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Conformity assessment — General requirements for proficiency testing

Évaluation de la conformité — Exigences générales concernant les essais d'aptitude

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

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

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

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

ISO/IEC 17043 was prepared by the ISO Committee on conformity assessment (CASCO).

It was circulated for voting to the national bodies of both ISO and IEC, and was approved by both organizations.

This first edition of ISO/IEC 17043 cancels and replaces ISO/IEC Guide 43-1:1997 and ISO/IEC Guide 43-2:1997, which have been technically revised.

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 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 International Standard 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. ISO/IEC 17011 requires accreditation bodies to take account of laboratories' participation and performance in proficiency testing. There is a growing need for proficiency testing for other conformity assessment activities, such as inspection or product certification. Most of the requirements in this International Standard apply to those evolving areas, especially regarding management, planning and design, personnel, assuring quality, confidentiality, and other aspects, as appropriate.

This International Standard 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 both parts of ISO/IEC Guide 43:1997. ISO/IEC Guide 43 included not only guidance on development and operation of proficiency testing and selection and use of proficiency testing by laboratory accreditation bodies, but also useful descriptions of typical types of proficiency testing. This International Standard has preserved and updated the principles for the operation of proficiency testing described in ISO/IEC Guide 43 and has retained in Annexes A to C information 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.

Conformity assessment — General requirements for proficiency testing

1 Scope

This International Standard specifies general requirements for the competence of providers of proficiency testing schemes and for the development and operation of proficiency testing schemes. These requirements are intended to be general for all types of proficiency testing schemes, and they can be used as a basis for specific technical requirements for particular fields of application.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO/IEC 17000:2004, *Conformity assessment — Vocabulary and general principles*

ISO/IEC Guide 99:2007, *International vocabulary of metrology — Basic and general concepts and associated terms (VIM)*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO/IEC 17000:2004, ISO/IEC Guide 99:2007 and the following apply.

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   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   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   For the purposes of this International Standard, 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   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 this International Standard 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
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   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
statistical method 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   The standard deviation applies only to ratio and differential scale results.

NOTE 2   Not all proficiency testing schemes evaluate proficiency based on the dispersion of results.

3.14
subcontractor
organization or individual engaged by the proficiency testing provider to perform activities specified in this International Standard and that affect the quality of a proficiency testing scheme

NOTE   The term "subcontractor" includes what many proficiency testing providers call collaborators.

3.15
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   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   Metrological traceability requires an established calibration hierarchy.

NOTE 3   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   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   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   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   The ILAC[1] considers the elements for confirming metrological traceability to be an unbroken metrological traceability chain to an international measurement standard or a national measurement standard, a documented measurement uncertainty, a documented measurement procedure, accredited technical competence, metrological traceability to the SI, and calibration intervals (see ILAC P-10:2002).

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1) International Laboratory Accreditation Cooperation.

NOTE 8   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]

3.16
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   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   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   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   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]

4   Technical Requirements

4.1   General

The development and operation of proficiency testing schemes shall be undertaken by proficiency testing providers having competence to conduct interlaboratory comparisons and access to expertise with the particular type of proficiency test items. Proficiency testing providers or their subcontractors shall also have competence in the measurement of the properties being determined.

NOTE   ISO/IEC 17025 or ISO 15189 can be used to demonstrate the competence of a proficiency testing provider's laboratory, or the laboratory subcontracted to perform tests or measurements related to the proficiency testing schemes. ISO Guide 34 can be used to demonstrate the competence of producers of reference materials that provide proficiency test items.

4.2   Personnel

4.2.1   The proficiency testing provider shall have managerial and technical personnel with the necessary authority, resources and technical competence required to perform their duties.

4.2.2   The proficiency testing provider's management shall define the minimum levels of qualification and experience necessary for the key positions within its organization and ensure those qualifications are met.

4.2.3   The proficiency testing provider shall use personnel who are either employed by, or under contract to it. Where contracted and additional technical and key support personnel are used, the proficiency testing provider shall ensure that such personnel are supervised and competent and that they work in accordance with the management system.

NOTE   Where technical experts are used on an ad-hoc basis or as part of an advisory or steering group (see 4.4.1.4), the existence of formal agreements through, for example, group terms of reference or other means, can be considered to satisfy this requirement.

4.2.4   The proficiency testing provider shall authorize specific personnel to:

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.

