7.12 Evaluation of performance

7.12.1. The proficiency testing provider shall use valid methods of evaluation which meet the purpose of the proficiency testing scheme. The methods shall be documented and include a description of the basis for the evaluation.

7.12.2. Where appropriate for the purpose of the proficiency testing scheme, the proficiency testing provider shall provide expert commentary on the performance of participants with regard to the following:

- a) overall performance against prior expectations, taking measurement uncertainties into account;
- b) variation within and between participants, and comparisons with any previous proficiency testing rounds, similar proficiency testing schemes, or published precision data;
- c) variation between methods or procedures;
- d) possible sources of error (with reference to outliers) and suggestions for improving performance;
- e) advice and educational feedback to participants as part of the continual improvement procedures of participants;
- f) situations where unusual factors make evaluation of results and commentary on performance impossible;
- g) any other suggestions, recommendations or general comments; and
- h) conclusions.

NOTE It can be useful to provide individual summary sheets for participants periodically during or after completion of a particular proficiency testing scheme. These can include updated summaries of performance for individual participants over successive proficiency testing rounds of a continuous proficiency testing scheme. Such summaries can be further analysed and trends highlighted, if required.

7.13 Reports

7.13.1. Proficiency test reports shall be clear and comprehensive and include data covering the results of all participants, together with an indication of the performance of individual participants.

NOTE Where all original data cannot be reported to participants, a summary of the results, e.g. in tabulated or graphical form, can be supplied.

7.13.2. Reports shall include the following, unless it is not applicable or the proficiency testing provider has valid reasons for not doing so:

- a) the name and contact details for the proficiency testing provider;
- b) the name and contact details for the coordinator;
- c) the name(s), function(s), and signature(s) or equivalent identification of person(s) authorizing the report;
- d) an indication of which activities are provided by external contractors;
- e) the date of issue and status (e.g. preliminary, interim, or final) of the report;
- f) page numbers and a clear indication of the end of the report;
- g) a statement of the extent to which results are confidential;
- h) the report number and clear identification of the proficiency testing scheme;
- i) a clear description of the proficiency test items used, including necessary details of the proficiency test item's preparation and homogeneity and stability assessment;
- j) the participants' results;
- k) statistical data and summaries, including assigned values and range of acceptable results and graphical displays;
- l) procedures used to establish any assigned value;
- m) details of the metrological traceability and measurement uncertainty of any assigned value;
- n) procedures used to establish the standard deviation for proficiency assessment, or other criteria for evaluation;

- o) assigned values and summary statistics for test methods/procedures used by each group of participants (if different methods are used by different groups of participants);
- p) comments on participants' performance by the proficiency testing provider and technical advisers;
- q) information about the design and implementation of the proficiency testing scheme;
- r) procedures used to statistically analyse the data;
- s) advice on the interpretation of the statistical analysis; and
- t) comments or recommendations, based on the outcomes of the proficiency testing round.

NOTE For continuous proficiency testing schemes, it can be sufficient to have simpler reports, such that many of the elements in this clause could be excluded from routine reports, but included in proficiency testing scheme protocols or in periodic summary reports that are available to participants.

7.13.3. Reports shall be made available to participants within planned timescales. In sequential proficiency testing schemes, e.g. where the turn-around time may be very long, and in schemes involving perishable materials, preliminary or anticipated results may be provided before final results are disclosed.

NOTE This allows for early investigation of possible error.

7.13.4. The proficiency testing provider shall have a policy for the use of reports by individuals and organizations.

7.13.5. When it is necessary to issue a new or amended report for a proficiency testing scheme, this shall include the following:

- a) a unique identification;
- b) a reference to the original report that it replaces or amends; and
- c) a statement concerning the reason for the amendment or re-issue.

7.14 Communication with participants

7.14.1. The proficiency testing provider shall make detailed information available about the proficiency testing scheme. This shall include:

- a) relevant details of the scope of the proficiency testing scheme;
- b) any fees for participation;
- c) documented eligibility criteria for participation;
- d) criteria for determining the assigned value and the evaluation of performance
- e) confidentiality arrangements; and
- f) details of how to apply.

7.14.2. Participants shall be advised promptly by the proficiency testing provider of any changes in proficiency testing scheme design or operation.

7.14.3. There shall be documented procedures for enabling participants to appeal against the evaluation of their performance in a proficiency testing scheme. The availability of this process shall be communicated to proficiency testing scheme participants.

7.14.4. Relevant records of communications with participants shall be maintained and retained, as appropriate.

7.14.5. If the proficiency testing provider issues statements of participation or performance, they shall contain sufficient information to not be misleading.

7.15 Requirements for handling of appeals

7.15.1 The proficiency testing provider shall have a documented procedure for handling appeals that shall include at least the following:

- a) a description of the process for receiving and investigating the appeal, and deciding what actions shall be taken in response;
- b) tracking and recording the appeal, including the actions undertaken to resolve it;
- c) ensuring appropriate action is taken.

7.15.2. A description of the process for handling appeals shall be publicly available.

7.15.3. The proficiency testing provider shall acknowledge receipt of the appeal, and provide the appellant with the outcome and, if applicable, progress reports.

7.15.4. The proficiency testing provider receiving the appeal shall be responsible for gathering all necessary information to determine whether the appeal is valid.

7.15.5. The proficiency testing provider shall be responsible for all decisions during the process for handling appeals.

7.15.6. The decision on the appeal shall be made by, or reviewed and approved by, persons not involved in the decision that is the subject of the appeal in question.

7.15.7. Investigation and decision on appeals shall not result in any discriminatory actions.

7.16 Handling of complaints

7.16.1. The proficiency testing provider shall have a documented procedure for handling complaints that shall include at least the following:

- a) a description of the process for receiving, substantiating and investigating the complaint, and deciding what actions shall be taken in response;
- b) tracking and recording the complaint, including the actions undertaken to resolve it;
- c) ensuring that any appropriate action is taken.

