

Conformity assessment and ISO CASCO for standards writers



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What is conformity assessment

- Is all the **activities** we complete **to determine** if a product or service **meets specific requirements** (usually contained in a standard)

definition

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



Conformity assessment activities

Testing

determination of one or more characteristics of an object of conformity assessment

Certification

third party assurance that: product (services), process, personnel, organization or management system conforms to specific requirements

Inspection

Examination of a product design, product, process or installation and determination of its conformity with specific requirements or, on the basis of professional judgement, with general requirements.

Supplier's declaration of conformity

first-party attestation

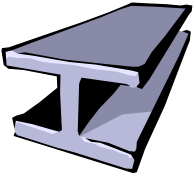

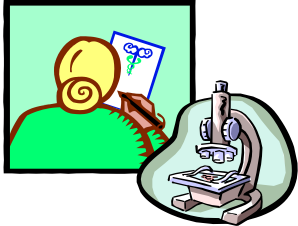


Accreditation

third-party attestation related to a conformity assessment body conveying formal demonstration of its competence

Mutual recognition & Peer assessment

Arrangement whereby more than two parties recognize or accept one another's conformity assessment results
Assessment of a body against specified requirements by representatives of other bodies in, or candidates for, an agreement

Conformity assessment claims

<u>Object</u>	<u>Test done by:</u>	<u>Attestation type</u>
 + <u>Requirements</u> 	 1st party (the manufacturer, service provider)	SDoC (Self Declaration of Conformity)
	 2nd party (the purchaser, the client)	Contract
	 3rd party - independent (certification body, laboratory, inspection body...)	Certificate

3rd party bodies can be accredited.
 Accreditation bodies are assessed by their peers



Conformity assessment in action

How do you determine if a product meets a technical requirement ?

Action	Conformity assessment activity
Design the TV	Test design in laboratory
TV set meets the technical specification or standard	Test TV samples from production line
Manufacture the TV	Quality management system (QMS) in place in the factory (certification of QMS)
TV sets in storage	Inspect samples of the TV sets prior to distribution to make sure no damage
Distribute the TV to shops	Take samples from the shop to ensure it meets specification (Market Surveillance) the regulator may do this





Certificate

SQS herewith certifies that the company named below has a management system which meets the requirements of the normative bases specified below.



**ISO Central Secretariat
(International Organization
for Standardization)
CH-1211 Genève 20**

Certified area

The entire ISO Central Secretariat

Field of activity

**Coordination, production and diffusion of
International Standards and support services**

Normative bases

**ISO 9001:2008 Quality Management System
ISO 14001:2004 Environmental Management System**

Swiss Association for Quality and
Management Systems SQS
Bernstrasse 103, CH-3052 Zollikofen
Issue date: May 2, 2011

This SQS Certificate is valid up to
and including May 1, 2014
Scope numbers 8, 35
Registration number 12311

V. Edelmann



What is ISO/CASCO

- It is the ISO committee that works on issues relating to conformity assessment
- It publishes standards for the operation of conformity assessment bodies and develops policies related to conformity assessment
- 126 members of ISO participate in CASCO and 22 external organizations are in liaison

CASCO structure

Policy groups : work on *conformity assessment policies*

Coordinates the technical work of Casco and assists the Casco Chair in identifying strategic conformity assessment issues

Chairman's policy and coordination group (CPC)

Liaises with other ISO technical committees (TCS)

Technical interface group (TIG)

Provides a forum for industry sectors and regulators to interact with CASCO

Strategic Alliance and Regulatory Group (STAR)

Technical working group : development of *conformity assessment standards*

Standards' development work is carried out by working groups made up of experts put forward by the ISO Member Bodies



Working Group (WG)

CASCO

ISO / CASCO
On conformity assessment



ISO/CASCO Toolbox

The **ISO/CASCO Toolbox** is the set of conformity assessment standard developed by **ISO CASCO for the operation of**

**conformity
assessment bodies**
(laboratories,
certification bodies and
inspection bodies)

accreditation bodies

for **peer evaluation** and
other associated
activities

ISO/CASCO has over 35 published standards and guides



TOOLBOX

Terms and definitions ISO/IEC 17000

Requirements for accreditation bodies – ISO/IEC 17011

Requirements for
**Testing/
calibration**
Testing and
calibration
laboratories
ISO/IEC 17025
Proficiency
testing
ISO/IEC 17043

