

SLOVENSKI STANDARD
oSIST prEN ISO/IEC 17043:2009
01-februar-2009

Ugotavljanje skladnosti - Splošne zahteve za preskušanje strokovne usposobljenosti (ISO/IEC/DIS 17043:2008)

Conformity assessment - General requirements for proficiency testing (ISO/IEC/DIS 17043:2008)

Konformitätsbewertung - Allgemeine Anforderungen an Eignungsprüfungen (ISO/IEC DIS 17043:2008)

Évaluation de la conformité - Exigences générales pour les essais d'aptitude (ISO/IEC/DIS 17043:2008)

Ta slovenski standard je istoveten z: prEN ISO/IEC 17043

ICS:

03.120.20	Certificiranje proizvodov in podjetij. Ugotavljanje skladnosti	Product and company certification. Conformity assessment
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oSIST prEN ISO/IEC 17043:2009 **en**

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

DRAFT
prEN ISO/IEC 17043

November 2008

ICS 03.120.20

English version

**Conformity assessment - General requirements for proficiency
testing (ISO/IEC/DIS 17043:2008)**

Évaluation de la conformité - Exigences générales pour les
essais d'aptitude (ISO/IEC/DIS 17043:2008)

This draft European Standard is submitted to CEN/CENELEC members for parallel enquiry. It has been drawn up by the Technical Committee CEN/CLC/TC 1.

If this draft becomes a European Standard, CEN/CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

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Foreword

This document (prEN ISO/IEC 17043:2008) has been prepared by Technical Committee ISO/CASCO "Committee on conformity assessment" in collaboration with Technical Committee CEN/CLC/TC 1 "Criteria for conformity assessment bodies", the secretariat of which is held by BSI.

This document is currently submitted to the parallel Enquiry.

Endorsement notice

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CASCO

Secretariat: ISO/CS

Voting begins on
2008-11-13Voting terminates on
2009-04-13

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Conformity assessment — General requirements for proficiency testing

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

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The CEN Secretary-General has advised the ISO Secretary-General that this ISO/DIS covers a subject of interest to European standardization. **In accordance with the ISO-lead mode of collaboration as defined in the Vienna Agreement, consultation on this ISO/DIS has the same effect for CEN members as would a CEN enquiry on a draft European Standard.** Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month FDIS vote in ISO and formal vote in CEN.

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

In accordance with the provisions of Council Resolution 15/1993 this document is circulated in the English language only.

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization. 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.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member 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, individual staff performance 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-g. Proficiency testing does not usually address purposes, 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 purposes, 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 who specify requirements for laboratories. The International Standard 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 Parts 1 and 2 of the previous ISO/IEC Guide 43. 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. ISO/IEC 17043 has preserved and updated the principles for the operation of proficiency testing described in ISO/IEC Guide 43 and has retained in Annexes A-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, ISO/IEC Guide 99 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 comparisons

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 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 may 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 schemes – where the objective is to quantify one or more measurands of the proficiency test item ;
- b) qualitative schemes —where the objective is to identify or describe one or more characteristics of the proficiency test item;
- c) sequential scheme — where one or more items are distributed sequentially and returned to the organizer at intervals;
- d) bulk interlaboratory testing – where aliquots or portions of a homogeneous bulk material are provided, and the necessary tests and measurements are conducted within a defined time period;
- e) single occasion exercises — where proficiency test items are provided on a single occasion;
- f) continuous schemes — 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 and/or for their broader programmes (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 methods

statistical methods 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 ratio and differential scale results of proficiency testing, based on the available information

NOTE 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 affects the quality of a proficiency testing scheme

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 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).

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 (VIM), 2.41.]