7.16.2. A description of the process for handling complaints shall be publicly available.

7.16.3. Upon receipt of a complaint, the proficiency testing provider shall confirm whether the complaint relates to proficiency testing activities and, if so, shall resolve the complaint.

7.16.4. The proficiency testing provider receiving the complaint shall be responsible for gathering all necessary information to determine whether the complaint is substantiated.

7.16.5. Whenever possible the proficiency testing provider shall acknowledge receipt of the complaint, and provide the complainant with the outcome and, if applicable, progress reports.

7.16.6. Investigation and resolution of complaints shall not result in any discriminatory actions.

7.16.7. The resolution of complaints shall be made by, or reviewed and approved by, persons not involved in the subject of the complaint in question. Where resources do not permit this, any alternative approach shall not compromise impartiality.

7.16.8. Whenever possible, the proficiency testing provider shall give formal notice of the end of the complaint handling to the complainant.

7.16.9. The proficiency testing provider shall be responsible for all decisions at all levels of the handling process for complaints.

7.17 Nonconforming work

7.17.1. The proficiency testing provider shall have a procedure(s) that shall be implemented when any aspect of its activities does not conform to its own procedures or the agreed requirements of its customers. The procedure(s) shall ensure that:

- a) the responsibilities and authorities for the management of nonconforming work are defined;

- b) actions (including halting work of ongoing programmes and withholding reports, as necessary) are defined and are based upon the risk levels established by the proficiency testing provider;
- c) an evaluation of the significance of the nonconforming work is made, including an impact analysis on previous activities;
- d) a decision on the need for action and timescale is taken immediately, together with any decision about the acceptability of the nonconforming work;
- e) proficiency testing scheme participants and other customers, as appropriate, are informed and the nonconforming proficiency test items or reports already sent to participants are recalled or disregarded;
- f) the responsibility for authorization of the resumption of work is defined.

NOTE Identification of nonconforming work or problems with the management system or with technical activities can occur at various places within the management system and technical operations. Examples are participant complaints, management reviews and internal or external audits, quality control, preparations of proficiency test items, homogeneity and stability tests, data analysis, instructions to participants, and materials handling and storage.

7.17.2. The proficiency testing provider shall retain records of nonconforming work and actions as specified in 7.10.1 bullets b) to f).

7.17.3. Where the evaluation indicates that nonconforming work could recur or that there is doubt about the compliance of the proficiency testing provider or external service provider with their own procedures, the corrective action procedure in 8.7 shall be promptly followed.

8 Management system requirements

8.1. General requirements

8.1.1. The proficiency testing provider shall establish, document, implement and maintain a management system to support and demonstrate the consistent fulfilment of the requirements of this document and its scope of activities, including the type, range and volume of proficiency testing that it provides.

8.1.2. The management system of the proficiency testing provider shall include at least the following:

- policies;
- responsibilities;
- management system documentation (see 8.2)
- control of management system documents (see 8.3)
- control of records (see 8.4)
- actions to address risks and opportunities (see 8.5)
- improvement (see 8.6)
- corrective action (see 8.7)
- internal audits (see 8.8)
- management reviews (see 8.9)

8.1.3. A proficiency testing provider may meet 8.1.1 by establishing, implementing and maintaining a quality management system (e.g. in accordance with the requirements of ISO 9001). This quality management system shall support and demonstrate the consistent fulfilment of the requirements of sections 4 through 7 in this document.

8.2. Management system documentation

8.2.1. The proficiency testing provider management shall establish, document and maintain policies and objectives for the fulfilment of the purposes of this document and shall ensure that the policies and objectives are acknowledged and implemented at all levels of the organization.

8.2.2. The policies and objectives shall address the competence, impartiality and consistent operation of the proficiency testing provider.

8.2.3. Proficiency testing provider management shall provide evidence of commitment to the development and implementation of the management system and to continually improving its effectiveness.

8.2.4. All documentation, processes, systems and records related to the fulfilment of the requirements of this document shall be included in, or referenced from the management system.

8.2.5. All personnel involved in proficiency testing activities shall have access to the parts of the management system documentation and related information that are applicable to their responsibilities.

8.3. Control of management system documents

8.3.1. The proficiency testing provider shall control the documents (internal and external) that relate to the fulfilment of this document.

8.3.2. The proficiency testing provider shall ensure that:

- a) documents are approved for adequacy prior to issue by authorized personnel;
- b) documents are periodically reviewed, and updated as necessary;
- c) changes and current revision status of documents are identified;
- d) relevant versions of applicable documents are available at points of use and, where necessary, their distribution is controlled;
- e) documents are uniquely identified;
- f) the unintended use of obsolete documents is prevented, and suitable identification is applied to them if they are retained for any purpose.

8.4. Control of records

8.4.1. The laboratory shall establish and retain legible records to demonstrate fulfilment of the requirements in this document.

8.4.2. The laboratory shall implement the controls needed for the identification, storage, protection, back-up, archive, retrieval, retention time, and disposal of its records. The laboratory shall retain records for a period consistent with its contractual obligations. Access to these records shall be consistent with the confidentiality commitments, and records shall be readily available.

NOTE Additional requirements regarding technical records are given in 7.11.

8.5. Actions to address risks and opportunities

8.5.1. The proficiency testing provider shall consider the risks and opportunities associated with the proficiency testing activities in order to:

- a) give assurance that the management system achieves its intended results;
- b) enhance opportunities to achieve the purpose and objectives of the proficiency testing provider;
- c) prevent, or reduce, undesired impacts and potential failures in the proficiency testing activities; achieve improvement.

8.5.2. The proficiency testing provider shall plan:

- a) actions to address these risks and opportunities;

b) how to:

- integrate and implement these actions into its management system;
- evaluate the effectiveness of these actions.

NOTE Although this document specifies that the proficiency testing provider plans actions to address risks, there is no requirement for formal methods for risk management or a documented risk management process. Proficiency testing providers can decide whether or not to develop a more extensive risk management methodology than is required by this document, e.g. through the application of other guidance or standards.

8.5.3. Actions taken to address risks and opportunities shall be proportional to the potential impact on the validity of proficiency testing activities.

