ISO

casco

How to develop scheme documents

Guidance for ISO technical committees

Contents

1 Introduction

1.1

The ISO Committee on Conformity Assessment (CASCO) is the committee that develops ISO/IEC International Standards and other documents for conformity assessment bodies (CABs) and accreditation bodies (ABs). Conformity assessment is the demonstration that specified requirements are fulfilled. Conformity assessment activities include testing, inspection, evaluation, examination, auditing, assessment, declaration, certification, accreditation, peer assessment, attestation, verification and validation.

1.2

Conformity assessment schemes, henceforth called "schemes", relate to a group of products, processes, services, persons, systems and bodies (known as "objects of conformity assessment") having sufficiently similar characteristics.

1.3

A scheme can establish, for example:

a) The object of conformity or the type of object
b) The intended benefits and objectives of the scheme
c) The specified requirements against which fulfillment is demonstrated
d) The methodology for various activities to demonstrate the fulfilment of specified requirements
e) Any requirements placed on CABs and any specific applications or interpretations of requirements, where applicable
f) Any specific applications or additions of ISO/IEC 17011, if applicable
g) Any specific application of or additions to ISO/IEC 17020, ISO/IEC 17021-1, ISO/IEC 17024, ISO/IEC 17029, ISO/IEC 17065, if applicable

TERMS AND DEFINITIONS

Conformity assessment scheme

Set of rules and procedures that describes the objects of conformity assessment, identifies the specified requirements for the object of conformity assessment, and provides the methodology for performing conformity assessment

Note 1: a conformity assessment scheme may operate within a conformity assessment system.

Note 2: a conformity assessment scheme may be operated at an international, national, sub-national, regional, or industry-sector level.

Note 3: a scheme can cover part or all of the conformity assessment functions explained in ISO/IEC 17000 Annex A.

Source: DIS ISO/IEC 17000, 2.9

1.4

There are different types of schemes, such as certification schemes (e.g., product personnel, management systems) or inspection, validation and verification schemes. Accreditation schemes are not addressed in this brochure.

1.5

A scheme can be set up as voluntary self-regulation or for commercial marketing purposes, such as to facilitate market entry for a type or class of products or to improve market-perception for a group of suppliers. Regulators can also use schemes to drive compliance with legal requirements.

1.6

Schemes can be developed by:

a) Industry associations and consortia
b) Purchasers
c) Regulators
d) Non-governmental groups
e) CABs
f) National standards-bodies (NSBs) and
g) Other interested parties, e.g. insurance organizations

TERMS AND DEFINITIONS

Accreditation scheme

Rules and processes relating to the accreditation of conformity assessment bodies to which the same requirements apply

Note 1: accreditation scheme requirements include but are not limited to: ISO/IEC 17020, ISO/IEC 17021-1, ISO/IEC 17024, ISO/IEC 17025, ISO 17034, ISO/IEC 17043, ISO/IEC 17065, and ISO 15189.

Source: ISO/IEC 17011, 3.8

TERMS AND DEFINITIONS

Conformity assessment system

Set of common rules and procedures for the management of similar or related conformity assessment schemes

Note 1: a conformity assessment system may be operated at an international, national, sub-national, regional, or industry-sector level.

Source: DIS ISO/IEC 17000, 2.8

1.7

ISO technical committees (ISO/TCs) and subcommittees (SCs) can develop sector-specific schemes in the form of International Standards or other ISO documents, in consultation with CASCO. The applicable policy is given in ISO/IEC Directives, Part 2, 2018, Clause 33.2.

2 Scope

2.1

This document describes guidelines for ISO/TCs and SCs on drafting scheme-documents to ensure a consistent approach to scheme development and compliance with the ISO/IEC Directives and CASCO policy.

2.2

Although this brochure is primarily intended for ISO/TCs and SCs, it can be used by other scheme developers and interested parties, where applicable.

3 What is a scheme document?

3.1

A scheme document describes the content of the scheme, including the practical methodology and details required to perform conformity assessment on the object. It is a document that identifies applicable requirements from other documents for the various components (e.g. specific product technical requirements, requirements for certification, and markings).

