
Ugotavljanje skladnosti – Slovar in splošna načela (ISO/IEC DIS 17000)

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

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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) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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 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).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: [Foreword - Supplementary information](#).

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

This second edition cancels and replaces ISO/IEC 17000:2004.

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

- addition of new terms: object of conformity assessment ([2.2.1](#)), validation ([2.3.5](#)), and verification ([2.3.6](#)),
- deletion of the term product from the body of the document and addition to the [Annex B](#) (Related terms defined in other documents),
- extension of the [Annex B](#),
- editorial revision of [Annex A](#) (Functional Approach) limited to changes that reflect the changes to the normative content of ISO/IEC 17000.
- addition of an informative [Annex C](#), showing the relationship between the concepts of ISO/IEC 17000.

Introduction

0.1 Terms and definitions applicable to conformity assessment

International Standards and other publications relating 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 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 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*, produced the first edition of this document in 2004 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 concepts unique to particular activities such as accreditation, certification of persons and use of marks of conformity, are found in the International Standards or other documents related to those activities and are not included in this document.

In 2017, CASCO WG49 was convened to revise ISO/IEC 17000:2004, retaining the framework of the functional approach described in [Annex A](#).

Conformity assessment interacts with other fields such as management systems, metrology, standardization and statistics. This document 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 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 document, particularly under Clauses 4 and 5, 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.

0.4 Selection of terms and definitions

Some of the terms included in this document relate to concepts that are 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 document. 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 definitions published outside the ISO/IEC 17000 series are generally applicable in conformity assessment contexts.

0.5 Conformity and compliance

This document 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” ([2.2.1](#)) is included. In English,

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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).

For the purposes of research, users are encouraged to share their views on this document and their priorities for changes to future editions. Click on the link below to take part in the online survey:

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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. 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 accreditation bodies, in both voluntary and regulatory environments.

This document 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.

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 bold-face followed by its entry number in parentheses. Such terms may be replaced by their complete definition.

2 Terms and definitions

2.1 Terms relating to conformity assessment in general

2.1.1

conformity assessment

demonstration that *specified requirements* ([2.2.1](#)) are fulfilled

Note 1 to entry: The process of conformity assessment as described in the functional approach in the [Annex A](#) can have a negative outcome.

Note 2 to entry: The field of conformity assessment includes activities defined elsewhere in this document, such as but not limited to *testing* ([2.3.2](#)), *inspection* ([2.3.3](#)), *validation* ([2.3.5](#)), *verification* ([2.3.6](#)) and *certification* ([2.4.6](#)), as well as the *accreditation* ([2.4.7](#)) of *conformity assessment bodies* ([2.1.6](#)).

Note 3 to entry: Conformity assessment is explained in [Annex A](#) as a series of functions. Tasks contributing to any of these functions may be described as conformity assessment activities.

2.1.2

object of conformity assessment

object

entity to which *specified requirements* ([2.2.1](#)) apply

Note 1 to entry: Examples are product, process, service, system, installation, project, data, design, material, claim, person, body or organization or any combination thereof.

Note 2 to entry: The term “body” is used in this document to refer to *conformity assessment bodies* ([2.1.6](#)) and *accreditation bodies* ([2.1.7](#)). 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* ([2.1.1](#)).

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2.1.3

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* (2.1.2)

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.

Note 2 to entry: Examples include activities performed by providers, designers or owners of the object, investors in the object, and advertisers or promoters of the object.

Note 3 to entry: If a first party activity is performed not by the person or organization itself but by an external body, this is still called first party provided that the external body is acting on behalf of or under the control of that person or organization (e.g. internal audits performed by a consultant who is not part of the staff of the organization).

2.1.4

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* (2.1.2)

Note 1 to entry: 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 a second party activity is performed not by the person or organization itself but by an external body, this is still called second party provided that the external body is acting on behalf of or under the control of that person or organization (e.g. supply chain audits conducted by an external body on behalf of the purchaser).

