

Redline version
compares Second edition to
First edition



Conformity assessment — Vocabulary and general principles

Évaluation de la conformité — Vocabulaire et principes généraux

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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. ~~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~~ 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 ~~rules given in~~ editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

~~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 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.

~~ISO/IEC 17000~~ This document was prepared by the ISO Committee on ~~conformity assessment~~ 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~~ **second** edition cancels and replaces ~~Clauses 12 to 17 of ISO/IEC Guide 2:1996. Clauses 1 to 11 of ISO/IEC Guide 2 are not the responsibility of ISO/CASCO and are unaffected by this International Standard.~~ 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

0.1 Terms and definitions applicable to conformity assessment

ISO and ISO/IEC Guides and, more recently, International Standards relating generically to conformity assessment activities such as testing, inspection and various forms of certification are prepared by working groups of the ISO Committee on conformity assessment (CASCO). For many years, ISO/IEC Guide 2, last revised in 1996, has 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 take conformity assessment terminology (Clauses 12 to 17) out of ISO/IEC Guide 2 and provide instead a self-contained vocabulary more readily applicable within the planned ISO/IEC 17000 series of standards and in the drafting or revision of related guides. CASCO Working Group 5, *Definitions*, has accordingly prepared this International Standard in consultation with other active CASCO working groups, as a consistent framework within which more specific concepts may be defined appropriately and denoted by the most appropriate terms. Extra terms for concepts unique to particular activities within conformity assessment, such as accreditation, certification of persons and marks of conformity, are found in the International Standard or Guide related to that activity. Such concepts are not included in this International Standard.

Until pre-existing CASCO publications are revised, the terminology used in those documents remains valid in its context, this International Standard is not intended to be applied retrospectively.

Conformity assessment interacts with other fields such as management systems, metrology, standardization and statistics. This International Standard does not define the boundaries of conformity assessment. These remain elastic.

0.2 Terms and definitions applicable to trade policy

Clause 7 includes some terms and definitions, drawn mainly from the superseded clauses of ISO/IEC Guide 2, for several broader concepts. 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.

0.3 A functional approach to conformity assessment

The terms and definitions specified in this International Standard, particularly under Clauses 4 and 5, reflect the adoption by CASCO in November 2001 of the functional approach recommended earlier that year in the final report of a CASCO – CEN/CENELEC TC 1 joint working group.

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.

0.4 Selection of terms and definitions

Some of the terms included in this International Standard relate to concepts it was considered essential to define. Others it was thought helpful to explain. Many of the general terms used to distinguish conformity assessment concepts are used in common language in a broader sense or with a wider range of meanings. Some also appear in other standard vocabularies with definitions specific to the relevant field of application.

An alphabetical index lists the terms defined in this International Standard. Standards defining other relevant terms are given in Annex B with separate alphabetical lists. First are terms applicable to specific aspects of conformity assessment, as defined in other standards in the ISO/IEC 17000 series. Second are terms for which the definitions given in either the *International vocabulary of basic and general terms in metrology* (VIM) or ISO 9000 are generally applicable in conformity assessment.

~~contexts. For the terms “procedure” and “product”, both used extensively in other definitions, the ISO 9000:2000 definitions are reproduced in 3.2 and 3.3.~~

~~0.5 Changes in terminology~~

~~Attention is drawn to significant changes in the terms or their definitions from the superseded clauses of ISO/IEC Guide 2:~~

~~This International Standard does not include a definition of “conformity” on the grounds that it is not necessary to do so. “Conformity” does not feature in the definition of “conformity assessment”. The concept of “conformity assessment” is concerned with “fulfilment of specified requirements”, not with the wider concept of “conformity”. A definition of the term “specified requirement” (3.1) is included. In English, the term “compliance” is used to distinguish the action of doing what is required (e.g. an organization “complies” by making something conform or by fulfilling a regulatory requirement).~~

~~The ISO 9000 definition of “product” (3.3) includes services as a product category, so that it is no longer correct to refer to “products and services”.~~

~~Instead of “product, process or service”, the generic expression used in ISO/IEC Guide 2 for the “subject of standardization”, Note 2 to 2.1 introduces the expression “object of conformity assessment” as a means of referring to the product, process, system, person or body to which conformity assessment is applied. (The “subject” would more logically be the body doing the assessment.)~~

~~Instead of “assurance of conformity”, the term “attestation” (5.2) is used for the activity of conveying assurance through the issue of a “statement of conformity”.~~

~~The term “accreditation” is now applicable only to attestation regarding a conformity assessment body. The definition in ISO/IEC Guide 2, by contrast, would have been equally applicable to the certification of persons, as specified in ISO/IEC 17024. Following this change, the terms “conformity assessment body” (2.5) and “accreditation body” (2.6) are defined separately. More specific terms relating to accreditation are defined in ISO/IEC 17011.~~

~~To avoid ambiguity, the term “body” is used in this International Standard only when referring to conformity assessment bodies or accreditation bodies. Otherwise, the term “organization” is used in its general meaning, as in the ISO 9000 definition. 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.~~

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 International Standard 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. A description of the functional approach to conformity assessment is included in Annex A, as a further aid to understanding among users of conformity assessment, conformity assessment bodies and their accreditation bodies, in both voluntary and regulatory environments.