4.2.5   The proficiency testing provider shall maintain up-to-date records of the relevant authorization(s), competence, educational and professional qualifications, training, skills and experience of all technical personnel, including contracted personnel. This information shall be readily available and shall include the date on which competence to perform their assigned tasks was assessed and confirmed.

4.2.6   The proficiency testing provider shall formulate the objectives with respect to the education, training, and skills for each staff member involved with the operation of the proficiency testing scheme. The proficiency testing provider shall have a policy and procedures for identifying training needs and providing training of personnel. The training programme shall be relevant to the present and anticipated needs of the proficiency testing provider.

NOTE   It is advisable to consider the need to retrain staff periodically. Staff training policies can take account of technological change, the need to demonstrate ongoing competence and aim at continual skills upgrading.

4.2.7   The proficiency testing provider shall ensure that staff receive the necessary training to ensure competent performance of measurements, operation of equipment and any other activities which affect the quality of the proficiency testing scheme. The effectiveness of training activities shall be evaluated.

NOTE   Objective measures can be used to assess the attainment of competence.

4.3   Equipment, accommodation and environment

4.3.1   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.

4.3.2   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 subcontractors. The technical requirements for accommodation and environmental conditions that can affect the proficiency testing shall be documented.

4.3.3   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.

4.3.4   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.

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

4.3.6   Proficiency testing providers shall ensure that performance characteristics of laboratory methods and equipment used to confirm the content, homogeneity and stability of proficiency testing items are appropriately validated and maintained.

4.4   Design of proficiency testing schemes

4.4.1   Planning

4.4.1.1   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.

NOTE   Stakeholders' interests can be considered in developing a plan and relevant information.

4.4.1.2   The proficiency testing provider shall not subcontract the planning of the proficiency testing scheme (see 5.5.2).

NOTE   The proficiency testing provider can utilize advice or assistance from any advisors, experts or steering group (see 4.4.1.4).

4.4.1.3   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 subcontracted and the names and addresses of subcontractors 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.

4.4.1.4　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. This may be achieved, if necessary, by establishing an advisory group (named as appropriate).

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

a) planning requirements as listed in 4.4.1.3;

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.

4.4.2 Preparation of proficiency test items

4.4.2.1 The proficiency testing provider shall establish and implement procedures to ensure that proficiency test items are prepared in accordance with the plan described in 4.4.1.

NOTE It is advisable that the proficiency testing provider give due consideration to the preparation of sufficient numbers of proficiency test items, in order to allow for the need to replace any such proficiency test items lost or damaged during distribution, or intended to be provided for use after the results of the proficiency testing scheme have been evaluated. Such uses can include training aids for participants or use as a reference material.

4.4.2.2 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.

4.4.2.3 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.

4.4.2.4 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.

4.4.3 Homogeneity and stability

4.4.3.1 Criteria for suitable homogeneity and stability shall be established and shall be based on the effect that inhomogeneity and instability will have on 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 13528:2005, Annex B).

NOTE 4 Considerations for homogeneity and stability are further discussed in ISO Guide 34, ISO Guide 35 and ISO 13528.

4.4.3.2 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 statistically random selection of a representative number 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 random stratified or systematic selection of proficiency test items from the whole batch is more appropriate.

4.4.3.3 The assessment of homogeneity shall normally be performed after the proficiency test items have been packaged in the final form and before distribution to participants unless, for example, stability studies indicate that they should be stored in bulk form.

NOTE 1   Homogeneity can be demonstrated prior to packaging where no influence of packaging is reasonably expected.

NOTE 2   On some occasions, homogeneity testing cannot be carried out prior to distribution for practical, technical or logistical reasons.

4.4.3.4   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.

4.4.3.5   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.

4.4.3.6   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.

4.4.4   Statistical design

4.4.4.1   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.

4.4.4.2   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.

4.4.4.3   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.

4.4.5 Assigned values

4.4.5.1 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.

NOTE   Metrological traceability is not always possible or appropriate.

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

4.4.5.3 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.

4.4.5.4 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.

4.4.5.5 The proficiency testing provider shall have a policy regarding the disclosure of assigned values. The policy shall ensure that participants cannot gain advantage from early disclosure.

4.5 Choice of method or procedure

4.5.1 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.

4.5.2 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.

4.6 Operation of proficiency testing schemes

4.6.1 Instructions for participants

4.6.1.1   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.

