

## Session 7 – Conformity assessment standards



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# Introduction and overview of the CASCO toolbox

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## Introduction

The following section is intended to be an introduction to the core standards of the ISO/IEC 17000 series and not to cover them in detail.

More information can be found on [iso.org](https://www.iso.org) where some presentations are available on published standards that go in more details.



# CASCO toolbox standards

	Management Systems	Product	Process	Service	People	Inspection	Claims	Laboratory
Core conformity assessment standards	ISO/IEC 17021-1 and parts	ISO/IEC 17065			ISO/IEC 17024	ISO/IEC 17020	ISO/IEC 17029	ISO/IEC 17025
	Audit duration ISO/IEC TS 17023	Fundamentals for products ISO/IEC 17067	Certification scheme for process ISO/IEC 17032	Example of certification schemes ISO/IEC TR 17028	Vocabulary for personnel ISO/IEC 17027			Proficiency testing ISO/IEC 17043
		Tangible products ISO/IEC TR 17026						Reference material producers ISO 17034
Suppliers declaration	ISO/IEC 17050 parts 1 and 2							
Use of marks	ISO/IEC Guide 23 and ISO Guide 27							
Use of marks by third parties	ISO/IEC 17030							
Good CA practices	ISO/IEC Guide 60							
Accreditation standard	ISO/IEC 17011							
Peer assessment	ISO/IEC 17040 and ISO/IEC Guide 68							
Terms and definitions	ISO/IEC 17000							
Guide for drafting normative documents	ISO/IEC 17007							

Note: valid in 2019



## Commonalities

# CASCO Common structure

- 1 Scope
- 2 Normative references
- 3 Terms and definitions
- 4 Principles
- 5 General requirements
- 6 Structural requirements
- 7 Resource requirements
- 8 Information requirements
- 9 Process requirements
- 10 Management system requirements for CBs



## Common elements

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Impartiality

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Confidentiality

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Appeals

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Complaints

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Competence

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Management systems



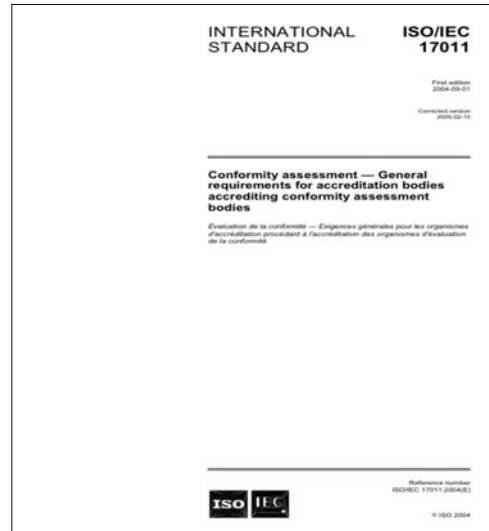
## Principles

- Impartiality
- Competence
- Responsibility
- Openness
- Confidentiality
- Responsiveness to complaints
- Risk-based approach



**ISO/IEC 17011**

## **ISO/IEC 17011: Conformity Assessment – Requirements for accreditation bodies accrediting conformity assessment bodies**



## **Purpose of ISO/IEC 17011**

Introduction – “. . . specifies requirements for accreditation bodies accrediting conformity assessment bodies.”

“. . . activities covered by accreditation include testing, calibration, inspection, certification of management systems, persons, products, processes and services, provision of proficiency testing, production of reference materials, validation and verification.”

“This document can be used to support peer evaluation mechanisms which have been created at regional and international levels and through which confidence is provided that accreditation bodies are operating in according with this document.”



## Key Issues and Major Edits

The main changes compared to the previous edition are as follows:

- Alignment with the common structure for the 17000 series standards and incorporation of CASCO Common Elements in clauses on impartiality, confidentiality, complaints and appeal and management system;
- Recognition of proficiency testing as an activity covered by accreditation;
- Addition of new definitions for “accreditation scheme” (see 3.8), “flexible scope of accreditation” (see 3.7), “remote assessment” (see 3.26) and “assessment programme” (see 3.27);
- Introduction of the concept of risk and risk-based assessments;
- Incorporation of the IAF and ILAC documents where appropriate;
- Incorporation of competence criteria in the document, including an informative annex on knowledge and skills; and
- Did not include a principles section in the new version.



