Introduction
to
conformity assessment
and
ISO/CASCO

Content

➢ **What is conformity assessment?**

➢ **What is ISO/CASCO?**

➢ **What is the ISO/CASCO Toolbox?**

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

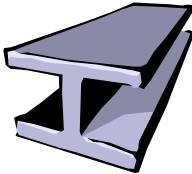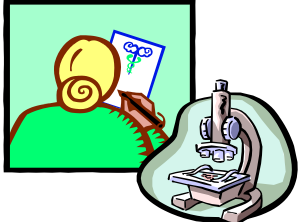| **Testing** | determination of one or more characteristics of an object of conformity assessment |
Certification	third party assurance that: product (services), process, personnel, organization or management system conforms to specific requirements
Inspection	Examination of a product design, product, 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

Object	Test done by:	Attestation type
	1st party (the manufacturer, service provider)	**SDoC** (Self Declaration of Conformity)
+ **Requirements**	**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

ACCREDITATION

What is ISO/CASCO?

➢ 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 (mostly together with IEC)

➢ 126 members of ISO participate in CASCO and 22 external organizations are in liaison

CASCO structure

Policy groups :
work on *conformity assessment policies*

Technical working group :
development of *conformity assessment standards*

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

Chairman's policy and coordination group (CPC)

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

Liaises with other ISO technical commitees (TCS)

Technical interface group (TIG)

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

Strategic Alliance and Regulatory Group (STAR)

WG WG WG WG WG WG

Working Group (WG)

CASCO

ISO / CASCO
On conformity assesment

ISO/CASCO Toolbox

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

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

accreditation bodies

for **peer evaluation** and other associated activities

ISO/CASCO has <u>over 35 published standards and guides</u>

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	**Persons**	**Products**
ISO/IEC 17021 and related parts ISO/IEC 17023	**ISO/IEC 17024**	**ISO/IEC 17065 ISO/IEC 17067 ISO/IEC TR 17026**

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

Peer assesment 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

Some CASCO standards

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An short overview

Contents

- **ISO/IEC 17025** *Testing and calibration laboratories*

- **ISO/IEC 17020** *Inspection bodies*

- **ISO/IEC 17065** *Product certification (for* products, processes and services)

- **ISO/IEC 17021** *Management system certification*

- **ISO/IEC 17024** *Personnel certification*

- **ISO/IEC 17000** *Vocabulary and general principles*

- **CASCO toolbox** (over 35 standards and guides)

ISO/IEC 17025: Requirements
Testing and calibration laboratories

INTERNATIONAL STANDARD

ISO/IEC 17025

Second edition
2005-05-15

General requirements for the competence of testing and calibration laboratories

Exigences générales concernant la compétence des laboratoires d'étalonnages et d'essais

Reference number
ISO/IEC 17025:2005(E)

© ISO 2005

Basic requirements that a laboratory should comply with to demonstrate it is competent to perform specified tests and calibrations:

- **Management system requirements** are common to all laboratories irrespective of the technical work they perform.

- **Technical requirements** have to be applied according to the specific field of work and require the laboratory to apply additional requirements specific to the field.

- This aspect of **additional requirements** is recognized in Annex B (informative) and contains "Guidelines for establishing applications for specific fields".
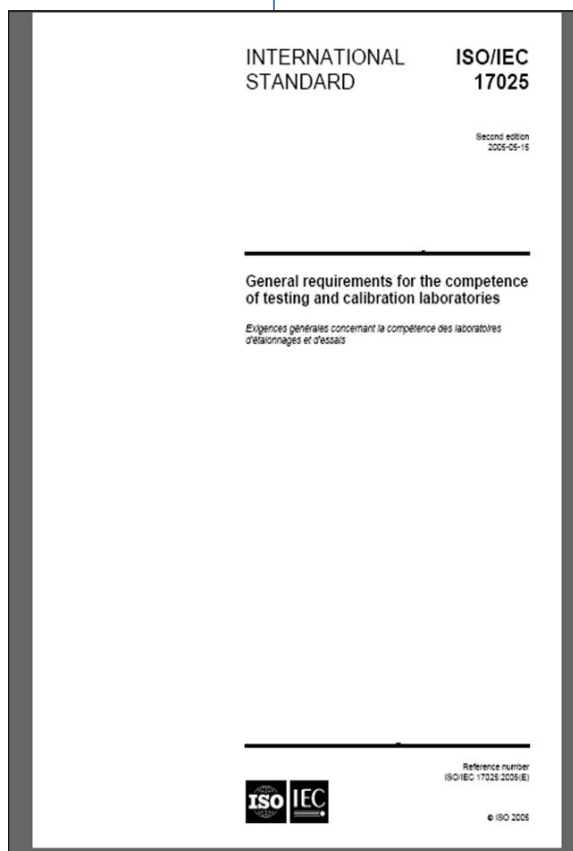
ISO/IEC 17025: Requirements
Testing and calibration laboratories

The **scope** for which the laboratory does testing needs to be **clearly specified** and stated.

