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

Évaluation de la conformité — Directives pour la rédaction de documents normatifs appropriés pour 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. In the field of conformity assessment, the ISO Committee on conformity assessment (CASCO) is responsible for the development of International Standards and Guides.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

Draft International Standards are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO/IEC 17007 was prepared by the ISO *Committee on conformity assessment* (CASCO).

It was circulated for voting to the national bodies of both ISO and IEC, and was approved by both organizations.

This first edition of ISO/IEC 17007 cancels and replaces ISO/IEC Guide 7:1994, of which it constitutes a technical revision.

Introduction

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

Conformity assessment activities include testing, inspection and various forms of certification. These activities can result in attestations such as declarations, reports, certificates, marks of conformity or the granting of permissions and licences (see also ISO/IEC 17000:2004).

This International Standard is intended for the following users:

— standards developers not applying the ISO/IEC Directives;

— industry associations and consortia;

— purchasers;

— regulators;

— consumers and non-government groups;

— accreditation bodies;

— conformity assessment bodies;

— conformity assessment scheme owners; and

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

This International Standard is intended to assist the above users in developing specific normative documents at national, regional or international levels, both in regulated or non-regulated applications.

Users of this International Standard may also find useful the good standardization practices defined in the ISO/IEC Directives (which specify the requirements for ISO and IEC normative documents containing specified requirements) and the WTO Agreement on Technical Barriers to Trade, Annex 3, *Code of Good Practice for the Preparation, Adoption and Application of Standards*. The ISO/IEC Directives, Part 2, 2004, 6.7, also covers aspects for conformity assessment.

This International Standard also includes guidance on specialized International Standards and Guides in the domain of conformity assessment, known as the conformity assessment toolbox. These are principally the work of CASCO in cooperation with IEC. Reference to these generic publications is included to emphasise that they contain internationally agreed provisions covering conformity assessment activities. Reliance on such publications facilitates reproducibility and mutual acceptance of conformity assessment results around the world.

To make this International Standard easy to follow, technical terminology has been avoided as much as possible. However, in some cases, the use of some technical terminology has been unavoidable. For example, the requirements in normative documents can relate to many different areas, e.g. a particular material, product, service, installation, process, system, person or body. In a conformity assessment context, these are all examples of an “object of conformity assessment”. To avoid repeating a list of the examples throughout the text, the term “object of conformity assessment” is used, for which a definition is provided in Clause 3.

The guidance in this International Standard is subdivided into three clauses, as follows:

— Clause 4 specifies five principles as the basis for the subsequent guidance;

— Clause 5 provides guidance for the preparation of normative documents that specify requirements for characteristics of objects of conformity assessment;

— Clause 6 provides guidance for the preparation of normative documents specifying requirements for conformity assessment systems.

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

1 Scope

This International Standard provides principles and guidance for developing normative documents that contain:

— specified requirements for objects of conformity assessment to fulfil;

— specified requirements for conformity assessment systems that can be employed when demonstrating whether an object of conformity assessment fulfils specified requirements.

This International Standard is intended for use by standards developers not applying the ISO/IEC Directives, industry associations and consortia, purchasers, regulators, consumers and non-government groups, accreditation bodies, conformity assessment bodies, conformity assessment scheme owners, and other interested parties, such as insurance organizations.

2 Normative references

The following referenced documents are indispensable for the application 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 17000:2004, *Conformity assessment — Vocabulary and general principles*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO/IEC 17000:2004 and the following apply. For convenience of use, the following definitions are repeated.

3.1
conformity assessment system
rules, procedures and management for carrying out conformity assessment

NOTE Conformity assessment systems may be operated at international, regional, national or sub-national level.

[ISO/IEC 17000:2004, 2.7]

3.2
conformity assessment scheme
conformity assessment programme
conformity assessment system related to specified objects of conformity assessment, to which the same specified requirements, specific rules and procedures apply

NOTE Conformity assessment schemes may be operated at international, regional, national or sub-national level.

[ISO/IEC 17000:2004, 2.8]

3.3
object of conformity assessment
particular material, product (including services), installation, process, system, person or body to which conformity assessment is applied

NOTE Adapted from ISO/IEC 17000:2004, 2.1, Note 2.