# ISO/IEC 17021-1

# ISO/IEC 17021-1

## Conformity Assessment – Requirements for bodies providing audit and certification of management systems



## Purpose of ISO/IEC 17021-1

To set out the requirements for certification bodies performing certification of management systems.

Accompanied by a set of principles on which the requirements are based to provide credible and reliable certification.

Requirements cover competence of persons involved in certification, the legal status, resources and structure of the certification body, the certification process, etc.





# Purpose of ISO/IEC 17021-1

Requirements are generic and do not address specifically the detailed requirements for a certification body as it implements the process and resource requirements for a specific standard e.g. an Environmental Management system or a Business Continuity Management system.

Additional requirements relating to certification of specific management system standards can be found in related standards all based on ISO/IEC 17021-1



Some related  
requirements for  
certification  
bodies  
performing  
certification to  
different  
management  
system (MS)  
standards

- ISO/IEC 17021-2
- ISO/IEC 17021-3
- ISO/IEC TS 17021-4
- ISO/IEC TS 17021-5
- ISO/IEC TS 17021-6
- ISO/IEC TS 17021-7
- ISO/IEC TS 17021-8
- ISO/IEC TS 17021-9
- ISO/IEC TS 17021-10 MS
- ISO/IEC TS 17021-11
- ISO TS 22003 MS
- ISO 28003 Security
- ISO 50003
- ISO/IEC 27006 Security

Competence for Environmental MS  
Competence for Quality MS  
Competence for Event Sustainability MS  
Competence for Asset MS  
Competence for Business Continuity MS  
Competence for Road Traffic Safety MS  
Competence for Sustainable Development in Communities MS  
Competence for Anti-bribery MS  
Competence for Occupational Health & Safety  
  
Competence for Facility MS  
Requirements for certification of Food Safety  
  
Requirements for certification of Supply Chain MS  
Requirements for certification of Energy MS  
Requirements for certification of Information MS



## 1. Scope

This part of ISO/IEC 17021 contains **principles** and **requirements** for the **competence, consistency** and **impartiality** of bodies providing audit and certification of all types of management systems.



## 3. Definitions

- **3.10 technical area**

area characterized by commonalities of processes relevant to a specific type of management system and its intended results

- **3.17 duration of management system certification audits**

part of audit time (3.16) spent conducting audit activities from the opening meeting to the closing meeting, inclusive



## 9. Process requirements

### 9.5 Certification decision

- Decision makers are **competent** and **different** to those who carried out the audit
- Shall **not contract** out the decision must be under organizational control of the CB (legally enforceable agreement if not employed)
- Defines what is considered organizational control
- CB shall conduct a review prior to making a decision - MNC's cleared MNC's plan
- Defines the information needed to make a decision



## 9. Process requirements

### 9.6 Maintaining certification

The CB can maintain certification based on positive recommendation **without further independent review and decision provided**

- an independent review is initiated when **there is a MNC or other situation** and
- competent personnel of the CB monitor its surveillance activities including auditors to ensure the certification activity is operating effectively



## 10. Management system requirements

### 10.1 Options

The certification body shall implement a management system in accordance with either:

- **Option A:** General management system requirements (see 10.2);
- or
- **Option B:** ISO 9001 (see 10.3).



# ISO/IEC 17020



## ISO/IEC 17020

Conformity Assessment –  
Requirements for the  
operation of various types of  
bodies performing  
inspection



## Purpose of ISO/IEC 17020

- To provide confidence in the bodies performing inspection
- Contains requirements for the competence, impartiality and consistent operation of inspection bodies.
- Specifies how an Inspection body should perform assessments with the objective of providing information about the conformity of inspected items with regulations, standards, specifications, inspection schemes or contracts.
- Specifies the competence of inspectors as many types of inspection involve professional judgement to determine acceptability against general requirements.
- Categorizes inspection bodies as type A, B or C which is a measure of their independence



# Purpose of ISO/IEC 17020

- Inspection can be an activity embedded in a larger process. For example, inspection can be used as a surveillance activity in a product certification scheme.
- Demonstrable independence of an inspection body can strengthen the confidence of the inspection body's clients with respect to the body's ability to carry out inspection work with impartiality.
- Inspection covers activities such as examination of materials, products, installations, plants, processes, work procedures or services.
- Unlike others forms of conformity assessment the performing the assessment (the inspector) makes the decision on conformity.