4.6.1.2   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.

4.6.2 Proficiency test items handling and storage

4.6.2.1   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.

4.6.2.2   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.

4.6.2.3   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.

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

4.6.3 Packaging, labelling and distribution of proficiency test items

4.6.3.1 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.

4.6.3.2 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.

4.6.3.3 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.

4.6.3.4 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.

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

NOTE This could be achieved in accordance with 4.6.1.1 by asking participants to inform the proficiency testing provider if proficiency test items have not been received in line with the schedule of dates provided.

4.7 Data analysis and evaluation of proficiency testing scheme results

4.7.1 Data analysis and records

4.7.1.1 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.

4.7.1.2 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.

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

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

4.7.1.5 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.

4.7.1.6 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.

4.7.2 Evaluation of performance

4.7.2.1 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. The evaluation of performance shall not be subcontracted (see 5.5.2).

4.7.2.2 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.

4.8   Reports

4.8.1 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. The authorization of the final report shall not be subcontracted (see 5.5.2).

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.

4.8.2 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 subcontracted by the proficiency testing provider;

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.

4.8.3   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.

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

4.8.5   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.

4.9   Communication with participants

4.9.1   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)   confidentiality arrangements; and

e)   details of how to apply.

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

4.9.3   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.

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

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

4.10 Confidentiality

4.10.1   The identity of participants in a proficiency testing scheme shall be confidential and known only to persons involved in the operation of the proficiency testing scheme, unless the participant waives confidentiality.

4.10.2   All information supplied by a participant to the proficiency testing provider shall be treated as confidential.

NOTE   Participants can elect to waive confidentiality within the proficiency testing scheme for the purposes of discussion and mutual assistance, e.g. to improve performance. Confidentiality can also be waived by the participant for regulatory or recognition purposes. In most instances, the proficiency testing results can be provided to the relevant authority by the participants themselves.

4.10.3   When an interested party requires the proficiency testing results to be directly provided by the proficiency testing provider, the participants shall be made aware of the arrangement in advance of participation.

4.10.4   In exceptional circumstances, when a regulatory authority requires proficiency testing results to be directly provided to the authority by the proficiency testing provider, the affected participants shall be notified of this action in writing.

5   Management requirements

5.1   Organization

5.1.1   The proficiency testing provider, or the organization of which it is part, shall be an entity that is legally identifiable and accountable.

5.1.2   It is the responsibility of the proficiency testing provider to carry out its proficiency testing operations in such a way as to meet the requirements of this International Standard and to satisfy the needs of the participants, regulatory authorities and organizations providing recognition.

5.1.3   The management system shall cover work carried out in the proficiency testing provider's permanent facilities, at sites away from its permanent facilities, and in associated temporary facilities.

5.1.4   If the proficiency testing provider is part of an organization performing other activities, then the proficiency testing provider shall identify the responsibilities of key personnel in the organization that have an

involvement in or could have influence on the proficiency test activities, in order to identify potential conflicts of interest. Where potential conflicts of interest are identified, procedures shall be put in place to ensure that all activities of the proficiency testing provider are conducted with impartiality.

5.1.5   The proficiency testing provider shall:

a)   have managerial and technical personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties, including the implementation, maintenance and improvement of the management system, and to identify the occurrence of departures from the management system or from the procedures for providing proficiency testing schemes, and to initiate actions to prevent or minimize such departures;

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

c)   have policies and procedures to ensure the protection of its participants' confidential information and proprietary rights, including procedures for their protection during electronic storage and transmission;

d)   have policies and procedures to avoid involvement in any activities that might diminish confidence in its competence, impartiality, judgement or operational integrity;

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

f)   specify the responsibility, authority, interrelationships and required competence of all personnel who manage, perform or verify work affecting the quality of the operation of proficiency testing schemes;

g)   ensure that the personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the objectives of the management system;

h)   provide adequate supervision of technical staff, including trainees, by persons familiar with procedures for each activity;

i)   have technical management which has overall responsibility for the technical operations and the provision of the resources needed to ensure the required quality of proficiency testing schemes, including access to the necessary technical expertise and experience in the relevant field of testing, calibration or inspection, as well as statistics, as indicated in 4.4.1.4;

j)   appoint a member of staff as quality manager (named as appropriate) who, irrespective of other duties and responsibilities, shall have defined responsibility and authority for ensuring that the management system is implemented and followed at all times; the quality manager shall have direct access to the highest level of management at which decisions are taken on the proficiency testing provider's policies or resources; and

k)   appoint deputies for key managerial personnel.