3.4
specified requirement
need or expectation that is stated

NOTE Specified requirements may be stated in normative documents such as regulations, standards and technical specifications.

[ISO/IEC 17000:2004, 3.1]

3.5
surveillance
systematic iteration of conformity assessment activities as a basis for maintaining the validity of the statement of conformity

[ISO/IEC 17000:2004, 6.1]

4 Principles

4.1 General

The principles listed below are the basis for the subsequent guidance in this International Standard. This International Standard does not give specific guidance for all situations that can occur. Therefore, the following principles may provide guidance for such situations:

— principle 1: separation of specified requirements for the object of conformity assessment from specified requirements related to conformity assessment activities (see 4.2);

— principle 2: neutrality towards parties performing conformity assessment activities (see 4.3);

— principle 3: functional approach to conformity assessment (see 4.4);

— principle 4: comparability of conformity assessment results (see 4.5);

— principle 5: good practice in conformity assessment (see 4.6).

Principles 1 and 2 are primarily directed towards the preparation of normative documents that contain specifications for objects of conformity assessment (Clause 5 provides further information). Principle 3 is directed towards the preparation of separate normative documents that contain specifications for how conformity assessment systems are structured and carried out. However, the functional approach can assist the developer of normative documents for characteristics of the object of conformity assessment to anticipate and formulate requirements that can be used in the subsequent conformity assessment activities.

4.2 Principle 1: separation of specified requirements for the object of conformity assessment from specified requirements related to conformity assessment activities

Normative documents that contain specified requirements for objects of conformity assessment, i.e. characteristics for an object of conformity assessment, should not contain provisions related to conformity assessment activities, except sampling and testing methods related to the specified characteristics. Normative documents that specify requirements for conformity assessment activities should be established separately.

Examples of conformity assessment provisions that should not be contained in normative documents for objects of conformity assessment are requirements or recommendations concerning:

— specific conformity assessment systems or schemes to be applied;

— who should undertake conformity assessment activities, such as a first, second, or third party;

— the type of conformity assessment body to be involved (e.g. testing laboratory, inspection body); or

— specific indications of conformity, such as marks of conformity.

The benefits of separating specified requirements for objects of conformity assessment from specified requirements related to conformity assessment activities include the following:

a) more rigorous consideration of the characteristics of the object and conformity assessment aspects in their proper contexts;

b) greater use of the normative document for the object by parties not pursuing conformity assessment;

c) easier reference to specified characteristics of the object and/or conformity assessment requirements by authorities such as regulators.

4.3 Principle 2: neutrality towards parties performing conformity assessment activities

Normative documents for objects of conformity assessment should be written so that conformity of the objects to the specifications can be assessed by any interested party. Interested parties can be:

— a manufacturer or supplier of the object (first party);

— a user or purchaser of the object (second party);

— an independent body (third party).

NOTE Users of the normative documents that contain specifications for objects of conformity assessment can select the parties that are acceptable. Examples of this include:

— regulators regulating the use of the first-party supplier's declarations of conformity (SDoC);

— purchasing organizations specifying specific acceptance criteria and performing tests in their own laboratories for purchased goods (second party);

— regulators requiring product certification by a recognized independent body (third party) before a product enters the market;

— purchasing organizations or regulators requiring certification of the supplier's quality management system as a prerequisite to supply goods or services.

4.4 Principle 3: functional approach to conformity assessment

Further information regarding principle 3 is provided in Clause 6.

In accordance with principle 3, normative documents that specify conformity assessment activities should consider the “functional approach to conformity assessment”, consisting of the following functions:

— selection;

— determination;

— review and attestation; and

— surveillance (if needed).

These conformity assessment functions are described more fully in 6.4, as well as in ISO/IEC 17000:2004, Annex A.

Each of the various kinds of users of conformity assessment has specific needs. As a result, there is much variety in the way conformity assessment is performed. However, all types of conformity assessment follow the same general approach, characterized by the functions listed above.

The benefits of the functional approach include the following:

a) thorough consideration of all functions of conformity assessment, including clear interfaces between conformity assessment functions;

b) greater substance and credibility that aims of conformity assessment functions are fulfilled;

c) greater consistency and possibility of harmonization among national, regional and international conformity assessment activities, thus facilitating mutual recognition and trade.

