



*Conformity
assessment
for standards
writers*

Do's and don'ts



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► Introduction

Conformity assessment is an area of standards development that covers activities used to ensure products, processes, services, persons, systems and bodies meet specified requirements. These activities can include testing, inspection, evaluation, examination, auditing, assessment, declarations, certification, accreditation, peer assessment, verification and validation.

All ISO and IEC International Standards must be developed in accordance with the ISO/IEC Directives. One of the areas covered in ISO/IEC Directives, Part 2, *Rules for the structure and drafting of International Standards*, is subclause 6.7, *Aspects of conformity assessment*.

The ISO Committee on conformity assessment (ISO/CASCO) oversees the implementation of this clause of the ISO/IEC Directives and provides advice to ISO technical committees (TCs) on how to word their standards in a compliant manner. Furthermore, ISO and IEC have published ISO/IEC 17007:2009, *Conformity assessment – Guidance for drafting normative documents suitable for use for conformity assessment*, which sets out some of the principles and guidance that are reflected in the Directives.

The following information provides an explanation of subclause 6.7, *Aspects of conformity assessment*, and a summary of ISO/IEC 17007. This information is provided to help ISO/TCs, subcommittees (SCs) and working groups (WGs) understand appropriate standards development practice when dealing with conformity assessment aspects.

► *Scope*

This document provides guidance to ISO/TCs and SCs on the drafting of documents specifying conformity assessment arrangements.

► *Related documents and annexes*

1. **In order to comprehend and implement this procedure, the persons responsible should be familiar with the following :**
 - b) ISO/IEC Directives, Part 2, 2011, 6.7, www.iso.org/directives
 - c) ISO/IEC 17000:2004, *Conformity assessment – Vocabulary and general principles*, especially its Annex A
 - d) ISO/IEC 17007:2009, *Conformity assessment – Guidance for drafting normative documents suitable for use for conformity assessment*.

► *Procedure*

2. **When an ISO TC/SC wishes to develop a document specifying arrangements for conformity assessment, the TC/SC must consult with CASCO, as specified in subclause 6.7. The response of CASCO may include one or more of the following steps :**
 - c) The CASCO Secretariat may review drafts prepared by the TC/SC and offer advice on how to comply with subclause 6.7.
 - d) The CASCO Secretariat may ask the Technical Interface Group (TIG) Convenor (or, upon the advice of the Convenor, the TIG members) to assist the TC/SC in the drafting of the conformity assessment aspects of the document.
3. **Subclause 6.7 applies to all International Standards, Guides and Technical Specifications (TS)**

However, it does not apply to an International Workshop Agreement (IWA), a Publicly Available Specification (PAS) or a Technical Report (TR) because they are not based on a consensus development process and therefore should not be employed as stand-alone requirements in internationally accepted conformity assessment practice. However, if an IWA, PAS or TR contains an inappropriate reference to conformity assessment, this should be corrected.

4. The definition of conformity assessment is given in ISO/IEC 17000:2004 :

**► 2.1
conformity assessment**

demonstration that specified requirements relating to a product, process, system, person or body are fulfilled.

Note 1 : The subject field of conformity assessment includes activities defined elsewhere in this International Standard, such as testing, inspection and certification, as well as the accreditation of conformity assessment bodies.

Note 2 : The expression “object of conformity assessment” or “object” is used in this International Standard to encompass any particular material, product, installation, process, system, person or body to which conformity assessment is applied. A service is covered by the definition of a product.

5. The above definition highlights certain key words that should be identified in ISO/TC and SC drafts :

- accreditation
- approval
- auditing
- calibration
- certificate
- certification
- conformity
- conformity assessment bodies
- conformity assessment
- declaration
- evaluation
- inspection
- laboratory management
- qualifications
- registration
- sampling
- surveillance
- testing
- uncertainty
- validation, and
- verification.

6. If any of these words appear in the draft, there may be conformity assessment implications.

► **ISO/IEC Directives, Part 2, subclause 6.7, Aspects of conformity assessment**

[6.7.1] All documents containing requirements for products, processes, services, persons, systems and bodies shall be written in accordance with the “neutrality principle”, such that conformity can be assessed by a manufacturer or supplier (first party), a user or purchaser (second party), or an independent body (third party).

7. The “neutrality principle” means that the content of the standard shall not state a preference for a form or one type of assessment over another. In other words, the standard must be written so it can be applied by any of the following:
- a) a manufacturer or supplier (first party)
 - b) a user or purchaser (second party)
 - c) an independent body (third party).

As noted in ISO/IEC 17000, the identification of first, second and third party activities is linked to the “object of conformity”.

[6.7.1] Such documents shall not include requirements related to conformity assessment other than requirements which are necessary to provide repeatable and reproducible conformity assessment results.

