



# SLOVENSKI STANDARD SIST EN ISO/IEC 17043:2010

01-april-2010

---

**Ugotavljanje skladnosti - Splošne zahteve za preskušanje strokovne usposobljenosti (ISO/CASCO 17043:2010)**

Conformity assessment - General requirements for proficiency testing (ISO/CASCO 17043:2010)

Konformitätsbewertung - Allgemeine Anforderungen an Eignungsprüfungen (ISO/CASCO 17043:2010)

Évaluation de la conformité - Exigences générales concernant les essais d'aptitude (ISO/CASCO 17043:2010)

ITeH STANDARD PREVIEW  
(standards.iteh.ai)

[SIST EN ISO/IEC 17043:2010](https://standards.iteh.ai/catalog/standards/sist/160be64c-3158-4179-9107-c94ee22779cf/sist-en-iso-iec-17043-2010)

[https://standards.iteh.ai/catalog/standards/sist/160be64c-3158-4179-9107-](https://standards.iteh.ai/catalog/standards/sist/160be64c-3158-4179-9107-c94ee22779cf/sist-en-iso-iec-17043-2010)

[c94ee22779cf/sist-en-iso-iec-17043-2010](https://standards.iteh.ai/catalog/standards/sist/160be64c-3158-4179-9107-c94ee22779cf/sist-en-iso-iec-17043-2010)

**Ta slovenski standard je istoveten z: EN ISO/IEC 17043:2010**

---

**ICS:**

03.120.20	Certificiranje proizvodov in podjetij. Ugotavljanje skladnosti	Product and company certification. Conformity assessment
-----------	--	--

**SIST EN ISO/IEC 17043:2010**

**en**

**iTeh STANDARD PREVIEW**  
**(standards.iteh.ai)**

[SIST EN ISO/IEC 17043:2010](#)

<https://standards.iteh.ai/catalog/standards/sist/160be64c-3158-4179-9107-c94ee22779cf/sist-en-iso-iec-17043-2010>

EUROPEAN STANDARD

EN ISO/IEC 17043

NORME EUROPÉENNE

EUROPÄISCHE NORM

February 2010

ICS 03.120.20

English version

## Conformity assessment - General requirements for proficiency testing (ISO/CASCO 17043:2010)

Évaluation de la conformité - Exigences générales  
concernant les essais d'aptitude (ISO/CASCO 17043:2010)

Konformitätsbewertung - Allgemeine Anforderungen an  
Eignungsprüfungen (ISO/CASCO 17043:2010)

This European Standard was approved by CEN on 30 January 2010.

CEN and 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. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN Management Centre or to any CEN and CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN and CENELEC member into its own language and notified to the CEN Management Centre has the same status as the official versions.

CEN and CENELEC members are the national standards bodies and national electrotechnical committees of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

[SIST EN ISO/IEC 17043:2010](https://standards.iteh.ai/catalog/standards/sist/160be64c-3158-4179-9107-c94ee22779cf/sist-en-iso-iec-17043-2010)

<https://standards.iteh.ai/catalog/standards/sist/160be64c-3158-4179-9107-c94ee22779cf/sist-en-iso-iec-17043-2010>



**CEN Management Centre:**  
Avenue Marnix 17, B-1000 Brussels

**CENELEC Central Secretariat:**  
Avenue Marnix 17, B-1000 Brussels

**Contents**

Page

Foreword.....3

**iTeh STANDARD PREVIEW  
(standards.iteh.ai)**

[SIST EN ISO/IEC 17043:2010](https://standards.iteh.ai/catalog/standards/sist/160be64c-3158-4179-9107-c94ee22779cf/sist-en-iso-iec-17043-2010)

<https://standards.iteh.ai/catalog/standards/sist/160be64c-3158-4179-9107-c94ee22779cf/sist-en-iso-iec-17043-2010>

## Foreword

This document (EN ISO/IEC 17043:2010) 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 European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by August 2010, and conflicting national standards shall be withdrawn at the latest by August 2010.

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

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

## iTeh STANDARD PREVIEW Endorsement notice (standards.iteh.ai)

The text of ISO/CASCO 17043:2010 has been approved by CEN as a EN ISO/IEC 17043:2010 without any modification.