NOTE 1 Options to address risks can include identifying and avoiding threats, taking risk in order to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences, sharing the risk, or retaining risk by informed decision.

NOTE 2 Opportunities can lead to expanding the scope of the proficiency testing activities, addressing new customers, using new technology and other possibilities to address customer needs.

8.6. Improvement

8.6.1. The proficiency testing provider shall identify and select opportunities for improvement and implement any necessary actions.

NOTE Opportunities for improvement can be identified through the review of the operational procedures, the use of the policies, overall objectives, audit results, corrective actions, management review, suggestions from personnel, risk assessment, analysis of data, and external assessments.

8.6.2. The proficiency testing provider shall seek feedback, both positive and negative, from its participants and other customers. The feedback shall be analysed and used to improve the management system, proficiency testing activities and customer service.

NOTE Examples of the types of feedback include customer satisfaction surveys, communication records and review of reports with participants and customers.

8.7. Corrective actions

8.7.1. When a nonconformity occurs, the proficiency testing provider shall:

- a) react to the nonconformity and, as applicable:
 - take action to control and correct it;
 - address the consequences;
- b) evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:
 - reviewing and analysing the nonconformity;
 - determining the causes of the nonconformity;
 - determining if similar nonconformities exist, or could potentially occur;
- c) implement any action needed;
- d) review the effectiveness of any corrective action taken;
- e) update risks and opportunities determined during planning, if necessary;
- f) make changes to the management system, if necessary.

8.7.2. Corrective actions shall be appropriate to the effects of the nonconformities encountered.

8.7.3. The proficiency testing provider shall retain records as evidence of:

- a) the nature of the nonconformities, cause(s) and any subsequent actions taken;
- b) the results of any corrective action.

8.8. Internal audits

8.8.1. The proficiency testing provider shall conduct internal audits at planned intervals to provide information on whether the management system:

- a) conforms to:
 - the proficiency testing provider's own requirements for its management system, including the proficiency testing activities;
 - the requirements of this document;
- b) is effectively implemented and maintained.

8.8.2. The proficiency testing provider shall:

- a) plan, establish, implement and maintain an audit programme including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the proficiency testing activities concerned, changes affecting the proficiency testing provider, and the results of previous audits;
- b) define the audit criteria and scope for each audit;
- c) ensure that the results of the audits are reported to relevant management;
- d) implement appropriate correction and corrective actions without undue delay;
- e) retain records as evidence of the implementation of the audit programme and the audit results.

NOTE ISO 19011 provides guidance for internal audits.

8.9. Management reviews

8.9.1. The proficiency testing provider management shall review its management system at planned intervals, in order to ensure its continuing suitability, adequacy and effectiveness, including the stated policies and objectives related to the fulfilment of this document.

8.9.2. The inputs to management review shall be recorded and shall include information related to the following:

- a) changes in internal and external issues that are relevant to the proficiency testing provider;
- b) fulfilment of objectives;
- c) suitability of policies and procedures;
- d) status of actions from previous management reviews;
- e) outcome of recent internal audits;
- f) corrective actions;
- g) assessments by external bodies;
- h) changes in the volume and type of the work or in the range of proficiency testing activities;
- i) customer and personnel feedback;
- j) complaints;
- k) effectiveness of any implemented improvements;
- l) adequacy of resources;
- m) results of risk identification;
- n) outcomes of the assurance of the validity of results; and
- o) other relevant factors, such as monitoring activities and training.

8.9.3. The outputs from the management review shall record all decisions and actions related to at least:

- a) the effectiveness of the management system and its processes;
- b) improvement of the laboratory activities related to the fulfilment of the requirements of this document;
- c) provision of required resource
- d) any need for change.

Annex A (informative)

Types of proficiency testing schemes

A.1 General

A.1.1. Proficiency testing is an essential aspect of laboratory practice in all areas of testing and calibration and can also be important for inspection and sampling. Proficiency testing schemes vary according to the needs of the sector in which they are used, the nature of the proficiency test items, the methods in use and the number of participants. However, in their simplest form, most proficiency testing schemes possess the common feature of comparison of results obtained by one laboratory with those obtained by one or more different laboratories.

A.1.2. Proficiency testing schemes will normally consist of at least one element of each of the following features:

1. Type of expected results:
 - a) qualitative (including data on nominal or ordinal scales)
 - b) quantitative (including data on interval or ratio scales)
 - c) interpretive (including descriptive or interpretive information)
2. Frequency:
 - a) single (or first) occasion
 - b) continuous
 - i. Many participants
 - ii. One Participant (e.g., on request);
3. Distribution format:
 - a) sequential from one participant to another, either directly or via the proficiency testing provider
 - b) simultaneous
4. Process:
 - a) pre-analytical (e.g. sample processing or test ordering etc.)
 - b) analytical
 - c) post analytical (e.g. interpretive)
5. Reference for assigned values:
 - a) international measurement reference (e.g. SI)
 - b) select group of competent laboratories
 - c) all participants
6. Performance criterion:
 - a) determination by expert judgement
 - b) determination by experience with previous rounds
 - c) comparison to other participants

A.1.3. There are a great many possible designs for proficiency testing designs (almost 3000 different designs, based on the options for the 6 characteristics), several of which can appear in the same proficiency testing scheme.

A.2 Types of proficiency testing schemes

A.2.1. Proficiency testing schemes have different features depending on the type of scheme, as outlined in definition 3.7, Note 1, a) to h). Some common applications of those types of proficiency testing schemes are discussed below.

A.2.2. Sequential participation schemes (sometimes known as measurement comparison schemes) involve the proficiency test item being circulated successively from one participant to the next, or occasionally circulated back to the proficiency testing provider for rechecking. The key features are typically those described below.