## ISO/IEC 17024

## ISO/IEC 17024

Conformity Assessment –  
General requirements for  
bodies operating  
certification of persons



## Purpose of ISO/IEC 17024

- Standard for certification of persons.
- Official Title – General requirements for bodies operating certification of persons
- Introduction – “. . . Has been drawn up with the objective of achieving and promoting a globally accepted benchmark for organizations operating certification of persons”
- Introduction – “. . . This international standard should be the basis for the recognition of the certification bodies and their certification schemes, in order to facilitate their acceptance at the national and international levels.”

# Purpose of ISO/IEC 17024

- Achieve and promote a globally accepted benchmark for organizations managing the certification of persons
- Create confidence in certification through globally accepted processes of assessment, subsequent surveillance and periodic re-assessment
- Harmonize a system to develop and maintain certification programs
- Establish an environment for mutual recognition and global exchange of personnel



## Some comments on ISO/IEC 17024

- Unique in that it contains requirements for schemes (clause 8)
- Certification of persons rather than personnel certifications.
- Contains requirements around the provision of training as this is considered a threat to impartiality. Independence of training activities from certification
- Distinguishes between examiners, exam administrators and invigilators
- Contains requirements on security and the need to have policies on this.
- Surveillance is if applicable
- Scheme reviewed and validated on an on-going basis
- Principles in the annex





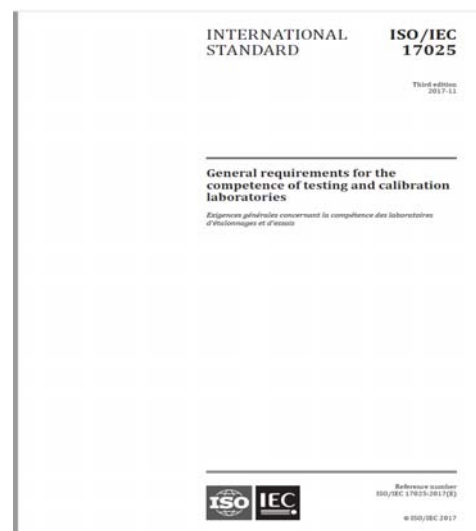
# ISO/IEC 17025

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## ISO/IEC 17025

General requirements for  
the competence of testing  
and calibration  
laboratories



# Purpose of ISO/IEC 17025

Provide framework for laboratories to demonstrate competence and impartiality

Provide basis to harmonize a system to develop and maintain confidence in the competence of laboratories and consistent generation of reliable results

Establish an environment for mutual recognition and global exchange of results from laboratories



# Purpose of ISO/IEC 17025

Scope: ....'specifies the general requirements for the **competence, impartiality and consistent operation of laboratories.**' Also addresses use of the standard: ....'Laboratory customers, regulatory authorities, organizations and schemes using peer-assessment, accreditation bodies, and others use this document in confirming or recognizing the competence of laboratories.'

**Definition for laboratory:**....body that performs one or more of the following activities:

- testing;
- calibration;
- sampling, associated with subsequent testing or calibration



## Other Main changes

From the Foreword of ISO/IEC 17025:2017:

- the risk-based thinking applied in this edition has enabled some reduction in prescriptive requirements and their replacement by performance-based requirements;
- there is greater flexibility than in the previous edition in the requirements for processes, procedures, documented information and organizational responsibilities;



## Other Main changes (2)

- Defined range of activities for laboratory
  - Excludes externally provided laboratory activities on an ongoing basis
- Emphasis on “Impartiality” vs. “Independence”
- Process orientation
- Information Technology: Risks, data integrity, confidentiality, validation of software, considering electronic documents
- Metrological traceability
- Decision Rules for statements of conformity (pass/fail)
- Management system options A or B



