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Conformity assessment — Guidance for drafting normative documents suitable for use for conformity assessment

Évaluation de la conformité — Recommandations pour la rédaction de documents normatifs applicables à l'évaluation de la conformité

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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 or www.iec.ch/members_experts/refdocs).

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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. In the IEC, see www.iec.ch/understanding-standards.

This document was prepared by the ISO Committee on Conformity Assessment (CASCO),in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/CLC/JTC 1, *Criteria for conformity assessment bodies,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO/IEC 17007:2009), which has been technically revised.

The main changes are as follows:

— definitions have been aligned with ISO/IEC 17000:2020 with new definitions added;

— 3 categories of provisions in normative documents have been introduced in the Scope and Clause 4;

— references to ISO/IEC 17067 have been added for content regarding schemes;

— the 5 principles described in Clause 4 have been updated;

— guidance for the development of standards for the three categories of provisions has been updated or added in Clauses 5, 6 and 7;

— in Annex A, an introductory part has been added before the Table A.1 to describe the conformity assessment and accreditation bodies specified by the CASCO toolbox; Table A.1 has been updated to contain all toolbox deliverables;

— Annex B has been replaced by a new one describing the approach to identify specified requirements, methods and procedures, rules and methodology for conformity assessment.

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 and www.iec.ch/national-committees.

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Introduction

This document provides principles and guidance on how to develop normative documents, such as standards, technical specifications, codes of practice and regulations, so that they are concise and clear, especially in the context of any subsequent conformity assessment activity.

Conformity assessment is a demonstration that specified requirements are fulfilled and includes activities such as assessment, auditing, design review, evaluation, examination, inspection, testing, surveillance, validation, verification and certification. The methods and procedures for performing such individual conformity assessment activities can be stated in normative documents. Likewise, normative documents can state rules and methodology through which approvals, certificates, consents, licenses, labels, markings, marks of conformity, permissions, reports and other types of statements of conformity are issued.

Normative documents, developed following the principles and guidance in this document, can be suitable for use in conformity assessment at national, regional or international levels, both in regulated or non-regulated applications.

Users of this document can also find useful information in the ISO/IEC Directives, ISO/IEC 17060, ISO/IEC 17067 and the WTO Agreement on Technical Barriers to Trade,[38] Annex 3.

ISO/IEC Directives, Part 2 covers aspects for conformity assessment, mandatory for standards developers in ISO, IEC and ISO/IEC committees.

This document also includes reference to documents in the domain of conformity assessment, known as the CASCO toolbox. These are principally the work of CASCO in cooperation with IEC. Reference to these standards and guides is included to emphasise that they contain internationally agreed, globally applied provisions covering conformity assessment. Reliance on these standards and guides as requirements for conformity assessment bodies and accreditation bodies facilitates acceptance of results around the world.

To make this document as usable as possible, technical terminology has been avoided as much as possible. However, in some cases, the use of some technical terminology is necessary. For example, the requirements in normative documents can relate to a particular material, product, service, installation, data, information, process, system, person or body. In the conformity assessment context, these are all examples of an “object of conformity assessment”.

In the same context, an “object of conformity assessment” or “object” is a generic term used to represent anything that can fulfil specified requirements. In a normative document suitable for use in conformity assessment, the term “object of conformity assessment” or “object” would not be used. A normative document should include a scope which either explicitly or implicitly specifies the related object of conformity assessment, for example, a type of product, process, service, installation, project, data, design, material, claim, person, body, organization, management system, conformity assessment body. In this document, the term “object of conformity assessment” or “object” is used so that this document can be applied regardless of the specific scope of any normative document.

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Conformity assessment — Guidance for drafting normative documents suitable for use for conformity assessment

1 Scope

This document specifies principles and gives guidance for developing normative documents that contain:

— specified requirements for the object of conformity assessment;

— specific methods and procedures for an individual conformity assessment activity (e.g. test methods);

— rules and methodology for conformity assessment (as part of conformity assessment schemes, including provisions for organizations that perform conformity assessment activities).