- a) A reference laboratory that is capable of providing a metrologically traceable assigned value with sufficiently small measurement uncertainty and reliability for the proficiency test item is used. For categorical or ordinal properties, the assigned value should be determined by consensus of experts or other authoritative source. It may be necessary for the proficiency test item to be checked at specific stages during the conduct of the proficiency testing scheme, in order to ensure that there is no significant change in the assigned value.
- b) The individual measurement results are compared with the assigned value established by the reference laboratory. The coordinator should take into account the claimed measurement uncertainty of each participant, or the claimed level of expertise. It may be difficult to compare results on a group basis as there may be relatively few participants having measurement capabilities that closely match each other.
- c) Proficiency testing schemes involving sequential participation take time (in some cases, years) to complete. This causes a number of difficulties, such as
 - ensuring the stability of the proficiency test item;
 - the strict monitoring of the circulation among participants and the time allowed for measurement by individual participants, and the need to supply feedback on individual performance during the proficiency testing scheme's implementation, rather than waiting until it finishes.
- d) Proficiency test items (measurement artefacts) used in this type of proficiency testing scheme can include, for example, measurement reference standards (e.g. resistors, micrometers and frequency counters) or, in medical programmes, histology slides with confirmed diagnoses etc.
- e) Proficiency testing schemes that follow this design but that are limited to situations where a single participant is tested independently are often called “measurement audits”.
- f) In some situations, the assigned value for a proficiency test item may be determined by consensus, after all participants (or in some situations, a subset of participants) have completed the measurement comparison.

A.2.3. One special application of sequential proficiency testing, often called “blind” or “double blind” proficiency testing, is where the proficiency test item is indistinguishable from normal customer items or samples received by the laboratory. This type of proficiency testing can be difficult, since it requires

coordination with a normal laboratory customer. In addition, because of unique packaging and shipping needs, bulk processing is usually not feasible and homogeneity testing is difficult.

A.2.4. Simultaneous participation proficiency testing schemes usually involve sub-samples from a source of material being distributed simultaneously to participants for concurrent testing. After completion of the testing, the results are returned to the proficiency testing provider and compared with the assigned value(s) to give an indication of the performance of the individual participants and the group as a whole. Examples of proficiency test items used in this type of scheme include food, body fluids, agricultural products, water, soils, minerals and other environmental materials. In some cases, separate portions of previously established reference materials are circulated. Advice or educational comments are typically part of the report returned to participants by the proficiency testing provider with the aim of promoting improvement in performance.

A.2.5. A common design for a proficiency testing scheme is the “split-level” design, where similar (but not identical) levels of measurand are included in two separate proficiency test items. This design is used to estimate the participant's precision at specific levels of a measurand. It avoids problems associated with replicate measurements on the same proficiency test item, or with the inclusion of two identical proficiency test items in the same proficiency testing round.

A.2.6. Partial-process and interpretive schemes, special types of proficiency testing schemes involve the evaluation of participants' abilities to perform parts of the overall testing or measurement process, covering pre-analytical, analytical and post-analytical aspects of the measurement cycle. For example, some existing proficiency testing schemes evaluate participants' abilities to transform and report a given set of data (rather than conduct the actual test or measurement), to make interpretations based on a given set of data or proficiency testing items, such as stained blood films for diagnosis, or to take and prepare samples or specimens in accordance with a specification. Some schemes might require participants to submit samples to the PT provider for review, or to provide a sampling plan.

A.2.7. Sampling schemes can involve online sampling and analysis or drawing samples from a source or sample preparation from a provided lot for subsequent testing or calibration. The proficiency testing schemes can thus be designed to evaluate correct selection of a sampling plan and application of sampling procedure or preparation of representative samples to obtain a correct conclusion. Performance criteria in these schemes can be on the basis of expert judgement. The proficiency test items can be case studies based on regulatory or customer requirements. These schemes have been applied in areas as sampling for ambient air, emissions, noise, indoor environment and coal to improve the quality of findings by the laboratories

A.3 External quality assessment (EQA) programmes

A.3.1. EQA programmes (such as those provided for laboratory medicine examinations) offer a variety of interlaboratory comparison schemes based on this traditional proficiency testing model, but with broader application of the schemes described in A.1 and A.2. Many EQA programmes are designed to provide insight into the complete path of workflow of the laboratory, and not just the testing (or examination) processes. Most EQA programmes are continuous schemes that include long term follow-up of laboratory performance. A typical feature of EQA programmes is to provide education to participants and promote quality improvement. Advisory and educational comments comprise part of the report returned to participants to achieve this aim.

A.3.2. Some EQA programmes assess performance of pre-analytical and post-analytical phases of testing, as well as the analytical phase. In such EQA programmes, the nature of the proficiency test item may differ significantly from that used in traditional proficiency testing schemes. The “proficiency test item” may be a questionnaire or case study circulated by the EQA provider to each participant for return of specific answers. Alternatively, pre-analytical information may accompany the proficiency test item, requiring the participant to select an appropriate approach to testing or interpretation of results, and not just to perform the test. In “sample review” schemes, participants may be required to provide the “proficiency test items” to the EQA provider. This may take the form of a processed specimen or sample (e.g. stained slide or fixed tissue), laboratory data (e.g. test results, laboratory reports or quality assurance/control records). It should be noted that these aspects are not unique to EQA programmes and many proficiency testing schemes, also provides assessment of processes across the measurement cycle.

A.4. Alternative Interlaboratory comparison schemes

A.4.1. In order to conduct proficiency testing, there must be valid measurement methods and appropriate proficiency test items; and, to be commercially viable, a sufficient number of potential participants. These might not be available in new fields of measurement, inspection, or sampling; or, for example, with testing for novel pathogens or biomarkers. In these situations, other types of interlaboratory comparisons can be useful.

A.4.2. Two common types of interlaboratory comparisons are collaborative studies to establish the performance characteristics of a measurement method, (ISO 5725 Parts 1-5) and collaborative studies to characterize a reference material (ISO Guide 35). These studies will not be discussed further in this document. It is also possible to conduct trial (or “pilot”) schemes, but without evaluating performance.

