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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.

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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.

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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

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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

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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.

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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.

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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

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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;

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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;

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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.

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