BSI Standards Publication

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

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National foreword

This British Standard is the UK implementation of EN ISO/IEC 17043:2023. It is identical to ISO/IEC 17043:2023. It supersedes BS EN ISO/IEC 17043:2010, which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CAS/1, Conformity assessment.

A list of organizations represented on this committee can be obtained on request to its committee manager.

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Published by BSI Standards Limited 2023

ISBN 978 0 539 14435 2

ICS 03.120.20

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This British Standard was published under the authority of the Standards Policy and Strategy Committee on 31 May 2023.

Amendments/corrigenda issued since publication

Date	Text affected

EUROPEAN STANDARD **EN ISO/IEC 17043**

EUROPÄISCHE NORM

May 2023

ICS 03.120.20

Supersedes EN ISO/IEC 17043:2010

English version

Conformity assessment - General requirements for the competence of proficiency testing providers (ISO/IEC 17043:2023)

Évaluation de la conformité - Exigences générales concernant la compétence des organisateurs d'essais d'aptitude (ISO/IEC 17043:2023)

Konformitätsbewertung - Allgemeine Anforderungen an die Kompetenz von Anbietern von Eignungsprüfungen (ISO/IEC 17043:2023)

This European Standard was approved by CEN on 17 April 2023.

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European foreword

This document (EN ISO/IEC 17043:2023) has been prepared by Technical Committee ISO/CASCO "Committee on conformity assessment" in collaboration with Technical Committee CEN-CENELEC/ JTC 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of an identical text or by endorsement, at the latest by November 2023, and conflicting national standards shall be withdrawn at the latest by November 2023.

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

This document supersedes EN ISO/IEC 17043:2010.

This document has been prepared under a Standardization Request given to CEN and CENELEC by the European Commission and the European Free Trade Association.

Any feedback and questions on this document should be directed to the users’ national standards body/national committee. A complete listing of these bodies can be found on the CEN and CENELEC websites.

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, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom.

Endorsement notice

The text of ISO/IEC 17043:2023 has been approved by CEN-CENELEC as EN ISO/IEC 17043:2023 without any modification.

Contents

Page

Foreword ... **v**

Introduction ... **vi**

1 Scope ... **1**

2 Normative references ... **1**

3 Terms and definitions ... **1**

4 General requirements ... **3**
4.1 Impartiality ... 3
4.2 Confidentiality ... 4

5 Structural requirements ... **4**

6 Resource requirements ... **5**
6.1 General ... 5
6.2 Personnel ... 5
6.3 Facilities and environmental conditions ... 6
6.4 Externally provided products and services ... 7

7 Process requirements ... **8**
7.1 Establishing, contracting and communicating the PT scheme objectives ... 8
7.1.1 Review of requests, tenders and contracts ... 8
7.1.2 PT scheme communication ... 8
7.2 Design and planning of a PT scheme ... 9
7.2.1 General ... 9
7.2.2 Statistical design ... 10
7.2.3 Determination of assigned values ... 11
7.3 Production and distribution of PT items ... 11
7.3.1 Production of PT items ... 11
7.3.2 Homogeneity and stability assessment of PT items ... 12
7.3.3 Handling and storage of PT items ... 12
7.3.4 Packaging, labelling and distribution of PT items ... 12
7.3.5 Instructions for participants ... 13
7.4 Evaluation and reporting of PT scheme results ... 14
7.4.1 Data analysis ... 14
7.4.2 Evaluation of performance ... 14
7.4.3 PT reports ... 15
7.5 Control of the PT scheme process ... 16
7.5.1 Technical records ... 16
7.5.2 Control of data and information management ... 16
7.5.3 Surveillance of the processes ... 17
7.5.4 Nonconforming work ... 17
7.6 Handling of complaints ... 18
7.7 Handling of appeals ... 19

8 Management system requirements ... **19**
8.1 General requirements ... 19
8.2 Management system documentation ... 20
8.3 Control of management system documents ... 20
8.4 Control of records ... 20
8.5 Actions to address risks and opportunities ... 21
8.6 Improvement ... 21
8.7 Corrective actions ... 22
8.8 Internal audits ... 22
8.9 Management reviews ... 23

Annex A (informative) **Types of PT schemes** ... **24**

Annex B (informative) **Statistical methods for PT** **28**
Bibliography **36**

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 or www.iec.ch/members_experts/refdocs).

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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. In the IEC, see www.iec.ch/understanding-standards.

This document was prepared by the ISO Committee on Conformity Assessment (CASCO), in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/CLC/JTC 1, *Criteria for conformity assessment bodies*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO/IEC 17043:2010), which has been technically revised.

The main changes are as follows:

— harmonization with ISO/IEC 17025:2017, including technical requirements and structure;

— harmonization with ISO 13528:2022 in terms of terminology;

— incorporation of requirements from ISO/CASCO PROC 33;

— inclusion of the requirement that testing activities, calibration activities and proficiency testing 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 and www.iec.ch/national-committees.

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 is intended to promote 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" (see 3.4) broadens the use of both the terms "laboratories" and "measurements or tests" for the purposes of this document to include all types of conformity assessment bodies and their activities, respectively. The term "method" as used in this document can be considered synonymous with the term "measurement procedure" as defined in ISO/IEC Guide 99.

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

a) evaluation of the performance of laboratories for specific measurements, tests, calibrations, examinations, inspections or sampling;

b) identification of problems in laboratories that, for example, can be related to measurement or test methods, effectiveness of training and supervision of personnel, or calibration of equipment;

c) establishment of the effectiveness of measurement or test methods and the comparability of measurement or test results;

d) provision of additional confidence to users of measurement or test results;

e) identification of differences in measurement or test results;

f) education of participating laboratories based on the outcomes of such comparisons;

g) validation of measurement uncertainty claims.

For the following types of interlaboratory comparisons, the term PT does not usually apply because laboratory competence must be established in advance, in order to ensure the validity of measurements or tests as well as the metrological traceability of assigned values:

h) evaluation of the performance characteristics of a measurement or test method (often described as collaborative trials);

i) assignment of values to reference materials;

j) support for statements of the equivalence of measurements of National Metrology Institutes (NMIs), or their Designated Institutes (DIs) through "key and supplementary comparisons", conducted on behalf of the International Bureau of Weights and Measures (BIPM) and associated Regional Metrology Organizations (RMOs).

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

The need for ongoing confidence in laboratory performance is essential not only 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 is intended to provide a consistent basis for all interested parties to determine the competence of organizations that provide PT.

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.

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 (PT) 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* (3.8)

[SOURCE: ISO 13528:2022, 3.3, modified — The words "or characteristic" have been added and the word “test” has been replaced with “testing”.]

3.2
consensus value
value derived from a collection of results in an *interlaboratory comparison* (3.4)

Note 1 to entry: The phrase “consensus value” is typically used to describe estimates of location and dispersion derived from *participant* (3.6) results in a round of a *proficiency testing scheme* (3.11), 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 13528:2022, 3.11.]