A.4.3 One special type of interlaboratory comparison design that is often used by participants' customers and some regulatory bodies is the “split-sample” design. Typically, split-sample interlaboratory comparison involves comparisons of the data produced by small groups of participants (often only two). In these interlaboratory comparisons, samples of a product or a material are divided into two or more parts, with each participant testing one part of the sample. Uses for this type of interlaboratory comparisons include identifying poor accuracy, describing consistent bias and verifying the effectiveness of corrective actions. This design may be used to evaluate one or both participants as suppliers of testing services, or in cases where there are too few participants for appropriate evaluation of results. Under such schemes, one of the participants may be considered to operate at a higher metrological level (i.e. lower measurement uncertainty), due to the use of reference methodology and more advanced equipment, etc., or through confirmation of its own performance through satisfactory participation in a recognized interlaboratory comparison scheme. Its results are considered to be the assigned values in such comparisons and it may act as an advisory or mentor laboratory to the other participants comparing split-sample data with it.

Annex B

(informative)

Statistical methods for proficiency testing

B.1. General

B.1.1. Proficiency test results can appear in many forms, spanning a wide range of data types and underlying statistical distributions. The statistical methods used to analyse the results need to be appropriate for each situation, and so are too varied to be specified in this International Standard. ISO 13528 describes preferred specific methods for each of the situations discussed below, but also states that other methods may be used as long as they are statistically valid and are fully described to participants. ISO 13528 also presents guidance on design and visual data analysis. Other references may be consulted for specific types of proficiency testing schemes, e.g. measurement comparison schemes for calibration.

B.1.2. The methods discussed in this annex and in the referenced documents cover the fundamental steps common to nearly all proficiency testing schemes, i.e.

- a) determination of the assigned value,
- b) calculation of performance criteria and statistics,
- c) evaluation of performance, and
- d) preliminary determination of proficiency test item homogeneity and stability.

B.1.3. With new proficiency testing schemes, initial agreement between results is often poor, due to new questions, new forms, artificial test items, poor agreement of test or measurement methods, or variable measurement procedures. Coordinators may have to use robust indicators of relative performance (such as percentiles) until agreement improves. Statistical methods may need to be refined once participant agreement has improved and proficiency testing is well established.

B.1.4. This annex does not consider statistical methods for analytical studies other than for treatment of proficiency test data. Different methods may be needed to implement the other uses of interlaboratory comparison data listed in the Introduction.

B.2. Determination of the assigned value and its uncertainty

B.2.1. There are various procedures available for the establishment of assigned values, which are required to be consistent with the objectives of the proficiency testing scheme. The most common procedures are listed below in an order that, in most cases, will result in increasing uncertainty for the assigned value. These procedures involve the use of:

- a) known values – with results determined by specific proficiency test item formulation (e.g. manufacture or dilution);
- b) certified reference values – as determined by definitive test or measurement methods (for quantitative tests);
- c) reference values – as determined by analysis, measurement or comparison of the proficiency test item alongside a reference material or standard, traceable to a national or international standard;

- d) consensus values from expert participants – experts (which may, in some situations, be reference laboratories) should have demonstrable competence in the determination of the measurand(s) under test, using validated methods known to be highly accurate and comparable to methods in general use;
- e) consensus values from participants – using statistical methods described in ISO 13528, and with consideration of the effects of outliers.

B.2.2 Assigned values should be determined to evaluate participants fairly, yet to encourage agreement among test or measurement methods, as stated in the objectives for the scheme. This is accomplished through selection of common comparison groups and the use of common assigned values, wherever possible.

B.2.3 Procedures for determining the uncertainty of assigned values are discussed in detail in ISO 13528, for each common statistic used (as mentioned above). Additional information on uncertainty is also provided in ISO/IEC Guide 98-3.

B.2.4 Statistical methods for determining the assigned value for qualitative data need to be determined by expert judgement or manufacture. In some cases, a proficiency testing provider may use a consensus value, as defined by agreement of a predetermined majority percentage of responses (e.g. 80% or more). However, the percentage used should be determined based on objectives for the proficiency testing scheme and the level of competence and experience of the participants.

B.2.5 Outliers are statistically treated as described below.

- a) Obvious blunders, such as those with incorrect units, decimal point errors, and results for a different proficiency test item should be removed from the data set and treated separately. These results should not be subject to outlier tests or robust statistical methods.
- b) When participants' results are used to determine assigned values, statistical methods should be in place to minimize the influence of outliers. This can be accomplished with robust statistical methods or by removing outliers prior to calculation. In larger or routine proficiency testing schemes, it may be possible to have automated outlier screens, if justified by objective evidence of effectiveness.
- c) If results are removed as outliers, they should be removed only for calculation of summary statistics. These results should still be evaluated within the proficiency testing scheme and be given the appropriate performance evaluation.

NOTE ISO 13528 describes specific robust methods for determination of the consensus mean and standard deviation, without the need for outlier removal.

B.2.6 Other considerations are outlined below.

- a) Ideally, if assigned values are determined by participant consensus, the proficiency testing provider should have a procedure to establish the trueness of the assigned values and for reviewing the distribution of the data.
- b) The proficiency testing provider should have criteria for the acceptability of an assigned value in terms of its uncertainty. In ISO 13528 criteria are provided that are based on a goal to limit the effect that uncertainty in the assigned value has on the evaluation, i.e. the criteria limit the probability of having a participant receive an unacceptable evaluation because of uncertainty in the assigned value.

B.3. Calculation of performance statistics

B.3.1 Performance for quantitative results

B.3.1.1 Proficiency test results often need to be transformed into a performance statistic, in order to aid interpretation and to allow comparison with defined objectives. The purpose is to measure the deviation from the assigned value in a manner that allows comparison with performance criteria. Statistical methods may range from no processing required to complex statistical transformations.

B.3.1.2 Performance statistics should be meaningful to participants. Therefore, statistics should be appropriate for the relevant tests and be well understood or traditional within a particular field.

B.3.1.3 Commonly used statistics for quantitative results are listed below, in order of increasing degree of transformation of participants' results.

- a) The difference, D_i , is calculated using Equation (B.1):

$$D_i = (x_i - x_{pt}) \quad (\text{B.1})$$

where

x_i is the result from participant i ;

x_{pt} is the assigned value.

