BS EN ISO/IEC 17000:2020

BSI Standards Publication

Conformity assessment - Vocabulary and general principles

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National foreword

This British Standard is the UK implementation of EN ISO/IEC 17000:2020. It is identical to ISO/IEC 17000:2020. It supersedes BS EN ISO/IEC 17000:2004, which is withdrawn.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 secretary.

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Conformity assessment - Vocabulary and general principles (ISO/IEC 17000:2020)

Évaluation de la conformité - Vocabulaire et principes généraux (ISO/IEC 17000:2020)

Konformitätsbewertung - Begriffe und allgemeine Grundlagen (ISO/IEC 17000:2020)

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European foreword

This document (EN ISO/IEC 17000:2020) has been prepared by Technical Committee ISO/CASCO "Committee on conformity assessment" in collaboration with Technical Committee CEN/CLC/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of an identical text or by endorsement, at the latest by December 2020, and conflicting national standards shall be withdrawn at the latest by December 2020.

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

This document supersedes EN ISO/IEC 17000:2004.

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, Turkey and the United Kingdom.

Endorsement notice

The text of ISO/IEC 17000:2020 has been approved by CEN as EN ISO/IEC 17000:2020 without any modification.

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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).

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) 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.

This document was prepared by the ISO Committee on Conformity Assessment (CASCO).

This second edition cancels and replaces the first edition (ISO/IEC 17000:2004), which has been technically revised.

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

— addition of new terms: “object of conformity assessment” (see 4.2), “owner” (see 4.13), “impartiality” (see 5.3), “independence” (see 5.4), “validation” (see 6.5), “verification” (see 6.6), “decision” (see 7.2), “expiry” (see 8.4) and “restoration” (see 8.5);

— change of concept of conformity assessment system;

— deletion of the definition of the term “product” from the body of the document and addition to Annex B;

— editorial revision of Annex A limited to changes in the terms and definitions in Clauses 4 to 9;

— extension of Annex 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.

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Introduction

The ISO Committee on conformity assessment (CASCO) develops International Standards relating to conformity assessment activities such as testing, inspection and various forms of certification. For many years, ISO/IEC Guide 2 included a core vocabulary for conformity assessment, built up from a small number of terms and definitions first compiled to facilitate communication and understanding about product certification based on standards for traditional manufactured goods.

In 2000, CASCO decided to remove conformity assessment terminology from ISO/IEC Guide 2 and provide instead a self-contained vocabulary more readily applicable within the planned international standards on conformity assessment and in the drafting or revision of related documents. The first edition of this document was published in 2004, as a consistent framework within which more specific concepts could be defined appropriately and denoted by the most appropriate terms.

Additional concepts unique to particular activities such as accreditation, certification of persons and use of marks of conformity are not included in this document but are provided in International Standards related to those activities.

Terms and definitions related to trade and regulation are given in Clause 9. These are intended not only to standardize usage within the conformity assessment community, but also to help policy makers concerned with the facilitation of trade within regulatory and international treaty frameworks.

The terms and definitions specified in this document, particularly in Clauses 6 and 7, reflect the adoption by CASCO in November 2001 of the functional approach.

To provide a better understanding of the defined concepts, their grouping and their relationships, a description of the functional approach is included in Annex A for information.

The terms included in this document relate to concepts considered essential to define. General terms used to denote conformity assessment concepts for which common language usage is sufficient are not included in this document. Terms not common across all International Standards for conformity assessment and with definitions specific to a particular application are not included in this document but are included in the specific relevant standard.

Relevant terms defined in other documents are listed in Annex B:

— terms applicable to specific aspects of conformity assessment, as defined in other conformity assessment standards;

— terms generally applicable in conformity assessment contexts for which definitions are published outside conformity assessment standards.

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Conformity assessment — Vocabulary and general principles

1 Scope

This document specifies general terms and definitions relating to conformity assessment (including the accreditation of conformity assessment bodies) and to the use of conformity assessment to facilitate trade.