NOTE   Where proficiency testing providers have a small number of personnel, individuals can have more than one function and it can be impractical to appoint deputies for all major functions.

5.1.6   Top management shall ensure that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the management system.

5.2   Management system

5.2.1   The proficiency testing provider shall establish, implement and maintain a management system appropriate to its scope of activities, including the type, range and volume of proficiency testing that it provides.

5.2.2   The proficiency testing provider shall define and document its policies, programmes, procedures and instructions to the extent necessary to assure the quality of all aspects of proficiency testing. The system's

documentation shall be communicated to, understood by, available to, and implemented by the appropriate personnel.

NOTE   These aspects include, but are not limited to, proficiency test item quality (e.g. homogeneity and stability), characterization (e.g. equipment calibration and method validation), assignment of property values (e.g. use of appropriate statistical procedures), evaluation of participant performance, distribution of proficiency test items, storage and transport procedures, statistical treatment of test results, and reporting.

5.2.3   The proficiency testing provider's management system policies related to quality, including a quality policy statement, shall be defined in a quality manual (named as appropriate). The overall objectives shall be established and reviewed during management review. The quality policy statement shall be issued under the authority of top management. It shall include at least the following:

a)   the management's commitment to the quality of its proficiency testing services to participants and other customers;

b)   the management's statement of the standard of service;

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

d)   a requirement that all personnel concerned with the proficiency testing activities familiarize themselves with the quality documentation and implement the policies and procedures in their work; and

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

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

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

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

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

5.2.8   Top management shall ensure that the integrity of the management system is maintained when changes to the management system are planned and implemented.

5.3   Document control

5.3.1   General

The proficiency testing provider shall establish and maintain procedures to control all documents that form part of its management system (internally generated, or from external sources), such as regulations, standards, other normative documents, proficiency testing scheme protocols, test or calibration methods, or both test and calibration methods, as well as drawings, software specifications, instructions and manuals.

5.3.2   Document approval and issue

5.3.2.1   All documents issued as part of the management system shall be reviewed and approved for use by authorized personnel prior to issue. A master list or equivalent document control procedure identifying the current revision status and distribution of documents in the management system shall be established and be readily available, in order to prevent the use of invalid or obsolete documents, or both.

5.3.2.2   The procedures adopted shall also ensure that:

a) authorized editions of appropriate documents are available at all locations where activities essential to the effective operation of proficiency testing schemes are performed;

b) documents are periodically reviewed and updated, as necessary, to ensure continuing suitability and compliance with applicable requirements;

c) invalid or obsolete documents are promptly removed from all points of issue or use, or otherwise assured against unintended use; and

d) obsolete documents retained for either legal or knowledge preservation purposes are suitably marked.

5.3.2.3   Management system documents generated by the proficiency testing provider shall be uniquely identified. Such identification shall include the date of issue or revision identification, or both, page numbering, the total number of pages or a mark to signify the end of a document, and the issuing authority/authorities.

5.3.3 Document changes

5.3.3.1   Changes to documents shall be reviewed and approved by the same function that performed the original review and approval, unless specifically designated otherwise. The designated personnel shall have access to pertinent background information upon which to base their review and approval.

5.3.3.2   Where practicable, the altered or new text shall be identified in the document or the appropriate attachments.

5.3.3.3   If the proficiency testing provider's document control system allows for the amendment of documents by hand, pending re-issue of the documents, the procedures and authorities for such amendments shall be defined. Amendments shall be clearly marked, initialled and dated. A revised document shall be issued as soon as practicable.

5.3.3.4   Procedures shall be established to describe how changes in documents maintained in computerized systems are made and controlled.

5.4   Review of requests, tenders and contracts

5.4.1   The proficiency testing provider shall establish and maintain policies and procedures for the review of requests, tenders and contracts. These reviews 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.

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.

5.4.2   Records of such reviews, including any changes, shall be maintained. Records shall also be maintained 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, or both.

5.4.3   The review shall cover all aspects of the request, including any work that is subcontracted by the proficiency testing provider.

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

5.4.5   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.