[SIST EN ISO/IEC 17043:2010  
https://standards.iteh.ai/catalog/standards/sist/160be64c-3158-4179-9107-  
c94ee22779cf/sist-en-iso-iec-17043-2010](https://standards.iteh.ai/catalog/standards/sist/160be64c-3158-4179-9107-c94ee22779cf/sist-en-iso-iec-17043-2010)

**iTeh STANDARD PREVIEW**  
**(standards.iteh.ai)**

[SIST EN ISO/IEC 17043:2010](#)

<https://standards.iteh.ai/catalog/standards/sist/160be64c-3158-4179-9107-c94ee22779cf/sist-en-iso-iec-17043-2010>

INTERNATIONAL  
STANDARD

ISO/IEC  
17043

First edition  
2010-02-01

---

---

**Conformity assessment — General  
requirements for proficiency testing**

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

**iTeh STANDARD PREVIEW**  
**(standards.iteh.ai)**

[SIST EN ISO/IEC 17043:2010](https://standards.iteh.ai/catalog/standards/sist/160be64c-3158-4179-9107-c94ee22779cf/sist-en-iso-iec-17043-2010)

[https://standards.iteh.ai/catalog/standards/sist/160be64c-3158-4179-9107-  
c94ee22779cf/sist-en-iso-iec-17043-2010](https://standards.iteh.ai/catalog/standards/sist/160be64c-3158-4179-9107-c94ee22779cf/sist-en-iso-iec-17043-2010)

---

---

Reference number  
ISO/IEC 17043:2010(E)



## ISO/IEC 17043:2010(E)

**PDF disclaimer**

This PDF file may contain embedded typefaces. In accordance with Adobe's licensing policy, this file may be printed or viewed but shall not be edited unless the typefaces which are embedded are licensed to and installed on the computer performing the editing. In downloading this file, parties accept therein the responsibility of not infringing Adobe's licensing policy. The ISO Central Secretariat accepts no liability in this area.

Adobe is a trademark of Adobe Systems Incorporated.

Details of the software products used to create this PDF file can be found in the General Info relative to the file; the PDF-creation parameters were optimized for printing. Every care has been taken to ensure that the file is suitable for use by ISO member bodies. In the unlikely event that a problem relating to it is found, please inform the Central Secretariat at the address given below.

## iTeh STANDARD PREVIEW (standards.iteh.ai)

[SIST EN ISO/IEC 17043:2010](https://standards.iteh.ai/catalog/standards/sist/160be64c-3158-4179-9107-c94ee22779cf/sist-en-iso-iec-17043-2010)

<https://standards.iteh.ai/catalog/standards/sist/160be64c-3158-4179-9107-c94ee22779cf/sist-en-iso-iec-17043-2010>

**COPYRIGHT PROTECTED DOCUMENT**

© ISO 2010

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office  
Case postale 56 • CH-1211 Geneva 20  
Tel. + 41 22 749 01 11  
Fax + 41 22 749 09 47  
E-mail [copyright@iso.org](mailto:copyright@iso.org)  
Web [www.iso.org](http://www.iso.org)

Published in Switzerland



## Contents

Page

Foreword .....	iv
Introduction.....	v
1 Scope .....	1
2 Normative references .....	1
3 Terms and definitions .....	1
4 Technical Requirements .....	4
4.1 General .....	4
4.2 Personnel .....	4
4.3 Equipment, accommodation and environment .....	5
4.4 Design of proficiency testing schemes.....	6
4.5 Choice of method or procedure .....	10
4.6 Operation of proficiency testing schemes.....	11
4.7 Data analysis and evaluation of proficiency testing scheme results .....	12
4.8 Reports .....	13
4.9 Communication with participants.....	14
4.10 Confidentiality.....	15
5 Management requirements.....	15
5.1 Organization.....	15
5.2 Management system .....	16
5.3 Document control.....	17
5.4 Review of requests, tenders and contracts.....	18
5.5 Subcontracting services.....	19
5.6 Purchasing services and supplies .....	19
5.7 Service to the customer.....	20
5.8 Complaints and appeals .....	20
5.9 Control of nonconforming work .....	20
5.10 Improvement .....	20
5.11 Corrective actions .....	21
5.12 Preventive actions .....	21
5.13 Control of records .....	22
5.14 Internal audits .....	22
5.15 Management reviews .....	23
Annex A (informative) Types of proficiency testing schemes .....	24
Annex B (informative) Statistical methods for proficiency testing.....	28
Annex C (informative) Selection and use of proficiency testing.....	35
Bibliography.....	39

**ISO/IEC 17043:2010(E)****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.

<https://standards.iteh.ai/catalog/standards/sist/160be64c-3158-4179-9107-c94ee22779cf/sist-en-iso-iec-17043-2010>

## 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.

**iTeh STANDARD PREVIEW**  
**(standards.iteh.ai)**

[SIST EN ISO/IEC 17043:2010](#)

<https://standards.iteh.ai/catalog/standards/sist/160be64c-3158-4179-9107-c94ee22779cf/sist-en-iso-iec-17043-2010>

# 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)*

[SIST EN ISO/IEC 17043:2010](https://standards.iteh.ai/catalog/standards/sist/160be64c-3158-4179-9107-c94ee22779cf/sist-en-iso-iec-17043-2010)

<https://standards.iteh.ai/catalog/standards/sist/160be64c-3158-4179-9107-c94ee22779cf/sist-en-iso-iec-17043-2010>

## 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

**ISO/IEC 17043:2010(E)****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<sup>1)</sup> 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).

---

1) International Laboratory Accreditation Cooperation.