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Conformity assessment — Fundamentals of and guidelines for conformity assessment schemes

Évaluation de la conformité — Éléments fondamentaux et lignes directrices pour les systèmes particuliers d'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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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 17067:2013), which has been technically revised.

The main changes are as follows:

— the scope has been expanded to apply to conformity assessment schemes in general;

— the title has been updated to reflect the extended scope;

— individual clauses have been rephrased to apply to conformity assessment schemes in general;

— clauses have been added to provide specifics (e.g. on product certification schemes) where necessary;

— guidelines for product certification schemes are maintained and moved to Annex A;

— annexes have been added to provide guidelines for other schemes (e.g. schemes including inspection, management system certification, peer assessment, accreditation).

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 fundamental concepts, principles and guidelines for conformity assessment schemes (which are sometimes referred to as “conformity assessment programmes”).

Conformity assessment performed in accordance with a conformity assessment scheme can provide assurance to interested parties via demonstration that specified requirements are fulfilled. Conformity assessment can thus provide assurance to interested parties in various areas, including, but not limited to, legal compliance, health and safety, suitability for intended use, performance, durability, compatibility, environmental impacts, governance and social impacts, resource use efficiency and resource circularity, management and use of information technology, climate change and sustainability matters.

This document is intended for those who have an interest in conformity assessment schemes, particularly those who own or operate schemes, or are considering development of a scheme. These people and their organizations can include:

a) governments and regulatory authorities;

b) industry, trade associations and organizations (e.g. retailers) within value chains;

c) procurement and purchasing agencies;

d) non-governmental organizations (NGOs);

e) consumer organizations;

f) bodies undertaking conformity assessment activities.

A conformity assessment scheme can be operated at an international, regional, national, sub-national level, or for a specific industry sector or value chain. A scheme can be documented or only orally created.

A conformity assessment scheme is defined as a set of rules and procedures that:

— describes objects of conformity assessment;

— identifies the specified requirements; and

— provides the methodology for performing conformity assessment.

This document is one of the ISO/IEC and ISO documents on conformity assessment that are developed and maintained by the ISO Committee on Conformity Assessment (CASCO). These ISO/IEC and ISO documents are colloquially known as the “CASCO toolbox” and contribute to the development of “conformity assessment procedures” as referenced in the World Trade Organization Agreement on Technical Barriers to Trade (WTO/TBT). These documents are applied and used by ISO and its members, IEC and its national committees, and organizations outside of ISO and IEC (e.g. regulatory authorities, NGOs, accreditation bodies and agreement groups) for globally accepted conformity assessment practice.

Where the context is unambiguous, "scheme" is used in short for the full terms "conformity assessment scheme" and “conformity assessment programme”. For ease of comprehension of this document, the terms "conformity assessment scheme" and “conformity assessment programme” are considered synonyms, unless explicitly stated otherwise.

Where the context is unambiguous, "system" is used in short for the full term "conformity assessment system".

Where the context is unambiguous, "object" is used in short for the full term "object of conformity assessment".

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Conformity assessment — Fundamentals of and guidelines for conformity assessment schemes

1 Scope

This document specifies the fundamental principles and concepts of conformity assessment schemes (programmes) and provides guidelines for understanding, developing, operating or maintaining them.

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, *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/

3.1
conformity assessment
demonstration that *specified requirements* (3.3) are fulfilled

Note 1 to entry: The process of conformity assessment as described in the functional approach in ISO/IEC 17000:2020, 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* (3.25), *inspection* (3.26), *validation* (3.27), *verification* (3.28), *certification* (3.17), and *accreditation* (3.18).

Note 3 to entry: Conformity assessment is explained in ISO/IEC 17000:2020, 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.

[SOURCE: ISO/IEC 17000:2020, 4.1]

3.2
object of conformity assessment
object
entity to which *specified requirements* (3.3) apply

EXAMPLE Product, process, service, system, installation, project, data, design, material, claim, person, body or organization, or any combination thereof.

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Note 1 to entry: The term "body" is used in this document to refer to the *conformity assessment body* (3.19) and *accreditation body* (3.20). 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* (3.1).

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

3.3
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.