Requirements for
**inspection
bodies**

ISO/IEC 17020

Requirements for
certification bodies

Management
systems

ISO/IEC 17021
and related parts
ISO/IEC 17023

Persons

ISO/IEC 17024

Products

ISO/IEC 17065
ISO/IEC 17067
ISO/IEC TR 17026

Conformity
assessments
of suppliers
ISO/IEC 17050-1
ISO/IEC 17050-2

Peer assessment ISO/IEC 17040

Mutual recognition
ISO/IEC Guide 68

ISO/IEC 17022 Audit reports



Conformity assessment bodies and CASCO standards

Certification bodies

use **ISO/IEC 17021** –
requirements for
certification of
Management
Systems, **ISO/IEC
17065** for products
ISO/IEC 17024 for
persons

Inspection bodies

use **ISO/IEC 17020**
– requirements for
inspection of
various items etc.

Laboratories use

ISO/IEC 17025 –
requirements for
competence of labs



ISO/IEC Directives Part 2

Aspects of conformity assessment

Clause 6.7

Do's and Don'ts



ISO/IEC Directives, Part 2

Directives ISO/CEI, Partie 2

Rules for the structure and drafting of International Standards

*Règles de structure et de
rédaction des Normes
internationales*

*Conformity
assessment
for standards
writers*

Do's and don'ts



Rules & principles

1. Sector specific CA requirements

- ISO/CASCO is the only committee entitled to develop **generic** conformity assessment standards (6.7.2 §1).
- ISO/TCs and SCs can develop **sector specific** conformity assessment requirements, provided (6.7.1 §3). :
 - they are separated from technical requirements in a distinct document or a part that can be applied independently;
 - they are developed in consultation with ISO/CASCO.

Rules & principles

2. Neutrality principle (6.7.1 §1)

The standard shall not state a preference for one form/type of assessment over another. The standard must be written so it can be applied by any of the following:

- a manufacturer or supplier (first party)
- a user or purchaser (second party)
- an independent body (third party - certification)

Rules & principles

3. Quality management systems requirements

Standards containing specific requirements for products, processes, services, systems and bodies shall **not make conformity dependent on a quality management systems standard (6.7.1 §5)**

Example – ISO/FDIS 6935-2:2015

Breach of the neutrality principle

Certification and inspection of reinforcement shall be performed in accordance with a certification scheme monitored by an external body

- *They are mandating 3rd party therefore this statement is not allowed. The TC has to delete or re-word in a manner that does not mandate certification.*

Example

No separation of technical & CA requirements (6.7.1 §3)

ISO 15835-1:2009, Steels for the reinforcement of concrete – Reinforcement couplers for mechanical splices of bars - Part 1 Requirements

1 Scope

This part of ISO 15835 specifies **requirements for couplers** to be used for mechanical splices in reinforced concrete structures under predominantly static loads and additional **requirements for couplers** to be used in structures subject to high cycle elastic fatigue loading and/or to low cycle elastic-plastic reverse loading.

This part of ISO 15835 also **provides directions for the evaluation of conformity of couplers**.

Example – 16745

This document specifies CA and product requirements in the same document

7.2 Procedure for review and independent verification

7.2.2 Verification of the carbon metric declaration

The independent verification procedure shall, as a minimum, be appropriate to determine whether the carbon declaration is in conformance with the relevant requirements of this International Standard.

The verification procedure shall be transparent. The independent verifier shall generate a report documenting the verification process, while adhering to obligations covering rules for data confidentiality

The verification procedure shall assess whether the information given in the carbon metric declaration accurately reflects the information in the documents on which the declaration is based. The verification procedure shall also determine if this information is valid.

- *They are describing conformity assessment requirements in the same document; this clause tells how to perform the verification: this is specifying how to assess that the requirements are met. This is allowed only in a separate part or in a separate document.*



Example

Quality management systems requirements (6.7.1 §3): This document requires use of a specific QMS

ISO 177121:2009, Freight containers — Mechanical seals

6 Evidence of tampering

6.1 General

This clause also requires that, for high-security seals desired to be Clause 6-compliant, a manufacturer can demonstrate the tamper-evident properties and related documentation to the auditors of an accredited process review organization; **this shall occur as part of the seal manufacturer's ISO 9001, Quality Operational Procedures (QOP) in accordance with Normative Annex A.**



Key words

If any of these words appear in your draft, there may be conformity assessment implications:

- accreditation
- approval
- auditing
- calibration
- certificate
- certification
- conformity
- conformity assessment bodies
- conformity assessment
- declaration
- evaluation
- validation/verification



What you need to do....

**in case you face an issue with
conformity assessment....**

Contact CASCO Secretariat casco@iso.org

Conformity assessment on [iso.org](https://www.iso.org)