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Conformity assessment — Code of good practice

Évaluation de la conformité — Code de bonne pratique

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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).

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

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

This first edition of ISO/IEC 17060 cancels and replaces ISO/IEC Guide 60:2004 which has been technically revised.

The main changes are as follows:

— transformation of a Guide (ISO/IEC Guide 60) into an International Standard (ISO/IEC 17060);

— inclusion of a new clause on the identification of the objects of conformity assessment;

— inclusion of language on risk-based approach;

— renumbering of Clause 4 in separate clauses;

— alignment of the terminology and text for consistency with other ISO/CASCO standards.

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.

Introduction

Conformity assessment involves activities to demonstrate the fulfilment of specified requirements. The specified requirements can be applied to a range of objects of conformity assessment, including but not limited to products, processes, services, systems, installations, projects, data, designs, materials, claims, persons, bodies or organizations, or any combination thereof. Conformity assessment includes activities that provide various types of assurance that requirements set out in specifications such as international, regional, or national standards, guides, recommendations, or other normative documents are fulfilled.

Rapid technological development, integration of economic and production systems, and increased levels of international trade have emphasized the need for convergence among conformity assessment practices and systems. International standards are increasingly accepted as one effective vehicle to improve competition and eliminate technical barriers to trade. However, the use of harmonized international practices in the area of conformity assessment needs continuous attention, where different practices and approaches persist. This environment can result in additional costs for manufacturers, service providers, exporters and consumers, and poses challenges for regulatory authorities and industry.

The evolution of international, regional and private-sector conformity assessment systems and schemes is also noteworthy. These systems continue to expand, building confidence for the users of conformity assessment services (including industry, regulators and consumers) and promoting global acceptance through a variety of methods.

Different conformity assessment practices and requirements, together with the lack of recognition of conformity assessment results, can restrict the exchange of goods and services. Efforts are required to ensure that all conformity assessment systems and practices:

— attempt to involve all interested parties,

— are non-discriminatory, transparent, impartial, and

— avoid unnecessary obstacles to trade.

Members of the conformity assessment community are encouraged to participate in the development of international standards and guides, to use them as the basis for their respective conformity assessment activities and systems, and to engage in information exchange and confidence building to increase knowledge and acceptance of other systems and approaches.

This document is intended to establish and promote conformity assessment policies and practices that facilitate trade and support the development of societal benefits and/or needs at international, regional, national and sub-national level.

They are characterized by openness, transparency, impartiality, confidentiality, coherence and effectiveness, thereby supporting credibility and consistency in conformity assessment.

This document is presented in a form suitable for use by conformity assessment bodies, accreditation bodies and other interested parties, whether governmental or non-governmental, at international, regional, national or sub-national levels. This document is intended to be used in conjunction with, or when preparing, International Standards relating to conformity assessment, and in conjunction with the World Trade Organization's (WTO's) Technical Barriers to Trade (TBT) Agreement.

Conformity assessment — Code of good practice

1 Scope

This document recommends good practices for all elements of conformity assessment, including objects of conformity assessment, specified requirements, activities, bodies, systems, schemes and results.

It is intended for use by individuals and bodies that wish to provide, promote or use impartial and reliable conformity assessment services. Providers of conformity assessment can include conformity assessment bodies, accreditation bodies, peer-assessment agreement groups, and organizations providing declarations of conformity. Individuals or organizations that promote or use conformity assessment can include, as appropriate, regulators, trade officials, and owners of conformity assessment systems and schemes.

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/

3.1
conformity assessment
demonstration that *specified requirements* (3.5) 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 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.

[SOURCE: ISO/IEC 17000:2020, 4.1, modified — The original Notes 2 and 4 to entry have been deleted, the original Note 3 to entry has been renumbered as Note 2 to entry and the words "ISO/IEC 17000:2020" have been added before "Annex A".]

3.2
conformity assessment scheme
conformity assessment programme
set of rules and procedures that describes the *objects of conformity assessment* (3.6), identifies the *specified requirements* (3.5) and provides the methodology for performing conformity assessment

Note 1 to entry: A conformity assessment scheme can be managed within a *conformity assessment system* (3.3).

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, modified – In Note 3 to entry, the words "ISO/IEC 17000:2020" have been added before "Annex A".]