5.5   Subcontracting services

5.5.1   When a proficiency testing provider subcontracts work, the proficiency testing provider shall demonstrate that the subcontractors' experience and technical competence are sufficient for their assigned tasks and that they comply with the relevant clauses of this International Standard and other appropriate standards.

5.5.2   The proficiency testing provider shall not subcontract the planning of the proficiency test scheme (see 4.4.1.2), the evaluation of performance (see 4.7.2.1) or the authorization of the final report (see 4.8.1).

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

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

NOTE   This notification can, for example, take the form of a statement in the proficiency testing scheme documentation, such as the following: "Various aspects of the proficiency testing scheme can from time to time be subcontracted. When subcontracting occurs, it is placed with a competent subcontractor and the proficiency testing provider is responsible for this work."

5.5.4   The proficiency testing provider shall be responsible to the participants and other customers for the subcontractor's work, except in the case where a regulatory authority specifies which subcontractor is to be used.

5.5.5   The proficiency testing provider shall maintain a register of all subcontractors used in the operation of proficiency testing schemes, including the scope of subcontracting and a record of the competence assessment against relevant parts of this International Standard and other appropriate standards for the work in question.

5.6   Purchasing services and supplies

5.6.1   The proficiency testing provider shall have a policy and procedure(s) for the selection of services and supplies that it uses and that affect the quality of its proficiency testing schemes. Procedures shall exist for the purchase, reception and storage of reagents, proficiency test items, reference materials and other consumable materials relevant for the proficiency testing schemes.

5.6.2   The proficiency testing provider shall ensure that purchased supplies, equipment and consumable materials that affect the quality of proficiency testing schemes are not used until they have been inspected or otherwise verified as complying with specifications or requirements. Records of actions taken to check compliance shall be maintained.

5.6.3   Purchasing documents for items affecting the quality of proficiency testing schemes shall contain data describing the services and supplies ordered. These purchasing documents shall be reviewed and approved for technical content prior to release.

5.6.4   The proficiency testing provider shall evaluate suppliers of critical supplies and services which affect the quality of proficiency testing schemes. The proficiency testing provider shall maintain records of these evaluations, and list those suppliers that are approved.

NOTE   It is understood that some proficiency testing providers can be required to implement their purchasing procedures in accordance with policies defined by their parent company or a host organization.

5.7   Service to the customer

5.7.1   The proficiency testing provider shall be willing to cooperate with participants and other customers in clarifying customers' requests and in monitoring the proficiency testing provider's performance in relation to the work performed, provided that the proficiency testing provider assures confidentiality to its participants.

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

NOTE   Examples of the types of feedback include customer satisfaction surveys and review of proficiency testing reports with customers.

5.8   Complaints and appeals

The proficiency testing provider shall have a policy and follow a procedure for the resolution of complaints and appeals received from participants, customers or other parties. Records shall be maintained of all complaints, appeals, investigations and corrective actions taken by the proficiency testing provider.

5.9   Control of nonconforming work

5.9.1   The proficiency testing provider shall have a policy and 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 policy and procedure(s) shall ensure that:

a)   the responsibilities and authorities for the management of nonconforming work are designated and actions (including halting work of ongoing programmes and withholding reports, as necessary) are defined and taken when nonconforming work is identified;

b)   an evaluation of the significance of the nonconforming work is made;

c)   a decision on the need for action and timescale is taken immediately, together with any decision about the acceptability of the nonconforming work;

d)   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; and

e)   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.

5.9.2   Where the evaluation indicates that nonconforming work could recur or that there is doubt about the compliance of the proficiency testing provider or subcontractor with their own policies and procedures, the corrective action procedure in 5.11 shall be promptly followed.

5.10 Improvement

The proficiency testing provider shall continually improve the effectiveness of its management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

5.11 Corrective actions

5.11.1 General

The proficiency testing provider shall establish a policy and procedure(s) and shall designate appropriate personnel for implementing corrective actions when nonconforming work or departures from the policies and procedures in the management system or technical operations have been identified.

NOTE   See 5.9.1, Note.

5.11.2 Cause analysis

The procedure for corrective action shall start with an investigation to determine the root cause(s) of the problem.

NOTE   Cause analysis is the key and sometimes the most difficult part in the corrective action procedure. Often, the root cause is not obvious and thus a careful analysis of all potential causes of the problem is required. Potential causes could include customer requirements, proficiency test items and their specifications, methods and procedures, staff skills and training, consumable supplies, preparations of proficiency test items, homogeneity and stability tests, statistical design, instructions to participants, and materials handling and storage.