[SOURCE: ISO/IEC 17000:2020, 5.1]

3.4
conformity assessment scheme
conformity assessment programme
set of rules and *procedures* (3.21) that describes the *objects of conformity assessment* (3.2), identifies the *specified requirements* (3.3) and provides the *methodology* (3.22) for performing *conformity assessment* (3.1)

Note 1 to entry: A conformity assessment scheme can be managed within a *conformity assessment system* (3.5).

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]

3.5
conformity assessment system
set of rules and *procedures* (3.21) for the management of similar or related *conformity assessment schemes* (3.4)

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

[SOURCE: ISO/IEC 17000:2020, 4.8]

3.6
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* (3.5) or *conformity assessment scheme* (3.4)

Note 1 to entry: A scheme owner does not necessarily operate the *scheme* (3.4).

Note 2 to entry: A system owner or a scheme owner can be a *conformity assessment body* (3.19) itself, a governmental authority, a trade association, a group of conformity assessment bodies or others.

[SOURCE: ISO/IEC 17000:2020, 4.13]

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3.7
participant
participant in a system
participant in a scheme
person or organization that implements or operates under the rules and *procedures* (3.21) of a *conformity assessment system* (3.5) or *scheme* (3.4) without being involved in their development, revision or approval

[SOURCE: ISO/IEC 17000:2020, 4.11]

3.8
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* (3.21) of a *conformity assessment system* (3.5) or *scheme* (3.4)

[SOURCE: ISO/IEC 17000:2020, 4.12]

3.9
first-party conformity assessment activity
conformity assessment (3.1) activity that is performed by the person or organization that provides or that is the *object of conformity assessment* (3.2)

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).

[SOURCE: ISO/IEC 17000:2020, 4.3]

3.10
second-party conformity assessment activity
conformity assessment (3.1) activity that is performed by a person or organization that has a user interest in the *object of conformity assessment* (3.2)

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).

[SOURCE: ISO/IEC 17000:2020, 4.4]

3.11
third-party conformity assessment activity
conformity assessment (3.1) activity that is performed by a person or organization that is independent of the provider of the *object of conformity assessment* (3.2) 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.

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[SOURCE: ISO/IEC 17000:2020, 4.5]

3.12
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* (3.3) by an *object of conformity assessment* (3.2)

Note 1 to entry: A description of "selection and determination activities" is included in 5.1, 5.3 and ISO/IEC 17000:2020, A.2 and A.3.

[SOURCE: ISO/IEC 17000:2020, 7.1, modified — Note to entry 1 added.]

3.13
decision
conclusion, based on the results of *review* (3.12), that fulfilment of *specified requirements* (3.3) has or has not been demonstrated

[SOURCE: ISO/IEC 17000:2020, 7.2]

3.14
attestation
issue of a statement, based on a *decision* (3.13), that fulfilment of *specified requirements* (3.3) has been demonstrated

Note 1 to entry: The resulting statement, referred to in this document as a "statement of conformity", is intended to convey the assurance that the specified requirements have been fulfilled. Such an assurance does not, of itself, provide contractual or other legal guarantees.

Note 2 to entry: First-party attestation and third-party attestation are distinguished by the terms *declaration* (3.16), *certification* (3.17) and *accreditation* (3.18), but there is no corresponding term applicable to second-party attestation.

[SOURCE: ISO/IEC 17000:2020, 7.3]

3.15
surveillance
systematic iteration of conformity assessment activities as a basis for maintaining the validity of the statement of conformity

[SOURCE: ISO/IEC 17000:2020, 8.1]

3.16
declaration
first-party *attestation* (3.14)

[SOURCE: ISO/IEC 17000:2020, 7.5]

3.17
certification
third-party *attestation* (3.14) related to an *object of conformity assessment* (3.2), with the exception of *accreditation* (3.18)

[SOURCE: ISO/IEC 17000:2020, 7.6]

3.18
accreditation
third-party *attestation* (3.14) related to a *conformity assessment body* (3.19), conveying formal demonstration of its competence, impartiality and consistent operation in performing specific conformity assessment activities

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

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3.19
conformity assessment body
body that performs conformity assessment activities, excluding *accreditation* (3.18)

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

3.20
accreditation body
authoritative body that performs *accreditation* (3.18)

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]

3.21
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/IEC 17000:2020, 5.2]

3.22
methodology
systematic collection of methods

Note 1 to entry: In *conformity assessment* (3.1), 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* (3.4). 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 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* (3.3).

