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Conformity assessment — Vocabulary and general principles

Évaluation de la conformité — Vocabulaire et principes généraux

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

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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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