4.5 Principle 4: comparability of conformity assessment results

The requirements for the objects of conformity assessment (Clause 5) and the requirements for the conformity assessment activities (Clause 6) should be specified in a clear and unambiguous manner, with sufficient detail to ensure that conformity assessment results will be comparable and reproducible.

An important outcome of standardization and of conformity assessment activities is confidence in the objects' fulfilment of specified requirements and the realization of the intended benefits (e.g. interoperability with other products or reduction of safety risks). If different parties (i.e. people, bodies and/or organizations) are applying the specified requirements to produce the object of conformity assessment, the resultant objects should all be comparable with respect to fulfilment of the requirements specified. If conformity with the specified requirements is assessed by different parties, the results of the conformity assessment should be comparable.

4.6 Principle 5: good practice in conformity assessment

Developers of normative documents for conformity assessment activities should consider International Standards and Guides as a source of good practice in conformity assessment.

ISO and IEC have developed a series of International Standards and Guides to promote the international comparability and credibility of conformity assessment activities, known as the conformity assessment toolbox. The criteria contained in these documents represent an international consensus on what constitutes good practice in conformity assessment. Using these documents fosters international compatibility and may avoid technical barriers to trade. Annex A lists all the documents that constitute the conformity assessment toolbox.

5 Guidance for the preparation of normative documents that specify requirements for objects of conformity assessment

5.1 General

5.1.1 Objects of conformity assessment may be products (including services), materials, installations, processes, systems, persons or bodies. Although the guidance in this clause may appear to be biased towards tangible products, developers of normative documents should interpret this guidance to apply to other objects of conformity assessment. Some examples are provided in 5.2.5.

5.1.2 This clause does not apply to conformity assessment systems and bodies as objects of conformity assessment.

5.2 Drafting specified requirements

5.2.1 Specified requirements relating to the characteristics of the object of conformity assessment should be stated in the clauses that form the normative parts of the document.

5.2.2 Specified requirements should be written in such a way that they are clear, direct and precise and will result in accurate and uniform interpretation, so that parties making use of the normative document are able to derive from the contents of the normative document a common understanding of its meaning and intent.

5.2.3 Normative documents for objects of conformity assessment should focus only on the criteria or performance characteristics of the object.

5.2.4 Normative documents may specify test methods for determining that the criteria or characteristics have been met. They should be expressed in such a way that any interested party may carry out the testing. It should be left to the users of the normative document to decide what conformity assessment activity (if any) will be utilized, who will carry out the conformity assessment and under what conditions.

5.2.5 Specified requirements should be written in terms of results or outcomes, together with limiting values and tolerances, where pertinent, and the methods of determination, such as test methods or inspection, in order to verify the specified characteristics. Examples of results or outcomes for a variety of objects of conformity assessment include:

— a manufactured component specified in terms of durability and interoperability within an assembly;

— market research service requirements in terms of defining market composition and reliability of data;

— process requirements for organic agriculture to ensure that production and supply result in food products free of inorganic contaminants;

— a security management system specified in terms of effectiveness of the security environment and continual improvement;

— requirements for personal financial planners in terms of the body of knowledge and experience necessary to demonstrate competence.

5.2.6 Specified requirements should be written in such a way that they facilitate the development of technology. In general, this is accomplished by:

— specifying requirements in terms of performance, rather than design or descriptive characteristics;

— specifying requirements related to the object, and not to the production process for the object.

5.2.7 Specified requirements should be divided into distinct, consistent and easily identifiable sections, in order to permit their incorporation by reference in codes, regulations and other standards. This structure permits selected clauses to be identified separately in a code or regulation when only part of the normative document is referenced.

5.2.8 If a set of specified requirements incorporates requirements stated in another document, the incorporation should be by specific reference and clearly indicate the referenced version, usually by the date (year) of publication. If the version of the referenced document is not specified, the conventional understanding is that the latest version of the document applies, including all amendments and revisions. The use of the term “latest issue” in conjunction with an undated reference should be avoided.

If the referenced document is not dated, it is possible that the format and content of the referenced requirements could change over time. The consequences of changes to the referenced requirements should be considered.