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

This International Standard does not set out to provide a vocabulary for all of the concepts that may need to be used in describing particular conformity assessment activities. Terms and definitions are given only where the concept defined would not be understandable from the general language use of the term, or where an existing standard definition is not applicable. 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.

NOTE 1 — The notes appended to certain definitions offer clarification or examples to facilitate understanding of the concepts described. In certain cases, the notes may differ in different languages for linguistic reasons, or additional notes may be given.

NOTE 2 — The terms and definitions are laid out in a systematic order, with an alphabetical index. A term in a definition or note that is defined in another entry is indicated by boldface followed by its entry number in parentheses. Such terms may be replaced by their complete definition.

ISO/IEC 17000:2020

<https://www.iso.org/standards/iso/2afa519f-84ff-44d4-b589-04b5909ad78c/iso-iec-17000-2020>

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/>

2.4 Terms relating to conformity assessment in general

2.4.1

conformity assessment

demonstration that *specified requirements* (3.15.1) relating to a *product* (3.3), process, system, person or body 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: ~~The subject field of conformity~~ **Conformity** assessment includes activities defined elsewhere in this ~~International Standard~~ document, such as but not limited to ~~testing (4.26.2), inspection (4.36.3), and certification (5.5)~~ **validation (6.5)**, as well as the ~~verification (6.6), certification (7.6), and accreditation (5.67.7)~~ **of conformity assessment bodies (2.5)**.

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: ~~The expression “object of conformity assessment” or “object” is used in this International Standard to encompass any particular material, product, installation, process, system, person or body to which conformity assessment is applied. A service is covered by~~ **This document does not include a definition of “conformity”. “Conformity” does not feature in the definition of a product (see Note 1 to “conformity assessment”). Nor does this document address the concept of compliance (3.3).**

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.

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).

~~2.2~~ 4.3

first-party conformity assessment activity

conformity assessment activity that is performed by the person or organization that provides ~~the object~~ **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 ~~with respect 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).

~~2.3~~ 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~~ **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: ~~Persons or organizations performing~~ **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** ~~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~~ **activity (e.g. supply chain audits conducted by an external body on behalf of the purchaser).**

~~Note 3 to entry: See Note to 2.2.~~

~~2.4~~ 4.5

third-party conformity assessment activity

conformity assessment activity that is performed by a person or ~~body~~ organization that is independent of the ~~person or organization that provides the object,~~ provider of the *object of conformity assessment* (4.2) and ~~of user interests in that~~ has no user interest in the object

Note 1 to entry: ~~Criteria for the independence of conformity assessment bodies and accreditation bodies are provided in the International Standards and Guides applicable to their activities (see 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 Bibliography) a contract.~~

~~Note 2 to entry: See Note to 2.2.~~

~~2.5~~ 4.6

conformity assessment body

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

~~Note 1 to entry: An accreditation body (2.6) is not a conformity assessment body.~~

~~2.6~~ 4.7

accreditation body

authoritative body that performs *accreditation* (~~5.6~~7.7)

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

~~2.7~~ 4.8

conformity assessment system

~~rules,~~ set of rules and *procedures* (~~3.2~~5.2) and management for carrying out for the management of similar or related *conformity assessment schemes* (~~2.1~~4.9)

Note 1 to entry: ~~Conformity assessment systems may~~ A conformity assessment system can be operated at an international, regional, national ~~or~~ sub-national, or industry sector level.

~~2.8~~ 4.9

conformity assessment scheme

conformity assessment programme

set of rules and ~~conformity assessment system (2.7)~~ *procedures* (5.2) ~~related to specified objects of conformity assessment that describes the objects of conformity assessment (4.2), to which the same identifies the specified requirements (3.15.1), specific rules and procedures (3.2) apply~~ provides the methodology for performing *conformity assessment* (4.1)

Note 1 to entry: A conformity assessment scheme can be managed within a *conformity assessment system* (4.8).

Note 2 to entry: ~~Conformity assessment schemes may~~ A conformity assessment scheme can be operated at an international, regional, national ~~or~~ sub-national, or industry sector level.

Note 3 to entry: A scheme can cover all or part of the conformity assessment functions explained in *Annex A*.

~~2.9~~ 4.10

access

access to a ~~system or~~ scheme

opportunity for an applicant to obtain a *conformity assessment* (~~2.1~~4.1) ~~under the rules of the system or scheme~~ service from a body under a *conformity assessment scheme* (4.9)