- Usually the scope is supported by **listing the specific test methods** the laboratory uses in case of testing and specific measurements and associated uncertainty in the case of calibration laboratories.
- This detailed definition of the scope allows the laboratory **to identify competent people** to do the work within their scope of activity.
- It also allows for the customers of the laboratory to identify a **suitable laboratory** for their purposes and have confidence in the tests and measurements made by the laboratory.
- When a laboratory is accredited to ISO/IEC 17025 its compliance is not only assessed to the generic standard ISO/IEC 17025 but also to any field specific requirements and to the laboratories' competence to perform the specific test methods.

ISO/IEC 17020: Requirements Inspection bodies

INTERNATIONAL STANDARD

ISO/IEC 17020

Second edition
2012-03-01

Conformity assessment — Requirements for the operation of various types of bodies performing inspection

Évaluation de la conformité — Exigences pour le fonctionnement de différents types d'organismes procédant à l'inspection

Reference number
ISO/IEC 17020:2012(E)

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Inspection :

• Examination of a product design, product, process or installation and determination of its conformity with specific requirements or, on the basis of professional judgment, with general requirements (e.g. inspection of fire extinguishers, lifts, restaurants, road vehicles (annually) etc).

• Provides **objective evidence** that an inspected item meets the specified needs of the customer (purchaser, manufacturer regulator).

• Heavily relies on **professional judgment** of the inspector whose competence is crucial to the success of this activity.

ISO/IEC 17020: Requirements Inspection bodies

Inspection can be used as a risk management tool:

- Many plants and installations use inspection to ensure that **equipment and plant facilities continue to operate safely and correctly**.
- Inspections are usually **performed on site** and allow for the clients to be informed immediately.
- Inspections of **items before shipping or confirmation with the order can prevent shipment of the wrong materials**, this is very important in building material shipments.

Requirements Certification bodies

3 main types of certification activities:

• **Product certification,** ISO/IEC 17065:2012 (products, processes and services certified)

• **Management system certification,** ISO/IEC 17021-1:2015 (ISO 9001 certified company)

• **Personnel certification,** ISO/IEC 17024:2012 (Welder/Food safety certified)

Requirements for product, process and service certification (ISO/IEC 17065)

The overall aim of certifying products, processes or services is to give confidence to all interested parties that a product, process or service fulfills specified requirements.

The value of certification is the degree of confidence and trust that is established by an impartial and competent demonstration of fulfillment of specified requirements by a third-party.

Product, process and service certification (ISO/IEC 17065)

4 basic drivers for product, process and service certification:

- provide consumers (users) of products with sufficient information to allow them to **make informed decisions** on products and services;
- assist the suppliers of certified products to **achieve market acceptance.** If the product has a recognizable mark on it consumers may be more willing to make the purchase;
- product certification plays a role in **regulated products** (subject to technical regulations);
- **assists manufactures** in selecting the components for their own products;
- retailers have **confidence** in the products they are selling.

Product, process and service certification (ISO/IEC 17065)

Product certification may consist of:
- initial product testing with assessment of the quality management system;
- followed up by testing of samples from factory and/or the open market;
- initial testing and surveillance testing;
- type testing : testing of a sample product.

The type of product certification scheme chosen:
- will depend on the level of risk to the consumer as well as other factors;
- for a very low risk product you may have a once-off type test;
- for a high risk product you may have a scheme which has type testing, requires an ISO 9001 management system in place with regular product testing from the factory and also products taken from the outlets for testing.

ISO/IEC 17065 Conformity assessment - *Requirements for bodies certifying products, processes and services*
- can be used in combination with a number of related product standards and guides to demonstrate that a product complies with specified criteria.