8. Test methods can be drawn up by ISO/TCs and SCs, however they must simply outline the process and thresholds of testing, and must not include provisions on who should undertake the test, or establish the conformity assessment structure that might employ such test methods within it.

[6.7.2] Committees shall not develop documents providing general requirements for conformity assessment schemes and systems. Development of such documents is the responsibility of the ISO policy committee ISO/CASCO in liaison with the IEC Conformity Assessment Board (IEC/CAB).

9. CASCO has developed a series of generic ISO/IEC guides and standards that outline the way in which conformity assessment should be undertaken for product standards, management system standards, peer assessment processes, accreditation and mutual recognition, inspection and the management of laboratories undertaking any form of testing or calibration. This list of existing standards can be found on ISO Online, www.iso.org.

[6.7.2] Committees wishing

- a) to propose the establishment of a conformity assessment scheme or system, or
 - b) to prepare documents specifying conformity assessment systems or schemes or sector-specific operating procedures for use by conformity assessment bodies and others for conformity assessment purposes,
- shall consult with the secretariat of ISO/CASCO or IEC/CAB or both as appropriate, prior to commencement of the work to ensure that any documents developed are in line with the conformity assessment policies and rules approved by ISO/CASCO and IEC/CAB as relevant.*

10. If ISO/TCs and SCs want to continue their work beyond setting specific requirements for products, management systems, personnel, etc., and to elaborate rules for how such standards can be used after they are published in conformity assessment situations, there must be consultation between the relevant ISO/TC or SC Secretariat and the CASCO Secretariat.

[6.7.1] Committees wishing to specify additional conformity assessment requirements for the product, process, service, persons, systems or bodies may only do so in a separate document or in a separate part of the document provided that the separate parts can be applied independently. Prior to commencing work on a separate document or separate part, a committee shall seek the approval of the ISO Committee on conformity assessment (ISO/CASCO) or IEC Standardization Management Board (IEC/SMB) or both as applicable.

11. There needs to be a clear distinction drawn in the work of ISO/TCs and SCs between standards containing specifications for a product, management system, personnel, etc., and documents setting down the operating procedures for a sector-specific conformity assessment scheme.
12. If the ISO/TC or SC wishes to create a separate standard (or standards) describing the operating rules for a conformity assessment system that relates only to first party declarations or third party certification, it can do this in consultation with the CASCO Secretariat, and those sector specific rules must be based on the generic CASCO documents for that form of conformity assessment.
13. In some instances, an ISO/TC or SC can describe the rules for a conformity assessment system in a separate part of the document only if the separate parts can be applied independently. It is recommended to consult TPMs or the CASCO Secretariat prior to taking this option.

Example 1 : *In the area of greenhouse gas emissions, ISO/TC 207, Environmental management, invited CASCO to establish a joint working group to develop ISO 14065:2007, Greenhouse gases – Requirements for greenhouse gas validation and verification bodies for use in accreditation or other forms of recognition.*

Example 2 : *In the area of food safety, ISO/TC 34, Food products, invited CASCO to establish a joint working group to develop ISO/TS 22003:2007, Food safety management systems – Requirements for bodies providing audit and certification of food safety management systems.*

14. CASCO's role is to ensure the sector schemes being developed are based on the generic CASCO documents. This is important for the schemes to gain international acceptance and to make sure they do not end up being technical barriers to trade or services.
15. Note that ISO does not have an operational role in running such conformity assessment systems or schemes. By contrast, the IEC has created and does operate conformity assessment systems through its three conformity assessment schemes related to electrical and electronic products (IECEE Scheme), electrical safety in explosive atmospheres (IECEx scheme) and supply of quality electronic components (IECQ scheme). ISO does not plan to establish similar schemes within its structures.

[6.7.3] When a committee develops a document relating to conformity assessment systems or schemes, or any other document addressing conformity assessment aspects, the document shall make normative reference to the relevant published ISO/IEC documents for conformity assessment procedures, including ISO/IEC 17000 and ISO/IEC 17025. The committee may include verbatim text from the ISO/IEC documents for conformity assessment procedures, but the committee shall not delete, change or interpret them. Committees shall consult with the ISO/CASCO or the IEC/CAB secretary or both, as appropriate, for advice on correctly referencing the ISO/IEC conformity assessment documents. Any request for addition, deletion, change or interpretation shall be submitted to the secretariats of ISO/CASCO and IEC/CAB for decision.

16. Consultation with the CASCO Secretariat is mandatory in such situations. When releasing documents for Draft International Standard (DIS) and Final Draft International Standard (FDIS) ballot, Technical Programme Managers (TPMs) need to be aware of this requirement and should only release documents with conformity assessment implications after evidence of consultation with the CASCO Secretariat has been confirmed.
17. Where a specific intervention with a TC requires additional liaison, this can be achieved by participating in TC meetings until objectives have been reached.