- b) The percent difference, $D_i\%$, is calculated using Equation (B.2):

$$D_i\% = \frac{(x_i - x_{pt})}{x_{pt}} \times 100\% \quad (\text{B.2})$$

- c) The z scores are calculated using Equation (B.3):

$$z_i = \frac{(x_i - x_{pt})}{\sigma_{pt}} \quad (\text{B.3})$$

where σ_{pt} is the standard deviation for proficiency assessment.

As described in ISO 13528, σ_{pt} can be calculated from the following:

- a fitness for purpose goal for performance, as determined by expert judgement or regulatory mandate (prescribed value);
- an estimate from previous rounds of proficiency testing or expectations based on experience (by perception);
- an estimate from a statistical model (general model);
- the results of a precision experiment; or
- participant results, i.e. a traditional or robust standard deviation based on participant results.

- d) The zeta score, ζ , is calculated using Equation (B.4), where calculation is very similar to the E_n number [see e) below], except that standard uncertainties are used rather than expanded uncertainties. This allows the same interpretation as for traditional z scores.

$$\zeta_i = \frac{(x_i - x_{pt})}{\sqrt{(u_{lab}^2 + u^2(x_{pt}))}} \quad (\text{B.4})$$

where

u_{lab} is the combined standard uncertainty of a participant's result;

$u(x_{pt})$ is the standard uncertainty of the assigned value.

e) E_n numbers are calculated using Equation (B.5):

$$E_{n,i} = \frac{(x_i - x_{pt})}{\sqrt{(U_{labi}^2 + U_{xpt}^2)}} \quad (\text{B.5})$$

where

U_{labi} is the expanded uncertainty of a participant's result;

U_{xpt} is the expanded uncertainty of the reference laboratory's assigned value.

NOTE 1 The formulae in Equations (B.4) and (B.5) are correct only if x and x_{pt} are independent.

NOTE 2 For additional statistical approaches, see ISO 13528 and the IUPAC International Harmonized Protocol.

B.3.1.4 The aspects below should be taken into consideration.

- f) The simple difference between the participant's result and the assigned value may be adequate to determine performance, and is most easily understood by participants. The quantity $(x_i - x_{pt})$ is called the "estimate of laboratory bias" in ISO 5725-4 and ISO 13528.
- g) The percent difference is independent of the magnitude of the assigned value, and is well understood by participants.
- h) Percentiles or ranks are useful for highly disperse or skewed results, ordinal responses, or when there are a limited number of different responses. This method should be used with caution.
- i) Transformed results may be preferred, or necessary, depending on the nature of the test. For example, dilution-based results are a form of geometric scale, transformable by logarithms.
- j) If consensus is used to determine σ_{pt} , the estimates of variability should be reliable, i.e. based on enough observations to reduce the influence of outliers and achieve sufficiently low uncertainty.
- k) If scores consider the participants' reported estimates of measurement uncertainty (e.g. with E_n scores or zeta scores), these will only be meaningful if the uncertainty estimates are determined in a consistent manner by all participants, such as in accordance with the principles in ISO/IEC Guide 98-3.

B.3.2. Performance for qualitative and semi-quantitative results

B.3.2.1 For qualitative or semi-quantitative results, if statistical methods are used, they must be appropriate for the nature of the responses. For qualitative data (also called “categorical” data), the appropriate technique is to compare a participant's result with the assigned value. If they are identical, then performance is acceptable. If they are not identical, then expert judgement is needed to determine if the result is fit for its intended use. In some situations, the proficiency testing provider may review the results from participants and determine that a proficiency testing item was not suitable for evaluation, or that the assigned value was not correct. These determinations should be part of the plan for the scheme and understood by the participants in advance of the operation of the scheme.

B.3.2.2 For semi-quantitative results (also called “ordinal” results), the techniques used for qualitative data (B.3.2.1) are appropriate. Ordinal results include, for example, responses such as grades or rankings, sensory evaluations, or the strength of a chemical reaction (e.g. 1+, 2+, 3+, etc.). Sometimes these responses are given as numbers, e.g. 1 = Poor, 2 = Unsatisfactory, 3 = Satisfactory, 4 = Good, 5 = Very Good.

B.3.2.3 It is not appropriate to calculate usual summary statistics for ordinal data, even if the results are numerical. This is because the numbers are not on an interval scale, i.e. the difference between 1 and 2, in some objective sense, may not be the same as the difference between 3 and 4, so averages and standard deviations cannot be interpreted. Therefore, it is not appropriate to use evaluation statistics such as z scores for semi-quantitative results. Specific statistics, such as rank or order statistics, designed for ordinal data, should be used.

B.3.2.4 It is appropriate to list the distribution of results from all participants (or produce a graph), along with the number or percentage of results in each category, and to provide summary measures, such as the modes (most common responses) and range (lowest and highest response). It may also be appropriate to evaluate results as acceptable based on closeness to the assigned value, e.g. results within plus or minus one response from the assigned value may be fit for the purpose of the measurement. In some situations, it may be appropriate to evaluate performance based on percentiles, e.g. the 5 % of results farthest from the mode or farthest from the assigned value may be determined to be unacceptable. This should be based on the proficiency testing scheme plan (i.e. fitness for purpose) and understood by participants in advance.

B.3.3. Combined performance scores

B.3.3.1. Performance may be evaluated on the basis of more than one result in a single proficiency testing round. This occurs when there is more than one proficiency test item for a particular measurand, or a family of related measurands. This would be done to provide a more comprehensive evaluation of performance.

B.3.3.2. Graphical methods, such as the Youden plot or a plot showing Mandel's *h*-statistics, are effective tools for interpreting performance (see ISO 13528).

B.3.3.3. In general, averaged performance scores are discouraged because they can mask poor performance on one or more proficiency test items that should be investigated. The most commonly used combined performance score is simply the number (or percentage) of results determined to be acceptable.

