



**SLOVENSKI STANDARD**  
**oSIST prEN ISO/IEC 17043:2022**  
**01-julij-2022**

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**Ugotavljanje skladnosti - Splošne zahteve za preskušanje strokovne usposobljenosti (ISO/IEC/DIS 17043:2022)**

Conformity assessment - General requirements for proficiency testing (ISO/IEC/DIS 17043:2022)

Konformitätsbewertung - Allgemeine Anforderungen an die Kompetenz von Anbietern von Eignungsprüfungen (ISO/IEC/DIS 17043:2022)

Évaluation de la conformité - Exigences générales concernant les essais d'aptitude (ISO/IEC/DIS 17043:2022)

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# DRAFT INTERNATIONAL STANDARD

## ISO/IEC DIS 17043

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

ICS: 03.120.20

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## Foreword

ISO (the International Organization for Standardization) and IEC (the International Electrotechnical Commission) form the specialized system for worldwide standardization. National bodies that are members of ISO or IEC participate in the development of International Standards through technical committees established by the respective organization to deal with particular fields of technical activity. ISO and IEC technical committees collaborate in fields of mutual interest. Other international organizations, governmental and non-governmental, in liaison with ISO and IEC, also take part in the work.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of document should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see [www.iso.org/directives](http://www.iso.org/directives)).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO and IEC shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see [www.iso.org/patents](http://www.iso.org/patents)) or the IEC list of patent declarations received (see <http://patents.iec.ch>).

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

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see [www.iso.org/iso/foreword.html](http://www.iso.org/iso/foreword.html).

This document was prepared by the ISO Committee on Conformity Assessment (CASCO). This second edition cancels and replaces the first edition (ISO/IEC 17043:2010) which has been technically revised.

The main changes compared to the previous edition are as follows:

- harmonization with the revision of ISO/IEC 17025, including technical requirements and structure;
- harmonization with the revision of ISO 13528 in terms of terminology;
- incorporation of requirements from ISO/CASCO PROC 33;
- inclusion of the requirement that testing activities, calibration activities and PT item production conform to the relevant requirements of appropriate ISO conformity assessment standards;
- deletion of Annex C and revision of Annexes A and B.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at [www.iso.org/members.html](http://www.iso.org/members.html).

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### Introduction

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

PT involves the use of interlaboratory comparisons for the evaluation of laboratory performance. The definition of interlaboratory comparison (3.4) and associated notes to the definitions broadens the use of both terms "laboratories" and "measurements and tests" for the purposes of this document to include all types of conformity assessment bodies and their activities, respectively.

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

- a) evaluation of the performance of laboratories for specific measurements, tests, calibrations, or examinations;
- b) identification of problems in laboratories which, for example, may be related to inadequate test or measurement procedures, effectiveness of training and supervision of personnel, or calibration of equipment;
- c) establishment of the effectiveness of test and measurement procedures and comparability of results;
- d) provision of additional confidence to users of test and measurement results;
- e) identification of differences in laboratory results;
- f) education of participating laboratories based on the outcomes of such comparisons; and
- g) validation of measurement uncertainty claims.

For the following types of interlaboratory comparisons the term PT does not usually apply because it is necessary to establish laboratory competence in advance, in order to assure the validity of tests and measurements as well as the metrological traceability of assigned values:

- h) evaluation of the performance characteristics of a measurement method – often described as collaborative trials;
- i) assignment of values to reference materials; and
- j) support for statements of the equivalence of measurements of National Metrology Institutes, or their Designated Institutes through "key and supplementary comparisons", conducted on behalf of the International Bureau of Weights and Measures (BIPM) and associated regional metrology organizations.

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

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



negative events. The PT provider is responsible for deciding which risks and opportunities need to be addressed.

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, accreditation bodies and other organizations that specify requirements for laboratories. Most of the requirements in this document apply to those evolving areas, especially regarding management, planning and design, personnel, assuring validity of results and performance evaluations, confidentiality, and other aspects, as appropriate.

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

In this document, the following verbal forms are used:

- “shall” indicates a requirement;
- “should” indicates a recommendation;
- “may” indicates a permission;
- “can” indicates a possibility or a capability.

Further details can be found in the ISO/IEC Directives, Part 2.

For the purposes of research, users are encouraged to share their views on this document and their priorities for changes to future editions. Click on the link below to take part in the online survey: XXXX (to be developed by the Secretariat later)

The survey to be developed at later stage by Secretariat.

The text highlighted in grey indicates clauses that contain CASCO/PROC33 text. It contains obligatory requirements common to all ISO/CASCO documents for "impartiality", "confidentiality", "competence", "complaints", "appeals" and "management system". This text cannot be modified unless a request for deviation is addressed to CASCO /CPC. This highlighted text is introduced to help with DIS comments and will be deleted for the final publication.

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

## 1 Scope

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

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

## 2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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

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

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

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

## 3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO/IEC 17000 and ISO/IEC Guide 99 and the following apply. ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <https://www.electropedia.org/>

### 3.1

#### assigned value

value attributed to a particular property or characteristic of a proficiency testing item

[SOURCE: ISO 13528:2015, 3.3, modified – Changed “test” to “testing” and words “or characteristic of” added]

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### 3.2

#### **consensus value**

value derived from a collection of results in an interlaboratory comparison

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

[SOURCE: ISO 13528:2015, 3.11, modified – Changed "test" to "testing".]

### 3.3

#### **customer**

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

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

### 3.4

#### **interlaboratory comparison**

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

[ISO 13528:2015, 3.1, modified – Changed "organization" to "design". The Notes to the entry have been added.]

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

Note 2 to entry: the term 'measurements or tests' is used throughout this document to apply to any activities undertaken by the proficiency testing participants that are subject to the proficiency testing, whether quantitative, qualitative or interpretative, unless otherwise qualified.

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

### 3.5

#### **outlier**

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

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

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

[ISO 13528:2015, 3.12, modified – Changed the word "blunder" to "gross error" in Note 1 to entry and added "proficiency testing" to "schemes" in Note 2 to entry.]

### 3.6

#### **participant**

person or organization that undertakes activities related to proficiency testing and submits their results for performance evaluation by the proficiency testing provider

**3.7****proficiency testing  
(PT)**

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

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

**3.8****proficiency testing item  
(PT item)**

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

**3.9****proficiency testing provider  
(PT provider)**

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

**3.10****proficiency testing round  
(PT round)**

single complete sequence of proficiency testing, including the evaluation and reporting of participants' performance

**3.11****proficiency testing scheme  
(PT scheme)**

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

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

**3.12****standard deviation for proficiency assessment**

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

Note 1 to entry: This can be interpreted as the population standard deviation of results from a hypothetical population of participants performing exactly in accordance with requirements.

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

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

[ISO 13528:2015, 3.4, modified – Changed "test" to "testing".]