3.3
conformity assessment system
set of rules and procedures for the management of similar or related *conformity assessment schemes* (3.2)

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]

3.4
normative document
document that provides rules, guidelines or characteristics for activities or their results

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

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

Note 3 to entry: The terms for different kinds of normative documents are defined considering the document and its content as a single entity.

[SOURCE: ISO/IEC Guide 2:2004, 3.1]

3.5
specified requirement
need or expectation that is stated

Note 1 to entry: Specified requirements can be stated in *normative documents* (3.4) 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]

3.6
object of conformity assessment
object
entity to which *specified requirements* (3.5) 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 and accreditation bodies. 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]

4 Good practices in conformity assessment

Good practices in conformity assessment comprise the following:

— identification of the objects of conformity assessment (see Clause 5);

— specified requirements (see Clause 6);

— conformity assessment activities and bodies (see Clause 7);

— conformity assessment systems and schemes (programmes) (see Clause 8);

— conformity assessment results (see Clause 9).

5 Identification of the objects of conformity assessment

Objects of conformity assessment should:

a) have their intended use and characteristics clearly identified;

b) be capable of having their conformity assessed;

c) have identified boundaries;

d) have their requirements separately specified from requirements for conformity assessment activities.

NOTE Objects of conformity assessment include, but are not limited to, products, components, assemblies, processes, services, systems, installations, projects, data, designs, materials, claims, persons, bodies or organizations, or any combination thereof.

6 Specified requirements

Specified requirements for an object of conformity assessment should:

a) define the relevant object of conformity assessment (see Clause 5);

b) be technically relevant;

c) be prepared in a transparent, open, impartial, coherent and consistent manner;

d) respond appropriately to compliance obligations, market, societal or economic needs;

e) take into account the views of interested parties;

f) avoid unnecessary obstacles to trade;

g) where appropriate, be written to be used directly in first-party, second-party or third-party conformity assessment activities;

h) apply a risk-based approach.

NOTE Specified requirements can be stated in normative documents. Guidance for drafting normative documents suitable for use for conformity assessment is given in ISO/IEC 17007.

7 Conformity assessment activities and bodies

Conformity assessment bodies and accreditation bodies should:

a) base their activities as far as possible on international standards, guides and recommendations developed by consensus, such as ISO/IEC International Standards;

b) be managed and operated to give sufficient assurance of the conformity of objects of conformity assessment with specified requirements;

NOTE This implies the maintenance of adequate competence in order to facilitate acceptance of conformity assessment results.

c) apply a risk-based approach;

d) protect all confidential information;

e) be impartial, show professional integrity, operate in an ethical, consistent and non-discriminatory manner and avoid conflicts of interests;

f) manage the risks to impartiality;

g) process applications and assessments in a prompt, impartial and efficient manner and ensure that expected timeframes are communicated to the client;

h) process complaints or appeals (where applicable) in a prompt, impartial and efficient manner, and take corrective action when justified;

i) provide and maintain records to include adequate documentation for any determination of denial, withdrawal, suspension, restoration or termination of the authorization to use evidence of conformity;

j) maintain and make readily available information on all services offered, including but not limited to related fees, certificates held or granted, scopes of accreditation, statements or declarations;

k) be subject to monitoring (as appropriate);

l) demonstrate their competence by a suitable mechanism;

m) provide conformity assessment findings or results highlighting, where applicable, any nonconformities or necessary actions;

n) take into account issues related to the participation of developing countries;

o) reflect the principles of non-discrimination and national treatment;

p) accept the results of relevant conformity assessment activities to avoid unnecessary duplication of work.

NOTE Conformity assessment includes activities such as testing, inspection, validation, verification and certification performed by conformity assessment bodies, and accreditation of conformity assessment bodies performed by accreditation bodies. The definitions of these terms are contained in ISO/IEC 17000.

8 Conformity assessment systems and schemes (programmes)

Conformity assessment systems and schemes (programmes) should:

a) be designed and administered in a transparent, open, non-discriminatory and reliable manner;

b) be designed and administered in such a way as to avoid creating technical barriers to trade;

c) be appropriate to the needs of interested parties, in order to facilitate acceptance of the conformity assessment results;

NOTE Examples of interested parties are consumer groups, non-governmental organizations, regulators, industry groups, voluntary organizations, developing countries.