This document is intended for the following users:

— standards developers;

— regulatory authorities;

— conformity assessment scheme owners;

— industry associations and consortia;

— conformity assessment bodies;

— accreditation bodies;

— purchasers;

— consumers and non-governmental groups;

— other interested parties, e.g. insurance organizations.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO/IEC 17000:2020, *Conformity assessment — Vocabulary and general principles*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO/IEC 17000 and the following apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

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3.1
specified requirement
need or expectation that is stated

Note 1 to entry: Specified requirements can be stated in *normative documents* (3.2).

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

[SOURCE: ISO/IEC 17000:2020, 5.1, modified — Examples of normative documents have been removed from note 1 to entry.]

3.2
normative document
<conformity assessment> document that provides:

a) *specified requirements* (3.1) for the *object of conformity assessment* (3.3);

b) specific methods and procedures for an individual *conformity assessment activity* (3.5) (e.g. test methods); or

c) rules and *methodology* (3.10) for *conformity assessment* (3.4) (as part of *conformity assessment schemes* (3.9), including provisions for organizations that undertake conformity assessment)

Note 1 to entry: The term "normative document" is a generic term that covers such documents as standards, technical specifications, codes of practice, legislation and regulations.

Note 2 to entry: A "document" is to be understood as any medium with information recorded on or in it.

3.3
object of conformity assessment
object
entity to which *specified requirements* (3.1) 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* (3.6) and *accreditation bodies* (3.8). 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* (3.4).

[SOURCE: ISO/IEC 17000:2020, 4.2]

3.4
conformity assessment
demonstration that *specified requirements* (3.1) are fulfilled

Note 1 to entry: The process of conformity assessment is described in the functional approach in ISO/IEC 17000:2020, Annex A as a series of functions and it can have a negative outcome, i.e. demonstrating that the specified requirements are not fulfilled.

Note 2 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.

[SOURCE: ISO/IEC 17000:2020, 4.1, modified — Note 1 to entry has been modified to add "as a series of functions"; the original notes 2 and 3 to entry have been deleted.]

3.5
conformity assessment activity
activity contributing to any of the functions in the functional approach described in ISO/IEC 17000:2020, Annex A

Note 1 to entry: Conformity assessment activities include but are not limited to testing, auditing, examination, evaluation, inspection, validation, verification, certification and *accreditation* (3.7).

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3.6
conformity assessment body
body that performs *conformity assessment activities* (3.5), excluding *accreditation* (3.7)

[SOURCE: ISO/IEC 17000:2020, 4.6]

3.7
accreditation
third-party attestation related to a *conformity assessment body* (3.6), conveying formal demonstration of its competence, impartiality and consistent operation in performing specific *conformity assessment activities* (3.5)

[SOURCE: ISO/IEC 17000:2020, 7.7]

3.8
accreditation body
authoritative body that performs *accreditation* (3.7)

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

[SOURCE: ISO/IEC 17000:2020, 4.7]

3.9
conformity assessment scheme
conformity assessment programme
set of rules and procedures that describes the *objects of conformity assessment* (3.3), identifies the *specified requirements* (3.1) and provides the *methodology* (3.10) for performing *conformity assessment* (3.4)

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

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 ISO/IEC 17000:2020, Annex A.

[SOURCE: ISO/IEC 17000:2020, 4.9]

3.10
methodology
systematic collection of methods

Note 1 to entry: In *conformity assessment* (3.4), a systematic approach, or collection of methods, for performing activities contributing to the functions described in ISO/IEC 17000:2020, Annex A, (the functional approach) is one part of a *conformity assessment scheme* (3.9). Individual demonstrations performed in accordance with the same conformity assessment scheme follow the same methodology.

Note 2 to entry: A method or procedure for a specific individual *conformity assessment activity* (3.5) within the functional approach (e.g. a sampling protocol, test method, calibration method, inspection procedure, a general plan for an audit of a management system, a general plan for validation or verification of a type of claim, the formatting of a statement of conformity) can be included or referenced in the methodology provided in a conformity assessment scheme. However, a method or procedure for a specific individual conformity assessment activity is not by itself a methodology for demonstrating the fulfilment of *specified requirements* (3.1).

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