3.2

Examples of scheme documents are: sustainable and traceable cocoa (**ISO 34101-4**), steels for reinforcing concrete (**ISO 15835-3**), and implementation of systems and software engineering processes (**ISO/IEC 29110-3-2**).

4 What is a scheme owner?

4.1

Every scheme has a scheme owner. A scheme owner can be a CAB itself, a governmental authority, an industry association or another body. Standards developing organizations (SDOs) can develop scheme documents and can be scheme owners. Although ISO can develop scheme documents, it is not a scheme owner.

4.2

When an ISO/TC develops a scheme document, the ISO/TC is then responsible for maintaining the document. A scheme owner in turn can then use this document to develop a scheme; the scheme owner is then responsible for maintaining the scheme.

4.3

In the absence of an identifiable scheme owner, any CAB wishing to provide evaluation for a scheme takes on the responsibility for the scheme. Where the scheme is not owned by a CAB, it is referred to as an "external scheme owner" (e.g. IATF, TIA, ECEE, IECEx, IECQ, IECRE).

5 Principles

The principles listed below should be included by the ISO/TCs and SCs when developing a scheme document.

Impartiality The operation and implementation of the scheme is impartial, so that it can provide confidence in its outcomes.
Any conflicts of interest are mitigated throughout the operation of the scheme.

Openness Openness means disclosing and giving access to appropriate information, while respecting confidentiality. This includes access to the scheme requirements.

Transparency Schemes are operated and administered in a transparent manner. Transparency means that schemes are developed so that they are accessible, in a non-discriminatory manner, to all interested parties.

Improvement Scheme owners measure their impact and demonstrate progress towards their intended outcomes, and ; regularly integrate learning to improve and to increase the benefits for end-users.

Relevance Schemes are developed in response to market needs. They are designed to be fit-for-purpose and to hence meet those market needs.

Engagement A balanced and representative group of interested parties is engaged in the development and management of the scheme.

Truthfulness Schemes are developed with the aim that the outcomes achieve the intended results and any communication, including claims, is a true and fair reflection of outcomes.

Efficiency All the components of a scheme are structured to deliver measurable, quality outcomes. Schemes contain the necessary requirements to achieve the intended outcomes and do not overburden society.