B.4. Evaluation of performance

B.4.1. Initial performance

B.4.1.1 Criteria for performance evaluation should be established after taking into account whether the performance measure involves certain features. The features for performance evaluation are the following:

- a) expert consensus, where the advisory group, or other qualified experts, directly determine whether reported results are fit for their intended purpose; agreement of experts is the typical way to assess results for qualitative tests;
- b) fitness for purpose, predetermined criteria that consider, for example, method performance specifications and participants' recognized level of operation;
- c) statistical determination for scores, i.e. where criteria should be appropriate for each score; common examples of application of scores are as follows:
 - 1) for z scores and zeta scores (for simplicity, only "z" is indicated in the examples below, but "ζ" may be substituted for "z" in each case):

- $|z| < 2,0$ indicates "satisfactory" performance and generates no signal;
- $2,0 < |z| < 3,0$ indicates "questionable" performance and generates a warning signal;
- $|z| > 3,0$ indicates "unsatisfactory" performance and generates an action signal;

2) for E_n numbers:

- $|E_n| < 1,0$ indicates "satisfactory" performance and generates no signal;
- $|E_n| > 1,0$ indicates "unsatisfactory" performance and generates an action signal.

B.4.1.2 For split-sample designs, an objective may be to identify in results inadequate calibration or large random fluctuation, or both. In these cases, evaluations should be based on an adequate number of results and across a wide range of concentrations. Graphical presentations are useful for identifying and describing these problems, and are described in ISO 13528. These graphs should use differences between results on the vertical axis, rather than plots of results from one participant versus another, because of problems of scale. One key consideration is whether results from one of the participants have, or can be expected to have, lower measurement uncertainty. In this case, those results are the best estimate of the actual level of measurand. If both participants have approximately the same measurement uncertainty, the average of the pair of results is the preferred estimate of actual level.

B.4.1.3 Graphs should be used whenever possible to show performance (e.g. histograms, error bar charts, ordered z score charts), as described in ISO 13528. These charts can be used to show:

- d) distributions of participant values;
- e) relationship between results on multiple proficiency test items;
- f) comparative distributions for different methods.

B.4.2. Monitoring performance over time

B.4.2.1 A proficiency test scheme can include procedures to monitor performance over time. The procedures should allow participants to see the variability in their performance, whether there are general trends or inconsistencies, and where the performance varies randomly.

B.4.2.2 Graphical methods should be used to facilitate interpretation by a wider variety of readers. Traditional “Shewhart” control charts are useful, particularly for self-improvement purposes. Data listings and summary statistics allow more detailed review. Standardized performance scores used to evaluate performance, such as the z score, should be used for these graphs and tables. ISO 13528 presents additional examples and graphical tools.

B.4.2.3 Where a consensus standard deviation is used as the standard deviation for proficiency testing, caution should be taken when monitoring performance over time, as the participant group can change, and can have unknown effects on the scores. It is also common for the interlaboratory standard deviation to decrease over time, as participants become familiar with the proficiency testing scheme or as methodology improves. This could cause an apparent increase in z scores, when a participant's individual performance has not changed.

B.5. Demonstration of proficiency test item homogeneity and stability

B.5.1 The requirements of this International Standard call for a demonstration of “sufficient homogeneity” with valid statistical methods, including a statistically random selection of a representative number of samples. Procedures for this are detailed in ISO 13528, which defines “sufficient homogeneity” relative to the evaluation interval for the proficiency testing scheme, and so the recommendations are based on allowances for uncertainty due to inhomogeneity relative to the evaluation interval. ISO 13528 describes several approaches for ensuring sufficient homogeneity and stability, depending on the experience of the proficiency testing provider.

B.5.2 There are different needs for requirements in ISO 17034 and ISO Guide 35, which are for determining reference values for certified reference materials, including their uncertainties. ISO Guide 35 uses statistical analysis of variance to estimate the “bottle-to-bottle” variability and “within-bottle” variability (as appropriate), and subsequently uses those variances as components of the uncertainty of the assigned value. Given the need to estimate components accurately for certified reference materials, the number of randomly selected samples may exceed what is needed for proficiency testing, where the main objective is to check for unexpected inconsistencies in batches of manufactured proficiency test items.

B.5.3 Stability is normally checked to ensure that the measurand(s) did not change during the course of the round. As specified in ISO 13528 and ISO Guide 35, proficiency test items should be tested under the variety of conditions that occur in the normal operation of a proficiency testing scheme, e.g. conditions of shipping and handling when distributed to participants. The criterion for acceptable instability is the same as the criterion for inhomogeneity in ISO 13528, although typically with fewer tests or measurements.

Annex C (informative)

Selection and use of proficiency testing

C.1. General

C.1.1. This annex establishes principles for the selection and use of proficiency testing schemes by participants and other interested parties. This annex is also intended to promote the harmonized use of proficiency testing schemes by interested parties (e.g. accreditation bodies, regulatory bodies, or customers of the participant).

C.1.2. Since results from proficiency testing schemes may be used in the evaluation of a participant's performance, it is important that both the interested parties and participants have confidence in the development and operation of the proficiency testing schemes.

C.1.3. It is also important for participants to have a clear understanding of the policies of the interested parties for participation in such proficiency testing schemes, the criteria they use for judging successful performance in proficiency testing schemes, and their policies and procedures for following up any unsatisfactory results from a proficiency test round. However, apart from specific requirements from regulatory bodies, it is the responsibility of the participants themselves to select the appropriate proficiency testing scheme and to evaluate their results correctly.

C.1.4. It should be recognized, however, that interested parties also take into account the suitability of test data produced from activities other than proficiency testing schemes, including, for example, results of participants' own internal quality control procedures with control samples, comparison with split-sample data from other participants and performance on tests of certified reference materials. Therefore, when selecting a proficiency testing scheme, the participant should take into consideration the other quality control activities that are available or have already been performed.

C.2. Selection of proficiency testing schemes

C.2.1 Laboratories (and other types of participants) need to select proficiency testing schemes that are appropriate for their scope of testing or scope of calibration. The proficiency testing schemes selected should comply with the requirements of this International Standard.

