

Session 4 – What is Conformity Assessment (CA)?



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Definition of CA



Formal definition of CA

- Demonstration that specified requirements relating to a product, process, system, person or body are fulfilled.
- (ISO/IEC 17000, Clause 2.1)



And in plain English...

- An activity which results in determining whether or not products, services, processes, management systems or persons meet the requirements of standards or other specifications.
- People conduct conformity assessment every day in their lives when you decide which car to buy based on your personal criteria.



Conformity assessment activities



CA activities include

- Accreditation
- Certification
- Inspection
- Validation
- Verification
- Testing



Some CA activities are

Accreditation

Third party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks.

Certification

Third party attestation related to products, processes, systems or person



Some CA activities are

Testing

Determination of one or more characteristics of an object of conformity assessment such as a product, material or process according to a procedure

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



Some conformity assessment activities are

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

- Note 1: Objective evidence can come from real or simulated sources.
- Note 2: Validation is considered to be a process to evaluate the reasonableness of the assumptions, limitations, and methods that support a claim about the outcome of future activities.
- Note 3: Validation is applied to claims regarding an intended future use based on projected information (confirmation of plausibility).



Some conformity assessment activities are

Verification

Confirmation of a claim, through the provision of objective evidence, that specified requirements have been fulfilled

- Note 1: Verification is considered to be a process for evaluating a claim based on historical data and information to determine whether the claim is materially correct, and conforms with specified requirements.
- Note 2: Verification is applied to claims regarding events that have already occurred or results that have already been obtained (confirmation of truthfulness).



Bodies performing conformity assessment

Bodies involved in CA

An **accreditation body** performs accreditation to assess the consistency, impartiality and competence of a conformity assessment body.

A **conformity assessment body** performs conformity assessment services. (examples are testing laboratories, inspection bodies, certification bodies, verification and validation bodies).



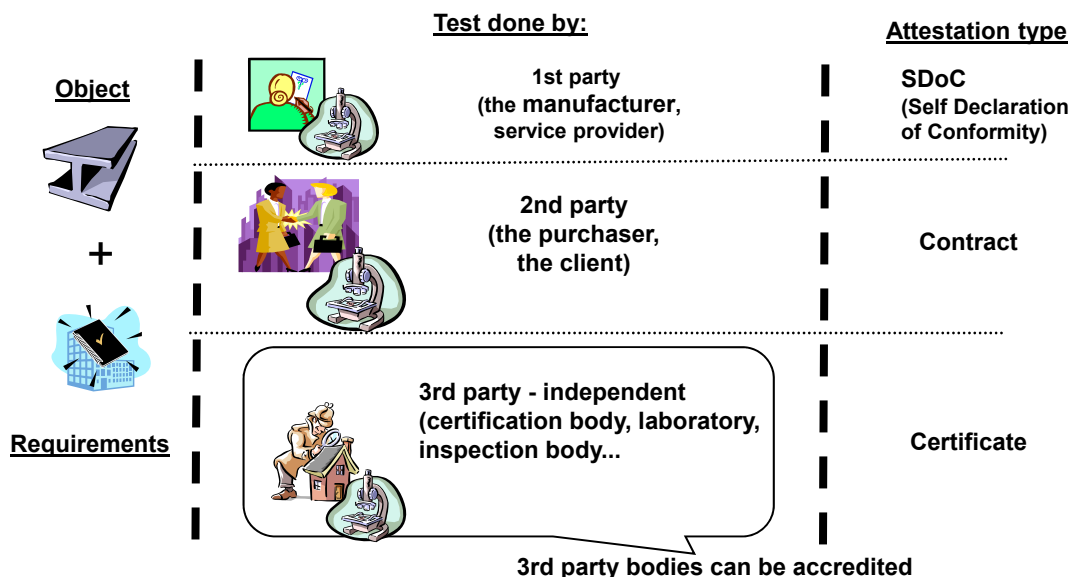
Who can perform conformity assessment?

CA can be performed by different parties

- 1st party - which is a self declaration made by, for example, the manufacturer or the service provider
- 2nd party - which is a declaration made by, for example, the client on the supplier
- 3rd party - which is a declaration made by independent organizations such as certification body, laboratory, inspection body, accreditation body, etc.