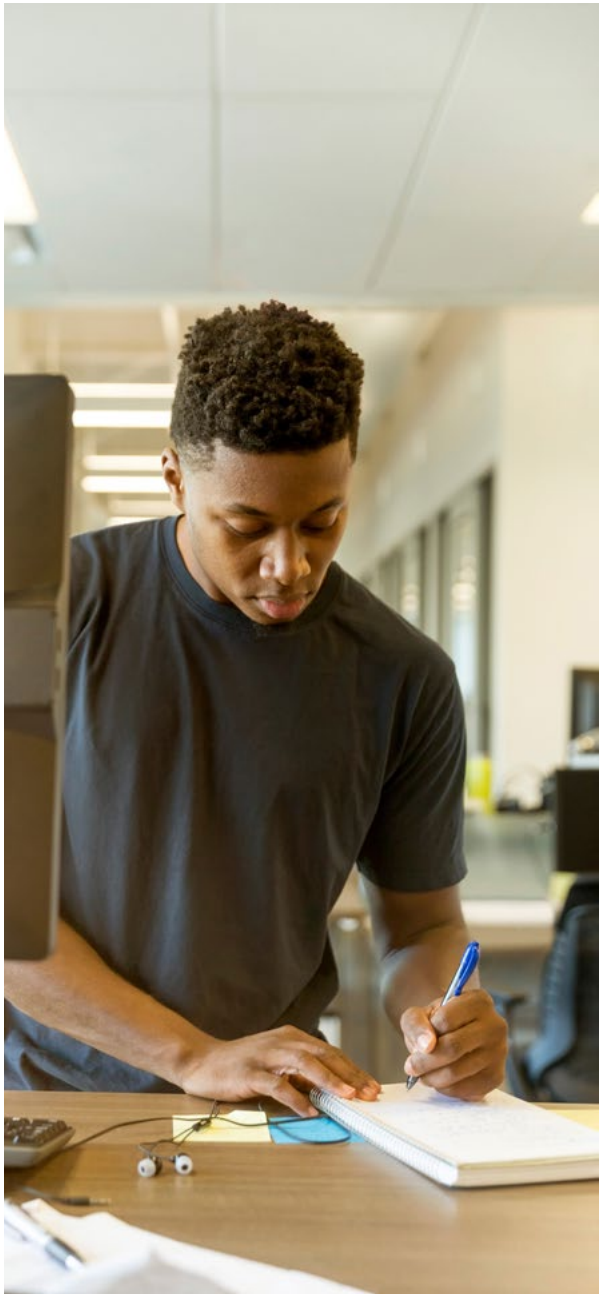
6 Scheme development

6.1
Identifying the need for schemes

6.1.1
Before developing the scheme document, the ISO/TC or SC should consider whether there is a need that a scheme (and conformity assessment performed in accordance with that scheme) will meet. This includes societal or economic needs or demand for demonstrating that an object of conformity assessment fulfills specified requirements. If the need exists, then the ISO/TC or SC must consider:

a) Issues related to implementing the scheme in economies (which may be emerging, transition or developed economies)
b) The objectives of the scheme
c) Any existing schemes that could fulfil the need or demand, or could serve as a model for a new scheme
d) International Standards developed by ISO and IEC, that form the basis for a range of schemes to fulfil societal, government and industry interests

Note: Generic requirements for CABs and ABs are contained in the ISO/IEC 17000 series of standards. Examples of applicable standards are ISO/IEC 17020, ISO/IEC 17021-1, ISO/IEC 17024, ISO/IEC 17029, and ISO/IEC 17065. The full list is available here: **go.iso.org/std-by-casco**.



e) The balance between the potential advantages (e.g. helping to enhance confidence in the objects of conformity assessment, improving quality and facilitating trade) and the potential disadvantages (e.g. adding costs, distorting market access and setting up technical barriers to trade)
f) The impact of the proposed scheme on affected parties
g) External and internal issues relevant to the scheme that can affect its ability to achieve the intended result(s)
h) Obtaining the input of interested parties when developing a scheme; buy-in and the need for the scheme should be established

6.2
Scheme design based on risk of noncompliance with specified requirements

6.2.1
The different components of the scheme should reflect the level of risk of noncompliance with specified requirements. The ISO/TC or SC should ensure the conformity assessment activities are proportional to the risk(s) identified.

6.2.2
Once the risks of noncompliance have been identified, the developer (and user, if applicable) of the scheme will be in a better position to select which conformity assessment activities to use (e.g. testing, inspection, declaration of conformity or certification) and the combination of the different components of the scheme (e.g. first, second or third-party activities).

6.3
Creating schemes

6.3.1
General

All schemes should be designed by persons who are competent in that capacity. Their competence should cover both the technical field of expertise and the adopted conformity assessment procedure.

When identifying the requirements to which fulfillment is to be demonstrated, scheme developers should specifically consider ISO/IEC 17007, *Conformity Assessment – Guidance for drafting normative documents*.

While International Standards are incorporated into many schemes worldwide, **schemes cannot prejudice existing standards and/or requirements, nor aim to replace them**. Developers of a scheme may identify additional requirements to those contained in the relevant, selected International Standards.

For example, requirements placed on CABs by the scheme owner cannot contradict or exclude any of the requirements included in the ISO/IEC 17000 family of standards. Additionally, if a scheme places additional requirements on national accreditation bodies (NABs), they should not contradict or exclude any of the requirements in ISO/IEC 17011.

Note: Examples of International Standards that deal with recognition include ISO/IEC 17011 (accreditation), ISO/IEC 17040 (peer assessment) and ISO/IEC 17043 (proficiency testing).

