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## 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.

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 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](http://www.iso.org/members.html).

## 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.

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.



**4.8****conformity assessment system**

set of rules and *procedures* (5.2) for the management of similar or related *conformity assessment schemes* (4.9)

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

**4.9****conformity assessment scheme**

conformity assessment programme

set of rules and *procedures* (5.2) that describes the *objects of conformity assessment* (4.2), identifies the *specified requirements* (5.1) and 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: A conformity assessment scheme can be operated at an international, regional, national 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](#).

**4.10****access**

access to a scheme

opportunity for an applicant to obtain a *conformity assessment* (4.1) service from a body under a *conformity assessment scheme* (4.9)

**4.11****participant**

participant in a system

participant in a scheme

person or organization that implements or operates under the rules and *procedures* (5.2) of a *conformity assessment system* (4.8) or *scheme* (4.9) without being involved in their development, revision or approval

**4.12****member**

member of a system

member of a scheme

person or organization that is involved in the development, revision or approval of the rules and *procedures* (5.2) of a *conformity assessment system* (4.8) or *scheme* (4.9)

**4.13****owner**

owner of a system

owner of a scheme

system owner

scheme owner

person or organization responsible for the development and maintenance of a *conformity assessment system* (4.8) or *conformity assessment scheme* (4.9)

Note 1 to entry: A scheme owner does not necessarily operate the *scheme* (4.9).

Note 2 to entry: A system owner or a scheme owner can be a *conformity assessment body* (4.6) itself, a governmental authority, a trade association, a group of conformity assessment bodies or others.

## 5 Terms related to basic concepts

### 5.1 specified requirement

need or expectation that is stated

Note 1 to entry: Specified requirements can be stated in normative documents such as regulations, standards and technical specifications.

Note 2 to entry: Specified requirements can be detailed or general.

### 5.2 procedure

specified way to carry out an activity or a process

Note 1 to entry: In this context, a process is defined as a set of interrelated or interacting activities that use inputs to deliver an intended result.

[SOURCE: ISO 9000:2015, 3.4.5, modified — The original Note to entry has been replaced with a new Note to entry.]

### 5.3 impartiality

objectivity with regard to the outcome of a conformity assessment activity

Note 1 to entry: Objectivity can be understood as freedom from bias or freedom from conflicts of interest.

### 5.4 independence

freedom of a person or organization from the control or authority of another person or organization

EXAMPLE A *conformity assessment body* (4.6) can be independent from the person who is the *object of conformity assessment* (4.2) or from the organization providing the *object of conformity assessment* (4.2).

## 6 Terms relating to selection and determination

### 6.1 sampling

selection and/or collection of material or data regarding an *object of conformity assessment* (4.2)

Note 1 to entry: Selection can be on the basis of a procedure, an automated system, professional judgement etc.

Note 2 to entry: Selection and collection can be performed by the same or different persons or organizations.

### 6.2 testing

determination of one or more characteristics of an *object of conformity assessment* (4.2), according to a *procedure* (5.2)

Note 1 to entry: The procedure can be intended to control variables within testing as a contribution to the accuracy or reliability of the results.

Note 2 to entry: The results of testing can be expressed in terms of specified units or objective comparison with agreed references.

Note 3 to entry: The output of testing can include comments (e.g. opinions and interpretations) about the test results and fulfilment of specified requirements.

Note 4 to entry: Additional information on the concepts of *testing* (6.2) and *inspection* (6.3) is given in A.3.4.

### 6.3 inspection

examination of an *object of conformity assessment* (4.2) and determination of its conformity with detailed requirements or, on the basis of professional judgement, with general requirements

Note 1 to entry: Examination can include direct or indirect observations, which can include measurements or the output of instruments.

Note 2 to entry: *Conformity assessment schemes* (4.9) or contracts can specify inspection as examination only.

Note 3 to entry: Additional information on the concepts of *testing* (6.2) and *inspection* (6.3) is given in A.3.4.

### 6.4 audit

process for obtaining relevant information about an *object of conformity assessment* (4.2) and evaluating it objectively to determine the extent to which *specified requirements* (5.1) are fulfilled

Note 1 to entry: The specified requirements are defined prior to performing an audit so that the relevant information can be obtained.

Note 2 to entry: Examples of objects for an audit are management systems, processes, products and services.

Note 3 to entry: For accreditation purposes, the audit process is called “assessment”.

### 6.5 validation

confirmation of plausibility for a specific intended use or application through the provision of objective evidence that *specified requirements* (5.1) have been fulfilled

Note 1 to entry: Validation can be applied to claims to confirm the information declared with the claim regarding an intended future use.

### 6.6 verification

confirmation of truthfulness through the provision of objective evidence that *specified requirements* (5.1) have been fulfilled

Note 1 to entry: Verification can be applied to claims to confirm the information declared with the claim regarding events that have already occurred or results that have already been obtained.

### 6.7 peer assessment

assessment of a body against *specified requirements* (5.1) by representatives of other bodies in, or candidates for, an *agreement group* (9.10)

Note 1 to entry: “Candidates” are included for the situation where a new group is being formed, at which time there would be no bodies in the group.

Note 2 to entry: The term “peer assessment” is sometimes referred to as “peer evaluation”.

## 7 Terms relating to review, decision and attestation

### 7.1 review

consideration of the suitability, adequacy and effectiveness of selection and determination activities, and the results of these activities, with regard to fulfilment of *specified requirements* (5.1) by an *object of conformity assessment* (4.2)

### 7.2 decision

conclusion, based on the results of *review* (7.1), that fulfilment of *specified requirements* (5.1) has or has not been demonstrated