5.11.3 Selection and implementation of corrective actions

5.11.3.1   Where corrective action is needed, the proficiency testing provider shall identify potential corrective actions. It shall select and implement the action(s) most likely to eliminate the problem and to prevent recurrence.

5.11.3.2   Corrective actions shall be appropriate to the magnitude and risk of the problem.

5.11.3.3   The proficiency testing provider shall document and implement any required changes resulting from corrective action investigations.

5.11.4 Monitoring of corrective actions

The proficiency testing provider shall monitor the results to ensure that the corrective actions taken have been effective.

5.11.5 Additional audits

Where the identification of nonconforming activities or departures from authorized procedures cast doubts on the compliance of the proficiency testing provider with its own policies and procedures, or on its compliance with this International Standard, the proficiency testing provider shall ensure that the appropriate areas of activity are audited in accordance with 5.14 as soon as possible.

NOTE   Such additional audits often follow the implementation of the corrective actions to confirm their effectiveness. An additional audit can be necessary only when a serious issue or risk to the proficiency testing scheme is identified.

5.12 Preventive actions

5.12.1 Areas for improvements and potential sources of nonconforming work, either technical or concerning the management system, shall be identified. When improvement opportunities are identified, or if preventive action is required, action plans shall be developed, implemented and monitored, to reduce the likelihood of such nonconforming work and to take advantage of the opportunities for improvement.

5.12.2 Any procedure for preventive action shall include the initiation of such actions and application of controls to ensure that they are effective.

5.13 Control of records

5.13.1 General

5.13.1.1   The proficiency testing provider shall establish and maintain procedures for identification, collection, indexing, access, filing, storage, maintenance and disposal of records. Quality records shall include reports from internal audits and management reviews, as well as records of corrective and preventive actions.

5.13.1.2   All records shall be legible and shall be stored and retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss. Retention times of records shall be established.

NOTE   Records can be in the form of any type of media, such as hard copy or electronic storage media.

5.13.1.3   All records shall be kept secure and confidential, and in accordance with relevant regulatory requirements.

5.13.1.4   The proficiency testing provider shall follow procedures to protect and back-up records stored electronically and to prevent unauthorized access or amendment of these records.

5.13.2 Technical records

5.13.2.1   The proficiency testing provider shall retain records of all technical data relating to each proficiency testing round for a defined period, including, but not necessarily limited to:

a)   results of homogeneity and stability testing;

b)   instructions to participants;

c)   participants' original responses;

d)   collated data for statistical analysis;

e)   information required for reports (see 4.8); and

f)   final reports (summary or individual, or both).

NOTE 1   It is advisable to retain sufficient information to establish an audit trail for the processing of results from proficiency testing rounds.

NOTE 2   Technical records are accumulations of data and information which result from carrying out all proficiency testing activities. They can include forms, contracts, work sheets, work books, check sheets, work notes, sub-contractor reports and participant feedback.

5.13.2.2   Data entry, checking and calculations shall be recorded at the time they are made and shall be identifiable to the specific task and to the personnel responsible.

5.13.2.3   When mistakes occur in records and alterations are made, actions shall be taken to:

a)   identify the change and date of alteration;

b)   avoid loss of original data; and

c)   identify the person making the alteration.

5.14 Internal audits

5.14.1 The proficiency testing provider shall conduct internal audits of its activities periodically, and in accordance with a predetermined schedule and procedure, in order to verify that its operations continue to

comply with the requirements of the management system and this International Standard. The internal audit programme shall address all elements of the management system, including the technical procedures and proficiency test item preparation, storage and distribution, as well as reporting activities for the operation of a proficiency testing scheme. It is the responsibility of the quality manager to plan and organize audits as required by the schedule and requested by management. Internal audits shall be carried out by trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited.

NOTE   It is advisable that the programme for internal auditing of the management system be completed every 12 months.

5.14.2 When audit findings cast doubt upon the effectiveness of the operations, including the suitability and correctness of proficiency test items, procedures, statistical evaluations and data presentation, the proficiency testing provider shall take timely corrective action and shall notify its customers or participants, or both, in proficiency testing schemes whose activities may have been affected.

5.14.3 The area of audited activity, the audit findings and any corrective actions that arise from them shall be recorded.