When designing schemes, the developers should follow the functional approach to conformity assessment, which provides a framework of basic conformity assessment functions and their relationships. The functional approach identifies the following generic functions or elements that are normally present in any scheme:

- **Selection** of the object(s) of conformity assessment, including selecting specified requirements to be assessed and planning information collection and sampling activities
- **Determination**, including the use of one or more determination methods (e.g. test, audit and/or examination) to develop complete information regarding fulfilment of the specified requirements by the object of conformity assessment or its sample
- **Review, decision and attestation**, including the review of evidence from the determination stage, before taking the decision as to whether or not the object of conformity assessment has been reliably demonstrated to fulfil the specified requirements, and a subsequent attestation based on this decision, and any subsequent marking or licensing and their related controls
- **Surveillance** (if needed), including the frequency and extent of surveillance activities and reassessments to ensure the object of conformity assessment continues to fulfil the specified requirements

Note: For the functional approach, see ISO/IEC 17000, Annex A.

6.3.2
Elements of a scheme

Scheme owner responsibility

When specifying the requirements of a scheme, the ISO/TC or SC should address the responsibilities of the scheme owner. These responsibilities can include, for example:

a) Validating the scheme before it is implemented
b) Establishing and changing the scheme, when necessary
c) Ensuring that the scheme continues to meet market needs
d) Adopting a continuous improvement development approach, to ensure the scheme remains relevant
e) Informing the ABs and CABs of any relevant information and developments relating to the scheme

Scope

When specifying the requirements of a scheme, the ISO/TC or SC should define the scope of the scheme so that it informs the interested parties of the nature and limits of the scheme.

The scheme generally comprises:

a) A description of the scope of conformity assessment activities
b) The (group of) products/services/processes/systems/competencies that the scheme covers
c) The aspects of the product/service/process/system/competency to which the statement of conformity relates

Process requirements

When specifying the requirements of a scheme, the ISO/TC or SC should define the process requirements, including the following (where applicable):

a) **Criteria for initial conformity assessment activities** (e.g. requirements for certification or recertification).
b) **Assessment methods for the initial conformity assessment activities**, as well as surveillance activities, e.g. auditing, testing, certification, and inspection.
c) **Criteria for suspending and withdrawing attestation.**
   These criteria should be included in the scheme to ensure that suspensions and withdrawals are done consistently. Examples of conditions under which the attestation can be suspended or withdrawn are:
   - A violation of the code of conduct
   - Failure to comply with the scheme requirements
   - Unsatisfactory surveillance results
   - An inability to continually fulfil the requirements of the scheme.

d) **Criteria for changing the scope or level of attestation.** The scheme should describe the criteria to be fulfilled when the scope or level of attestation is changed.
An example of changing the scope of attestation is a personnel certification body expanding the scope of certification for a food inspector, who was previously certified to only inspect meat, to now include certification to inspect fresh produce.
An example of reducing the level is a personnel certification body reducing the Level of certification of a certified Level 2 non-destructive testing person to a Level 1, due to inactivity associated with Level 2 in accordance with the scheme criteria.

e) **Criteria for scheme review and validation.** To remain relevant, the scheme should be reviewed and validated on an ongoing basis. Scheme owners should regularly update the scheme and document how it is reviewed and validated on an ongoing, systematic basis.

f) **Criteria for sampling.** The scheme should identify any sampling procedures if important for consistency between conformity assessment for an individual object.

g) **Criteria for audit cycle and audit time.** If periodic auditing is part of the methodology of the scheme, then the scheme needs to identify the length of the audit cycle.

h) **Criteria for auditor competence.** If periodic auditing is part of the methodology of the scheme, the scheme may need to identify requirements for auditor competence. Otherwise, each individual CAB will define its own requirements for auditor competence. The scheme will need to decide whether consistency can be achieved without identifying requirements for auditor competence.

i) **Criteria for complaints and appeals to the scheme owner.** The scheme developer should define and make publicly available a procedure for handling complaints and appeals against a client, a certification body or the scheme owner. Appeals and complaints that have not been, or cannot be resolved by the certification body, should be addressed to the scheme owner. The scheme owner should facilitate complaints (from clients or the public) regarding the scheme owner's management systems, the scheme owner's additional requirements for certification, and fraud or potential fraud. An example of an International Standard dealing with complaints is ISO 10002.