# ISO/IEC 17029

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## ISO/IEC 17029 Conformity Assessment – General principles and requirements for validation and verification bodies



# Purpose of ISO/IEC 17029

Standard for validation and verification bodies – covering 1<sup>st</sup>, 2<sup>nd</sup> and 3<sup>rd</sup> party assessment

Validation and verification as conformity assessment are understood to be a confirmation of reliability of information contained in claims. Other terms in use for the object of assessment by validation/verification are statement, declaration, assertion, prediction or report

Validation is applied to claims regarding an intended use or projected effect (confirmation of plausibility), while verification is applied to claims regarding events that have already occurred or results that have already been obtained (confirmation of truthfulness)..."



# Purpose of ISO/IEC 17029

A programme for validation/verification is needed.

The document specifies definitions, principles, rules, processes, and requirements for validation/verification process steps and competence of validators/verifiers.

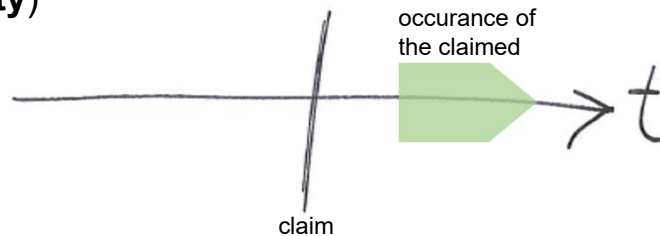
Programmes can be legal frameworks, international, regional or national standards, global initiatives, sector applications as well as individual agreements with clients of the validation/verification body'



# Validation/verification as conformity assessment

## Differentiation from each other

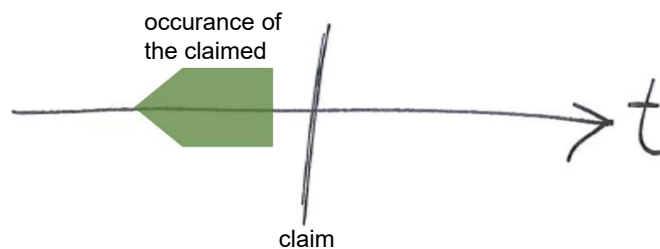
- **validation** – confirmation of a claim through the provision of objective evidence, that the requirements for a specific intended future use or application have been fulfilled (confirmation of **plausibility**)



# Validation/verification as conformity assessment

## Differentiation from each other

- **verification** – confirmation of a claim through the provision of objective evidence, that specified requirements have been fulfilled (confirmation of **truthfulness**)



## Some statements on ISO/IEC 17029

- Follows the functional approach
- Decision on specified requirements issued as a validation/verification statement
- Excluded are statements of conformity as a result of:
  - another conformity assessment activity (SDoC)
  - V&V steps which are essential parts of a defined process of another assessment activity
- The **object** of conformity is a **claim** (statement, declaration report etc.)
- Validation and verification is one period in time
- It has the 4 eyes principle



**ISO/IEC 17065**

## ISO/IEC 17065

Conformity Assessment –  
Requirements for bodies  
certifying products,  
processes and services



## Purpose of ISO/IEC 17065

Standard for Products, Processes, Services Certification

Introduction – “. . . The overall aim of certifying products, processes or services is to give confidence to all interested parties that a product, process or service fulfill 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....”



# Purpose of ISO/IEC 17065

Introduction – “. . . This international standard specifies requirements, the observance of which is intended to ensure that certification bodies operate certification schemes in a competent and impartial manner, thereby facilitating the recognition of such bodies and the acceptance of certified products, processes and services on a national and international basis and so furthering international trade....”

Product certification is perhaps the most visible type of certification because it is usually accompanied by a mark that is recognized and appreciated by regulators, consumers and other stakeholders. It is therefore crucial ensuring the reliability of these claims.



# Purpose of ISO/IEC 17065

- It must not restrict the role of the scheme owners
- It must not set requirements for scheme owners
- It is for product, process and service
- Applicable to all types of CB's simple to the complex
- Reflects the functional approach
- Annex B information on how to use the standards for process or service
- Certification scheme are a mandatory part of product certification



Thank you