5.14.4 Follow-up audit activities shall verify and record the implementation and effectiveness of any corrective actions taken.

5.15 Management reviews

5.15.1 In accordance with a pre-determined schedule and procedure, the proficiency testing provider's top management shall periodically conduct a review of the proficiency testing provider's management system and proficiency testing activities, in order to ensure their continued suitability and effectiveness and to introduce any necessary changes or improvements. The review shall take account of:

a)   the suitability of policies and procedures;

b)   reports from management and supervisory personnel;

c)   the outcome of recent internal audits;

d)   corrective and preventive actions;

e)   assessments by external bodies;

f)   changes in the volume and type of work;

g)   customer, advisory group or participant feedback;

h)   complaints and appeals;

i)   recommendations for improvement; and

j)   other relevant factors, such as resources and staff training.

NOTE 1   A typical period for conducting a management review is once every 12 months.

NOTE 2   Results can feed into the proficiency testing provider's planning system and can include the objectives and action plans.

NOTE 3   A management review includes consideration of related subjects at regular management meetings.

NOTE 4   Where the proficiency testing provider is part of a larger organization, it can be appropriate to hold a separate review meeting to cover proficiency testing activities.

5.15.2 Findings from management reviews, and the actions that arise from them, shall be recorded. The management shall ensure that those actions are discharged within an appropriate and agreed timescale.

Annex A
(informative)

Types of proficiency testing schemes

A.1 General

Proficiency testing has become an essential aspect of laboratory practice in all areas of testing, calibration and inspection. 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.

The nature of the test or measurement performed in proficiency testing schemes governs the method of comparing performance. There are three basic types of laboratory examinations: quantitative, qualitative and interpretive.

— The results of a quantitative measurement are numerical and are reported on an interval or a ratio scale. Tests for quantitative measurement may vary in their precision, trueness, analytical sensitivity, and specificity. In quantitative proficiency testing schemes, numerical results are usually analysed statistically.

— The results of qualitative tests are descriptive and reported on a categorical or ordinal scale, e.g. identity of micro-organisms, or by identification of the presence of a specific measurand (such as a drug or a grading of a characteristic). Assessment of performance by statistical analysis may not be appropriate for qualitative examinations.

— In interpretive tests, the "proficiency testing item" is a test result (e.g. a descriptive morphology statement), a set of data (e.g. to determine a calibration line) or other set of information (e.g. a case study), concerning an interpretative feature of the participant's competence.

Other proficiency testing schemes have additional features depending on their objective, as outlined in definition 3.7, Note 1, a) to h). Some common applications of those types of proficiency testing are discussed below and illustrated in Figure A.1. These schemes may be "single occasion" and performed once, or "continuous" and performed at regular intervals.

A.2 Sequential participation schemes

Sequential participation schemes (sometimes known as measurement comparison schemes) involve the proficiency test item being circulated successively from one participant to the next (i.e. sequential participation), or occasionally circulated back to the proficiency testing provider for rechecking. Model 1 in Figure A.1 provides a brief summary of this type of design, and 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) 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 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 scheme's implementation, rather than waiting until it finishes.

d) Proficiency test items (measurement artefacts) used in this type of proficiency test can include, for example, measurement reference standards (e.g. resistors, micrometers and frequency counters) or, in medical programmes, histology slides with confirmed diagnoses.

e) 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.3 Simultaneous participation schemes

A.3.1 General

Simultaneous participation proficiency testing schemes usually involve randomly selected sub-samples from a source of material being distributed simultaneously to participants for concurrent testing. In some schemes, participants are required to take samples, which are then considered to be the proficiency test items for analysis. 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. Model 2 in Figure A.1 represents typical proficiency testing schemes of this type, usually for testing laboratories. Model 3 presents a type of scheme that is frequently used in conjunction with simultaneous proficiency testing schemes, for oversight or educational purposes.

As discussed in Annex B, assigned values for these proficiency testing schemes may be determined in a variety of ways. However, either evaluations of performance are based on consensus values from participants (all participants, or a subset of "experts") or evaluations can be on the basis of independently-determined assigned values.

Known value schemes use assigned values that are determined independently of the participants and involve preparation of proficiency test items with a number of known measurands or characteristics. Certified reference materials can also be used in these schemes, as their certified value and measurement uncertainty can be used directly. A direct comparison can also be made between a proficiency test item and a certified reference material under repeatability conditions. However, care should be taken to ensure that the certified reference material is closely comparable with a proficiency test item. Proficiency test items from previous proficiency testing rounds may be used in this type of scheme, if the item has demonstrated stability.