Examples of schemes in operation

These include: schemes for sustainable-forest products and/or management systems (**PEFC**); food/feed-safety management systems (**FSSC2200**/**FAMI-QS**); certification schemes for welders (**IIW-IAB**); the **IEC CB-scheme** and other **IEC CA schemes**.

7 Marks

7.1

When specifying the requirements of a scheme, **the ISO/TC or SC should define the specific requirements for marks.** Where the scheme owns and licenses certificates, marks or other statements of conformity, there should be an enforceable agreement to control the use of such marks. Licences can include provisions related to the use of the certificate, mark or other statement of conformity in communications about the certified product/service/personnel, and requirements to be fulfilled when the attestation is no longer valid.

7.2

ISO/IEC 17030 and ISO/IEC Guide 23 contain additional information, when using marks of conformity, including confirmation of the ownership, use, and control of marks.

Useful reading

1) ISO/IEC Directives, Part 2, 2018, 33.2, *Conformity assessment schemes and systems*
2) ISO/IEC 17007, *Conformity assessment – Guidance for drafting normative documents suitable for use for conformity assessment*
3) ISO/IEC 17024, *Conformity assessment – General requirements for bodies operating certification of persons*, Clause 8, *Certification schemes*
4) ISO/IEC 17067, *Conformity assessment – Fundamentals of product certification and guidelines for product certification schemes*
5) ISO and UNIDO. *Building trust –The Conformity Assessment Toolbox*. ISO, 2010

6) ISEAL Alliance. *Principles for Credible and Effective Sustainability Standards Systems : ISEAL Credibility Principles*, 2013
7) International Accreditation Forum. *Policies and Procedures for Expansion of the Scope of the IAF MLA (IAF PL3)*, 2009
8) European Accreditation HHC Committee. *EA Procedure and Criteria for the Evaluation of Conformity Assessment Schemes by EA Accreditation Body Members*. EA-1/22 A-AB, 2014
9) ISO/IEC Guide 60, *Conformity assessment–Code of good practice*

Other cited documents

10) ISO 10002, *Quality management – Customer satisfaction – Guidelines for complaints handling in organizations*
11) ISO/IEC 17000, *Conformity assessment – Vocabulary and general principles*
12) ISO/IEC 17011, *Conformity assessment –Requirements for accreditation bodies accrediting conformity assessment bodies*
13) ISO/IEC 17020, Conformity assessment – *Requirements for the operation of various types of bodies performing inspection*
14) ISO/IEC 17021-1, *Conformity assessment –Requirements for bodies providing audit and certification of management systems* – Part 1*: Requirements*
15) ISO/IEC 17025, *General requirements for the competence of testing and calibration laboratories*
16) ISO/IEC 17029, *Conformity assessment – General principles and requirements for validation and verification bodies*
17) ISO/IEC 17030, *Conformity assessment – General requirements for third-party marks of conformity*
18) ISO/IEC 17034, *General requirements for the competence of reference material producers*
19) ISO/IEC 17040, *Conformity assessment – General requirements for peer assessment of conformity assessment bodies and accreditation bodies*
20) ISO/IEC 17043, *Conformity assessment – General requirements for proficiency testing*
21) ISO/IEC 17065, *Conformity assessment – Requirements for bodies certifying products, processes and services*
22) ISO/IEC Guide 23, *Methods of indicating conformity with standards for third-party certification systems*).
23) ISO 15189, *Medical laboratories – Requirements for quality and competence*
24) ISO 14065, *Greenhouse gases – Requirements for greenhouse gas validation and verification bodies for use in accreditation or other forms of recognition*

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ISO (International Organization for Standardization) is an independent, non-governmental international organization with a membership of 164* national standards bodies. Through its members, it brings together experts to share knowledge and develop voluntary, consensus-based, market-relevant International Standards that support innovation and provide solutions to global challenges.

ISO has published more than 22 500* International Standards and related documents covering almost every industry, from technology to food safety, to agriculture and healthcare.

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