C.2.2 In selecting a proficiency testing scheme, the following factors should be considered:

- a) the tests, measurements or calibrations involved should match the types of tests, measurements or calibrations performed by the participant;
- b) the availability to interested parties of details about the scheme design, procedures for establishment of assigned values, instructions to participants, statistical treatment of data, and the final summary report;
- c) the frequency at which the proficiency testing scheme is operated;

- d) the suitability of the organizational logistics for the proficiency testing scheme (e.g. timing, location, sample stability considerations, distribution arrangements) relevant to the group of participants proposed for the proficiency testing scheme;
- e) the suitability of acceptance criteria (i.e. for judging successful performance in the proficiency test);
- f) the costs;
- g) the proficiency testing provider's policy on maintaining participants' confidentiality;
- h) the timescale for reporting of results and for analysis of performance data;
- i) the characteristics that instil confidence in the suitability of proficiency test items (e.g. homogeneity, stability, and, where appropriate, metrological traceability to national or international standards);
- j) its conformance with this International Standard.

NOTE Some proficiency testing schemes can include tests which are not an exact match for the tests performed by the participant (e.g. the use of a different national standard for the same determination), but it can still be technically justified to participate in the proficiency testing scheme if the treatment of the data allows for consideration of any significant differences in test methodology or other factors.

C. 3. Policies on participation in proficiency testing schemes

C.3.1 If relevant, interested parties should document their policies for participation in proficiency testing schemes; such documented policies should be publicly available to laboratories and other interested parties.

C.3.2 Issues which should be addressed in participation policies for specific proficiency testing schemes include:

- a) whether participation in specific proficiency testing schemes is mandatory or voluntary;
- b) the frequency of participation;
- c) the criteria used by the interested party to judge satisfactory or unsatisfactory performance;
- d) whether participants may be required to participate in follow-up proficiency testing schemes if performance is judged to be unsatisfactory;
- e) how the results of proficiency testing will be used in the evaluation of performance and subsequent decisions;
- f) details of the interested party's policy on preserving participants' confidentiality.

C.4 Use of proficiency testing by participants

C.4.1 Participants should draw their own conclusions about their performance from an evaluation of the organization and design of the proficiency testing scheme. Reviews should consider the relation

between the proficiency testing scheme and the needs of the participant's customers. The information that should be taken into consideration includes:

- a) the origin and character of proficiency test items;
- b) the test and measurement methods used and, where possible, the assigned values for particular test or measurement methods;
- c) the organization of the proficiency testing scheme (e.g. the statistical design, the number of replicates, the measurands, the manner of execution);
- d) the criteria used by the proficiency testing provider to evaluate the participants' performance;
- e) any relevant regulatory, accreditation or other requirements.

C.4.2 Participants should maintain their own records of performance in proficiency testing, including the outcomes of investigations of any unsatisfactory results and any subsequent corrective or preventive actions.

C. 5. Use of results by interested parties

C.5.1. Accreditation bodies

C.5.1.1 The requirements for an accreditation body with regard to use of proficiency testing are specified in ISO/IEC 17011:2017.

NOTE Further policies on proficiency testing relevant to the compliance of accreditation bodies with requirements for membership in the ILAC mutual recognition arrangement are specified in ILAC P-9.

C.5.1.2 The results from proficiency testing schemes are useful for both participants and accreditation bodies. There are, however, limitations on the use of such results to determine competence. Successful performance in a specific proficiency testing scheme may represent evidence of competence for that exercise, but may not reflect ongoing competence. Similarly, unsuccessful performance in a specific proficiency testing scheme may reflect a random departure from a participant's normal state of competence. It is for these reasons that proficiency testing should not be the only tool used by accreditation bodies in their accreditation processes.

C.5.1.3 For participants reporting unsatisfactory results, the accreditation bodies should have policies to

- a) ensure that the participants investigate and comment on their performance within an agreed time-frame, and take appropriate corrective action,
- b) (where necessary) ensure that the participants undertake any subsequent proficiency testing to confirm that any corrective actions taken by them are effective, and
- c) (where necessary) ensure that on-site evaluation of the participants is carried out by appropriate technical assessors to confirm that corrective actions are effective.

C.5.1.4 The accreditation bodies should advise their accredited bodies of the possible outcomes of unsatisfactory performance in a proficiency testing scheme. These may range from continuing accreditation subject to successful attention to corrective actions within agreed time-frames, temporary

suspension of accreditation for the relevant tests (subject to corrective action), through to withdrawal of accreditation for the relevant tests.

NOTE Generally speaking, the options selected by an accreditation body will depend on the history of performance of the participant over time and from the most recent on-site assessments.

C.5.1.5 The accreditation bodies should have policies for feedback from accredited bodies relating to action taken on the basis of results of proficiency testing schemes, particularly for unsatisfactory performance.

C.5.2. Other interested parties

C.5.2.1 Participants may need to demonstrate their competence to other interested parties, such as customers or in a subcontracting mandate. Proficiency testing results, as well as other quality control activities, can be used to demonstrate competence, although this should not be the only activity.

NOTE Proficiency testing data used to validate claims of competence are normally used by organizations in conjunction with other evidence, such as accreditation. See C.5.1.2.

C.5.2.2 It is the responsibility of the participants to ensure that they have provided all the appropriate information to interested parties wishing to evaluate the participants as to their competence.

C.6. Use of proficiency testing by regulatory bodies

C.6.1 The results from proficiency testing schemes are useful for regulatory bodies that need to evaluate the performance of participants covered by regulations.

C.6.2 If the proficiency testing scheme is operated by a regulatory body, it should be operated in accordance with the requirements of this International Standard.

C.6.3 Regulatory bodies that use independent proficiency testing providers should

- a) seek documentary evidence that the proficiency testing schemes comply with the requirements of this International Standard before recognizing the proficiency testing scheme, and
- b) discuss with participants the scope and operational parameters of the proficiency testing scheme, in order that the participants' performance may be judged adequately in relation to the regulations.

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