Claims of Conformity assessment

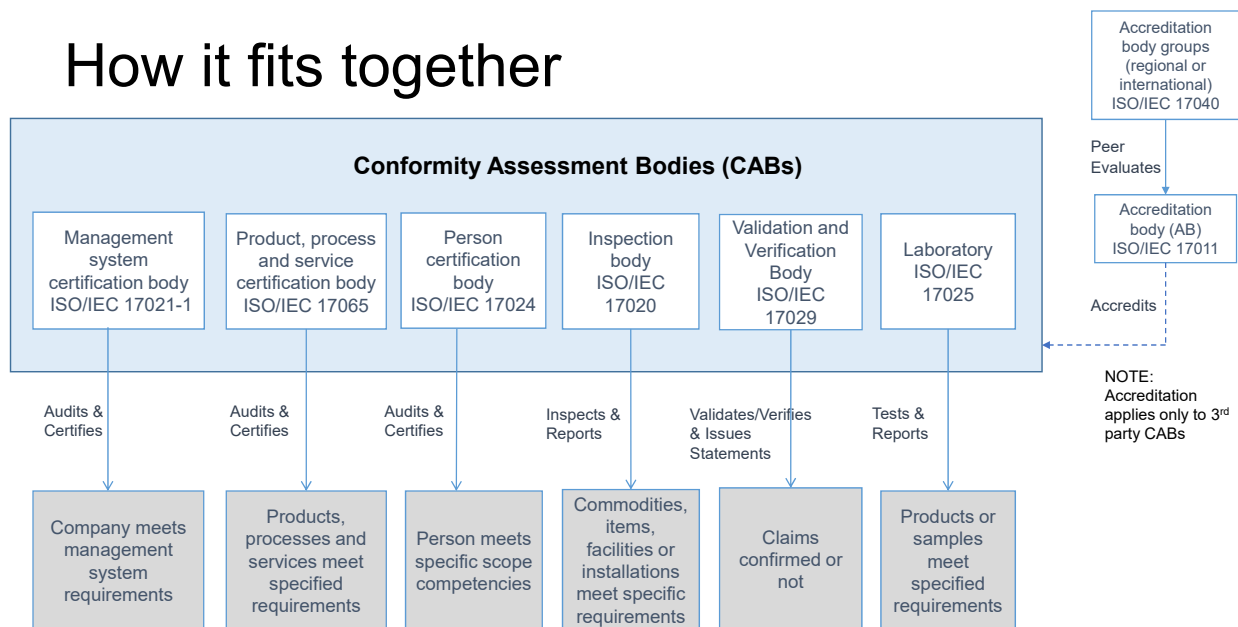


How it fits together?

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How it fits together



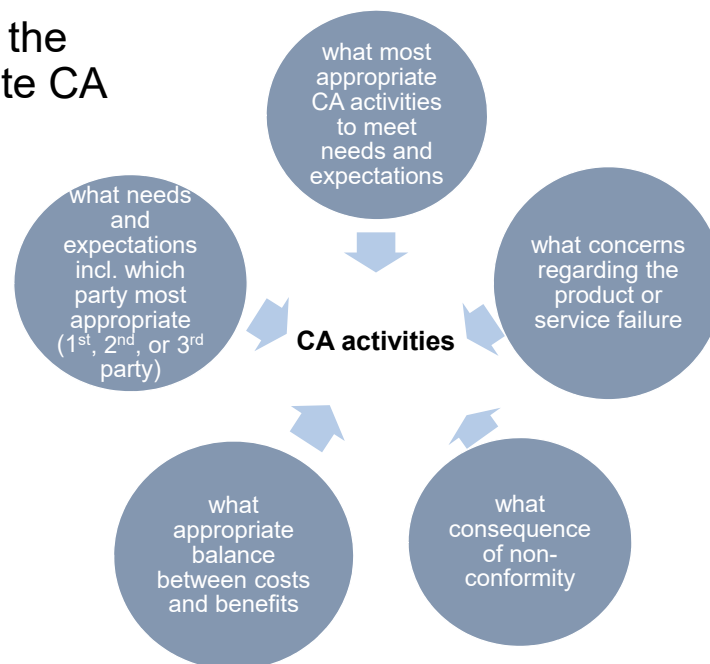
Outputs from conformity assessment

Conformity assessment activity	Conformity assessment standard	Party performing conformity assessment			Functional approach Selection, Determination, Review and Attestation Stages	Surveillance (when needed) ^b	Outputs
		First party	Second party ^a	Third party			
Certification of management systems	ISO/IEC 17021-1			✓	✓	✓	Certificate
Certification of products, processes and services	ISO/IEC 17065			✓	✓	✓	Certificate
Certification of persons	ISO/IEC 17024			✓	✓	✓	Certificate
Inspection	ISO/IEC 17020	✓	✓	✓	✓		Report
Validation and verification	ISO/IEC 17029	✓	✓	✓	✓		Statement or a Claim
Testing	ISO/IEC 17025	✓	✓	✓	✓		Report
Supplier's declaration of conformity	ISO/IEC 17050	✓			✓		Declaration

^aAt present, ISO and IEC do not have specific International Standards or Guides for second-party conformity assessment systems. Second-party conformity assessment systems can be developed to rely on first-party declarations, third-party attestations and certification, or second-party acceptance criteria.

^bSurveillance is part of the conformity assessment system and not an external market surveillance activity.

Selecting the appropriate CA approach



Who benefits from CA?

- **Consumers:** Conformity assessment provides consumers with confidence that a product, service, process, management system or person will perform as expected.
- **Service providers and manufacturers:** Conformity assessment provides assurance that what they provide meet specifications and deliver on customer expectations or meet market requirements.
- **Regulators:** Conformity assessment gives regulators the confidence that the requirements in regulations have been met.



More on CA

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



Thank you