One special application of proficiency testing, often called "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.3.2 Split-level designs

A common design for proficiency testing 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 a specific level 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.3.3 Split-sample testing schemes

One special type of proficiency testing design that is often used by participants' customers and some regulatory bodies is the "split-sample" design.

NOTE   This design is not to be confused with a split-level design, which is discussed in A.3.2.

Typically, split-sample proficiency testing involves comparisons of the data produced by small groups of participants (often only two). In these proficiency testing schemes, samples of a product or a material are divided into two or more parts, with each participant testing one part of the sample (see Figure A.1, model 5). Uses for this type of scheme 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.

A.3.4 Partial-process schemes

Special types of proficiency testing involve the evaluation of participants' abilities to perform parts of the overall testing or measurement process. 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.

A.4 External quality assessment (EQA) programmes

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.2 and A.3 and illustrated in Figure A.1. Many EQA programmes are designed to provide insight into the complete path of workflow of the laboratory, and not just the testing 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.

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 (see Figure A.1, model 3) 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 (see Figure A.1, model 4). 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) or documentation (e.g. procedures or method verification criteria).

Model 1 Sequential	Model 2 Simultaneous	Model 3 Interpretive	Model 4 Sample review	Model 5 Split sample
Produce/procure test items or artefacts	Produce/procure test items	Produce test items. Develop questionnaire or case study	Determine test items to be received from participant	Participants agree on analytes and sample types for comparison
Determine assigned value [a] and its uncertainty	Determine assigned value [a] and acceptable range of results	Distribute questionnaire, case study or test item to participants	Distribute specifications to participants	Participant(s) split appropriate sample(s) and send to others
Distribute to first participant	Distribute test items to participants	Receive results and interpretations from participants	Receive test items from participants	Participants share results or send to a coordinator
Have participant return item or send to next participant	Receive results and method information from participants	Determine acceptable criteria for responses and interpretations	Determine acceptable criteria for responses	Graph or otherwise compare results in this and previous studies
Review participant results and uncertainty for acceptability	Compare participant results and method information with acceptable range	Compare participant results and interpretations with criteria	Compare participant test items with criteria	Compare with pre-established criteria or discuss needs for action
Produce reports and issue advisory/ educational comments	Produce reports and issue advisory/ educational comments	Produce reports and issue advisory/ educational comments	Produce reports and issue advisory/ educational comments	Produce reports and records with any agreed conclusions or actions, including data and graphs

[a]   Depending how the assigned value is derived, it will be either determined prior to the distribution of the proficiency test items or after the return of participant results.

Figure A.1 — Examples of common types of proficiency testing schemes

Annex B
(informative)

Statistical methods for proficiency testing

B.1 General

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. Some of the methods in ISO 13528, especially for homogeneity and stability testing, are modified slightly in the IUPAC[2] Technical Report "The International Harmonized Protocol for the proficiency testing of analytical chemistry laboratories"[18]. These documents also present 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.

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 statistics,

c) evaluation of performance, and

d) preliminary determination of proficiency test item homogeneity and stability.

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.

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. 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);

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2) International Union of Pure and Applied Chemistry.

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 the IUPAC International Harmonized Protocol, 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. 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 and the IUPAC International Harmonized Protocol, 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 (also called "categorical" or "nominal" values), or semi-quantitative values (also called "ordinal" values) are not discussed in ISO 13528 or the IUPAC International Harmonized Protocol. In general, these assigned values 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 a specific robust method 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 and in the IUPAC International Harmonized Protocol, 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, is calculated using Equation (B.1):

$$D = (x - X)$$
(B.1)

where

x is the participant's result;

X is the assigned value.

b)   The percent difference, $D_{\%}$, is calculated using Equation (B.2):

$$D_{\%} = \frac{(x - X)}{X} \times 100$$
(B.2)

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

$$z = \frac{x - X}{\hat{\sigma}}$$
(B.3)

where $\hat{\sigma}$ is the standard deviation for proficiency assessment.

As described in ISO 13528, $\hat{\sigma}$ 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.

$$\zeta = \frac{x - X}{\sqrt{u_{\text{lab}}^2 + u_{\text{av}}^2}}$$
(B.4)