[6.7.1] No document containing requirements for products, processes, services, persons, systems and bodies shall make conformity dependent on a quality management systems standard, i.e. it shall not, for example, make normative reference to ISO 9001.

18. ISO/TCs and SCs shall not include a requirement for a quality management system standard in standards containing specific requirements for products, processes, services, persons, systems and bodies.

► **ISO/IEC 17007:2009, Conformity assessment – Guidance for drafting normative documents suitable for use for conformity assessment**

19. ISO/IEC 17007:2009 contains guidance for drafting normative documents suitable for use for conformity assessment. The clauses that specify the information already contained in subclause 6.7 of the directives are not detailed below to avoid repetition. The additional relevant clauses are :

20. Subclause 5.2 of ISO/IEC 17007 on Drafting specified requirements notes :

- a) specified requirements relating to the characteristics of the object of conformity assessment should be stated in the normative parts of the document (5.2.1)
- b) specified requirements should be written in such a way that they are clear, direct and precise and will result in accurate and uniform interpretation (5.2.2)
- c) normative documents for objects of conformity assessment should focus only on the criteria or performance characteristics of the object (5.2.3)
- d) specified requirements should be written in terms of results or outcomes, together with limiting values and tolerances, where pertinent (5.2.5)
- e) specified requirements should be divided into distinct, consistent and easily identifiable sections to permit their incorporation by reference in codes, regulations and other standards (5.2.7)
- f) 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 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 (5.2.8)
- g) specified requirements should be stated unambiguously using wording that is objective, logical, valid and specific (5.2.9)
- h) specified requirements may contain more than one category, type, class or grade within the same documents or in separate documents if necessary. Where multiple types, classes, grades, etc. are permitted, the document should specify how these are to be identified to the user (5.2.10).

21. Subclause 5.4 of ISO/IEC 17007 on Test methods notes :

- a) test methods should describe clearly how the test is to be performed including the choice and preparation of the samples, use of testing equipment, the data

to be recorded, the acceptance criteria, acceptance and rejection limits and what is acceptable in terms of uncertainty of measurement, accuracy, reproducibility and repeatability (5.4.1)

- b) test methods should be selected bearing in mind their effectiveness, economy and practical application (5.4.3)
- c) non-destructive tests should be chosen whenever they provide the same level of confidence as destructive tests (5.4.4)
- d) the document should specify the sequence of tests when the sequence can influence the results (5.4.5)
- e) if different test methods are permitted from those that are specified, it should be required to maintain a documented correlation of the test results with the specified test methods (5.4.7)
- f) test methods should follow the metrological principles concerning validation, measurement traceability and estimation of uncertainty described in ISO/IEC 17025:2005, Clause 5 (5.4.8)
- g) when specifying test methods, it is good practice to investigate whether the test methods referred to specify requirements related to testing equipment. If this is not the case, such requirements should be considered for inclusion in the normative document. Requirements related to testing equipment should follow the provisions concerning accuracy and calibration described in ISO/IEC 17025:2005, Clause 5 (5.4.9).

22. Committees may develop sector specific conformity assessment systems. The decision to do so should be taken after consideration of a number of factors including societal or economic need, the balance between the advantages and disadvantages, the impact on all affected parties, the parties most effective/efficient to perform the conformity assessment and the existence of conformity assessment systems that could fulfil the need (6.2.1).

23. When committees decide to develop conformity assessment systems :

- a) they must contact and consult with either ISO/CASCO or IEC/CAB Secretaries
- b) they should not be proposing anything contrary to the general requirements for conformity assessment developed by ISO/IEC, i.e. they must develop their systems to fit within the existing conformity assessment model of ISO/IEC

- c) developers of conformity assessment systems should be aware that ISO and IEC have developed International Standards and Guides which can form the basis for a range of conformity assessment systems (6.2.2)
- d) the choice of conformity assessment system should be based on risk assessment. Before deciding whether to develop a conformity assessment system or to use an existing one, a risk assessment should be undertaken (6.3.1).

24. The CASCO Secretariat shall pay attention to the list of reference documents and definitions included in the draft document; and where there is a variation from the definitions in ISO/IEC 17000, then the CASCO Secretariat shall check with the TC Secretary whether this was intentional and, if so, refer the matter to the appropriate Working Group or TIG.

25. The following items may be included in the standard in informative annexes or in the introduction, they should not be normative unless the standard is identified for use in a conformity assessment system, in which case one or more of these items may be normative:

- a) matters related to marks or labels of conformity, certificates of conformity or manufacturers' or suppliers' declarations of conformity
- b) dates for implementation or allocation of responsibilities to various parties making use of the standard
- c) requirements for manufacturing processes, unless it is impossible to adequately specify the product without doing so
- d) requirements for quality control during production.

***For further information on any of the above, please contact
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