ISO/IEC 17065: *Requirements for bodies certifying products, processes and services*

- The requirements of ISO/IEC 17065 allow PRODUCT certification bodies to demonstrate that they are competent, impartial and reliable;

- There are hundreds of marks of conformity for products in the market place;

- This is the most visible form of certification.
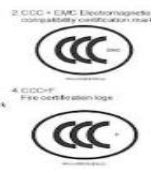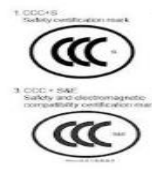
Requirements for management systems certification (ISO/IEC 17021-1)
Understanding the basics

What is a "management system"?

management system

*set of interrelated or interacting elements of an **organization** to establish **policies** and **objectives** and **processes** to achieve those objectives*

Definition from: ISO/IEC Directives, ISO Supplement, Annex SL, Appendix 2, cl. 3.04 (2014)

Management system certification bodies

The management system implemented within an organization is certified as meeting specific requirements.

Best know of these **is ISO 9001 certified** companies (over 1 million worldwide).

Other examples are **ISO 14001** (environmental management), **ISO 50001** energy efficiency, **ISO 27001** information security management systems and food safety management systems, **ISO 22000**.

Management system standards have been developed by other organizations.

Retailers have developed their own standards in many cases (**BRC Global Gap farm to Fork** etc).

However they **all use the ISO/CASCO Toolbox** to **determine conf**ormity and the bodies they use have to comply with the relevant CASCO standards when determining conformity with the standards.

Drivers for management system certification

Benefits of management system certification:

Provides independent assurance (and demonstration) an organization has implemented the system.	Certification not only demonstrates to the customers but also internally, it can provide motivation and satisfaction to staff that the organization operates in accordance with international standards.	Benefits top management and gives it confidence in the operation of the organization and its ability to meet customer expectations consistently.	Provides the company with marketing opportunities to potential customers. Provides access to international (regulated) markets where certification is an entry requirement.

Management systems certification process

A certification body that certifies an organization for :

- *Quality management systems* (QMS), ISO 9001
- *Environmental management systems (EMS), ISO 14001*
- *Food safety management systems (FSMS), ISO/TS 22000*
- *Other management systems ,* e.g. ISO 27001, etc.

SHOULD IMPLEMENT:
ISO/IEC 17021:2011, *Conformity assessment - Requirements for bodies providing audit and certification of management systems*

Requirement for bodies providing certification of persons (ISO/IEC 17024)

ISO/IEC 17024:2012 *Conformity assessment - General requirements for bodies operating certification of persons*

- Certification of persons has the objective of **recognizing the competence** of individuals to perform specific tasks.
- It recognizes that competence is not solely related to qualification but is based on the an individuals ability to **apply knowledge and skills to achieve intended results**.
- A person can be well qualified but be incompetent. There are good doctors and not so good doctors and bad doctors.
- Competence is not based on qualification alone.

Examples of personnel certification schemes (ISO/IEC 17024)

Auditors
- ISO 9001 (ISO/IEC 17021-3) Management system auditors
- ISO 22003 Food safety management system auditors
- ISO 14001 (ISO/IEC 17021-2) Environmental management system auditors

Various
- Welding operators ISO 9606
- Crane drivers
- Lift inspectors
- Pressure vessel inspectors (various)
- Scuba driving instructors

Food
- Food safety inspectors
- Health inspectors

Drivers and benefits of personnel certification (ISO/IEC 17024)

Provides a consistent framework and set of requirements to **allow recognition of competence**. Facilitates employment of certified persons

Allows for **mobility of certified persons**

It provides employers with **confidence in their certified employees** and clearly identifies the competencies required for different categories of professions and jobs.

It allows for competencies to be up dated and maintained as technologies change. This is of great benefit to the professions and employers.

Vocabulary & general principles (ISO/IEC 17000)

Purpose of ISO/IEC 17000:

- definition of the main terms used in conformity assessment;
- description of the basic principles applied in conformity assessment (see Annex A5):

    - functional approach
    - selection
    - determination
    - review and attestation
    - need for surveillance

Useful references

CASCO homepage:

http://www.iso.org/iso/home/about/conformity-assessment.htm

Resources for conformity assessment:

http://www.iso.org/iso/home/about/conformity-assessment/conformity-assessment_resources.htm

Conformity assessment tools for regulators:

http://www.iso.org/sites/cascoregulators/index.html

Building trust:

http://www.iso.org/iso/casco_building-trust.pdf