[SOURCE: ISO/IEC 17007:2026, 3.10]

3.23
complaint
expression of dissatisfaction, other than *appeal* (3.24), by any person or organization to a *conformity assessment body* (3.19) or an *accreditation body* (3.20), relating to the activities of that body, where a response is expected

[SOURCE: ISO/IEC 17000:2020, 8.7]

3.24
appeal
request by the person or organization that provides, or that is, the *object of conformity assessment* (3.2) to a conformity *assessment body* (3.19) or an *accreditation body* (3.20) for reconsideration by that body of a *decision* (3.13) it has made relating to that object

[SOURCE: ISO/IEC 17000:2020, 8.6]

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3.25
testing
determination of one or more characteristics of an *object of conformity assessment* (3.2), according to a *procedure* (3.21)

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 and *inspection* (3.26) is given in ISO/IEC 17000:2020, A.3.4.

[SOURCE: ISO/IEC 17000:2020, 6.2]

3.26
inspection
examination of an *object of conformity assessment* (3.2) 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 or contracts can specify inspection as examination only.

Note 3 to entry: Additional information on the concepts of *testing* (3.25) and *inspection* (3.26) is given in ISO/IEC 17000:2020, A.3.4.

[SOURCE: ISO/IEC 17000:2020, 6.3]

3.27
validation
confirmation of plausibility for a specific intended use or application through the provision of objective evidence that *specified requirements* (3.3) 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.

[SOURCE: ISO/IEC 17000:2020, 6.5]

3.28
verification
confirmation of truthfulness through the provision of objective evidence that *specified requirements* (3.3) 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.

[SOURCE: ISO/IEC 17000:2020, 6.6]

3.29
agreement group
bodies that are signatories to the agreement on which an arrangement is based

[SOURCE: ISO/IEC 17000:2020, 9.10]

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3.30
recognition
recognition of a conformity assessment result
acknowledgement of the validity of a conformity assessment result provided by another person or organization

Note 1 to entry: The expression "conformity assessment result" signifies the output of any conformity assessment activity (e.g. a report or certificate) and can include a finding of nonconformity.

[SOURCE: ISO/IEC 17000:2020, 9.5]

3.31
acceptance
acceptance of a conformity assessment result
use of a conformity assessment result provided by another person or organization

Note 1 to entry: The expression "conformity assessment result" signifies the output of any conformity assessment activity (e.g. a report or certificate) and can include a finding of nonconformity.

[SOURCE: ISO/IEC 17000:2020, 9.6]

4 Conformity assessment schemes (programmes) and systems

4.1 Difference between conformity assessment schemes and systems

4.1.1 The set of rules and procedures defined as a "conformity assessment scheme" or "conformity assessment programme" relates to:

a) a description of the object of conformity assessment (see 4.2);

b) identification of the specified requirements (see 4.3);

c) provision of the methodology (see 4.4 and Clause 5) for performing conformity assessment (e.g. rules for persons and organizations involved in conformity assessment, procedures for individual activities, rules and procedures for issuing statements of conformity).

4.1.2 Rules and procedures can be unique to a conformity assessment scheme or shared by multiple schemes. The rules and procedures shared by multiple schemes can be described and documented separately from the content of the individual schemes. Such common rules and procedures can relate to concepts (e.g. specific to a sector or an application), structure, methodology, requirements, or other content shared by the schemes. Documents providing such general contents for multiple schemes are different from documents containing an individual conformity assessment scheme. Sometimes these documents are referred to as "frameworks".

4.1.3 Depending on the object of conformity assessment and the needs of users of conformity assessment, a scheme can be used only once or repeatedly.

4.1.4 The rules and procedures in a scheme can be provided in a single document or in multiple documents linked by reference. Documented schemes can be intended for repeated use over a long period of time.

4.1.5 A conformity assessment system is also a set of rules and procedures. However, these rules and procedures are to manage several conformity assessment schemes that are similar or related. An example for a conformity assessment system is the IEC CA System to manage the IECEE, IECQ, IECRE, IECEx certification schemes. Whenever conformity assessment is performed, a scheme always exists, but a system for managing schemes is optional.

Figure 1 illustrates the relationship between a scheme and a system.

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