2.1.5

third-party conformity assessment activity

conformity assessment activity that is performed by a person or organization that is not the provider of the *object* (2.1.2) and has no user interest in the object

2.1.6

conformity assessment body

body that performs conformity assessment activities, excluding *accreditation* (2.4.7)

2.1.7

accreditation body

body that performs *accreditation* (2.4.7)

2.1.8

conformity assessment system

set of common rules and procedures for the management of similar or related *conformity assessment schemes* (2.1.9)

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

2.1.9

conformity assessment scheme

conformity assessment programme

set of rules and *procedures* (2.2.2) that describes the *objects of conformity assessment* (2.1.2), identifies the *specified requirements* (2.2.1) and provides the methodology for performing *conformity assessment* (2.1.1)

Note 1 to entry: A conformity assessment scheme may operate within a *conformity assessment system* (2.1.8).

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

Note 3 to entry: to entry: A scheme can cover part or all of the conformity assessment functions explained in [Annex A](#).

2.1.10

access

access to a system or scheme

opportunity for an applicant to obtain *conformity assessment* ([2.1.1](#)) under the rules of a *system* ([2.1.8](#)) or *scheme* ([2.1.9](#))

2.1.11

participant

participant in a system or scheme

person or organization that operates under the applicable rules without having the opportunity to take part in the management of the *system* ([2.1.8](#)) or *scheme* ([2.1.9](#))

2.1.12

member

member of a system or scheme

person or organization that operates under the applicable rules and has the opportunity to take part in the management of the *system* ([2.1.8](#)) or *scheme* ([2.1.9](#))

2.1.13

owner

owner of a system or scheme

system owner, scheme owner

person or organization responsible for the development and maintenance of a *system* ([2.1.8](#)) or *scheme* ([2.1.9](#))

Note 1 to entry: A scheme owner does not necessarily operate the scheme ([2.1.9](#)).

Note 2 to entry: A system or scheme owner can be a *conformity assessment body* ([2.1.6](#)) itself, a governmental authority, a trade association, a group of conformity assessment bodies or others.

2.2 Basic terms

2.2.1

specified requirement

need or expectation that is stated

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

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

2.2.2

procedure

specified way to carry out an activity or a process

Note 1 to entry: ISO 9000:2015 defines a process as a set of interrelated or interacting activities that use inputs to deliver an intended result.

[SOURCE: ISO 9000:2015, 3.2.3.5 modified — Note 1 to entry added.]

2.2.3

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.

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2.2.4

independence

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

Note 1 to entry: For example a *conformity assessment body* (2.1.6) can be independent from the person who is the *object of conformity assessment* (2.1.2) or from the organization providing the object of conformity assessment.

2.3 Conformity assessment terms relating to selection and determination

(see [Figure A.1](#))

2.3.1

sampling

selection of a sample of the *object of conformity assessment* (2.1.2), according to a *procedure* (2.2.2)

2.3.2

testing

determination of one or more characteristics of an *object of conformity assessment* (2.1.2), according to a *procedure* (2.2.2)

Note 1 to entry: For additional information on the concepts of *testing* (2.3.2) and *inspection* (2.3.3) see A.2.2.4.

Note 2 to entry: The procedure can be intended to control variables within testing as a contribution to the accuracy or reliability of the results.

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.

2.3.3

inspection

examination of an *object of conformity assessment* (2.1.2) and determination of its conformity with detailed requirements or, on the basis of professional judgement, with general requirements

Note 1 to entry: For additional information on the concepts of *testing* (2.3.2) and *inspection* (2.3.3) see A.2.2.4.

Note 2 to entry: Procedures or schemes can restrict inspection to examination only.

2.3.4

audit

process for obtaining relevant information about an *object of conformity assessment* (2.1.2) and evaluating it objectively to determine the extent to which *specified requirements* (2.2.1) 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 of conformity assessment for an audit are management systems, processes or products.

Note 3 to entry: For accreditation purposes, the audit process is called assessment (ISO/IEC 17011:2017, clause 3.22).

2.3.5

validation

confirmation of plausibility for a specific intended use or application, through the provision of objective evidence that *specified requirements* (2.2.1) 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.