The general principles of conformity assessment and a description of the functional approach to conformity assessment are provided in Annex A.

Conformity assessment interacts with other fields such as management systems, metrology, standardization and statistics. The boundaries of conformity assessment are not defined in this document.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

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 http://www.electropedia.org/

4 Terms related to conformity assessment in general

4.1
conformity assessment
demonstration that *specified requirements* (5.1) are fulfilled

Note 1 to entry: The process of conformity assessment as described in the functional approach in Annex A can have a negative outcome, i.e. demonstrating that the specified requirements are not fulfilled.

Note 2 to entry: Conformity assessment includes activities defined elsewhere in this document, such as but not limited to *testing* (6.2), *inspection* (6.3), *validation* (6.5), *verification* (6.6), *certification* (7.6), and *accreditation* (7.7).

Note 3 to entry: Conformity assessment is explained in Annex A as a series of functions. Activities contributing to any of these functions can be described as conformity assessment activities.

Note 4 to entry: This document does not include a definition of "conformity". "Conformity" does not feature in the definition of "conformity assessment". Nor does this document address the concept of compliance.

4.2
object of conformity assessment
object
entity to which *specified requirements* (5.1) apply

EXAMPLE Product, process, service, system, installation, project, data, design, material, claim, person, body or organization, or any combination thereof.

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Note 1 to entry: The term "body" is used in this document to refer to *conformity assessment bodies* (4.6) and *accreditation bodies* (4.7). The term "organization" is used in its general meaning and may include bodies according to the context. The more specific ISO/IEC Guide 2 definition of an organization as a body based on membership is not applicable to the field of *conformity assessment* (4.1).

4.3
first-party conformity assessment activity
conformity assessment activity that is performed by the person or organization that provides or that is the *object of conformity assessment* (4.2)

Note 1 to entry: The first-, second- and third-party descriptors used to characterize conformity assessment activities in relation to a given object are not to be confused with the legal identification of the relevant parties to a contract.

EXAMPLE Activities performed by providers, designers or owners of the object, investors in the object, and advertisers or promoters of the object.

Note 2 to entry: If an activity is performed by an external body acting on behalf of and controlled by a person or organization that provides or is the object, the activity is still called a first-party conformity assessment activity (e.g. internal audits performed by a consultant who is not part of the organization).

4.4
second-party conformity assessment activity
conformity assessment activity that is performed by a person or organization that has a user interest in the *object of conformity assessment* (4.2)

Note 1 to entry: The first-, second- and third-party descriptors used to characterize conformity assessment activities in relation to a given object are not to be confused with the legal identification of the relevant parties to a contract.

EXAMPLE Persons or organizations performing second-party conformity assessment activities include, for example, purchasers or users of products, or potential customers seeking to rely on a supplier's management system, or organizations representing those interests. Examples of organizations representing user interest include consumer advocacy organizations, regulators implementing legislation governing products and services for the protection of consumer and public interests, centralized government procurement organizations and private sector purchasing agents.

Note 2 to entry: If an activity is performed by an external body acting on behalf of and controlled by a person or organization with a user interest, the activity is still called a second-party conformity assessment activity (e.g. supply chain audits conducted by an external body on behalf of the purchaser).

4.5
third-party conformity assessment activity
conformity assessment activity that is performed by a person or organization that is independent of the provider of the *object of conformity assessment* (4.2) and has no user interest in the object

Note 1 to entry: The first-, second- and third-party descriptors used to characterize conformity assessment activities in relation to a given object are not to be confused with the legal identification of the relevant parties to a contract.

4.6
conformity assessment body
body that performs conformity assessment activities, excluding *accreditation* (7.7)

4.7
accreditation body
authoritative body that performs *accreditation* (7.7)

Note 1 to entry: The authority of an accreditation body can be derived from government, public authorities, contracts, market acceptance or scheme owners.

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