



CASCO

1-2 May 2019, Nairobi, Kenya



34th Plenary meeting

1-2 May 2019, Nairobi, Kenya





ISO/IEC 17029

Conformity assessment —
General principles and requirements for
validation and verification bodies

Validation/verification as conformity assessment

Object of conformity assessment:

information declared by the client (claim, report, statement, assertion, declaration, prediction, project plan, consolidated data...)

Validation/verification:

confirmation of a claim (**information declared** by the client)
through the provision of objective evidence

Validation/verification as conformity assessment

Differentiation from other CASCO tools:

- not resulting in a **characterisation** (testing)
- not providing **examination** (inspection)
- not providing an attestation of conformity for a **defined period** (certification)

Validation/verification as conformity assessment

Functional approach:

- **Selection** – pre-engagement, engagement and planning activities
- **Determination** – validation/verification execution activities, including evidence-gathering activities
- **Review**
- **Decision**
- **Attestation** – issue of the validation/verification statement
- **Surveillance** – not applicable

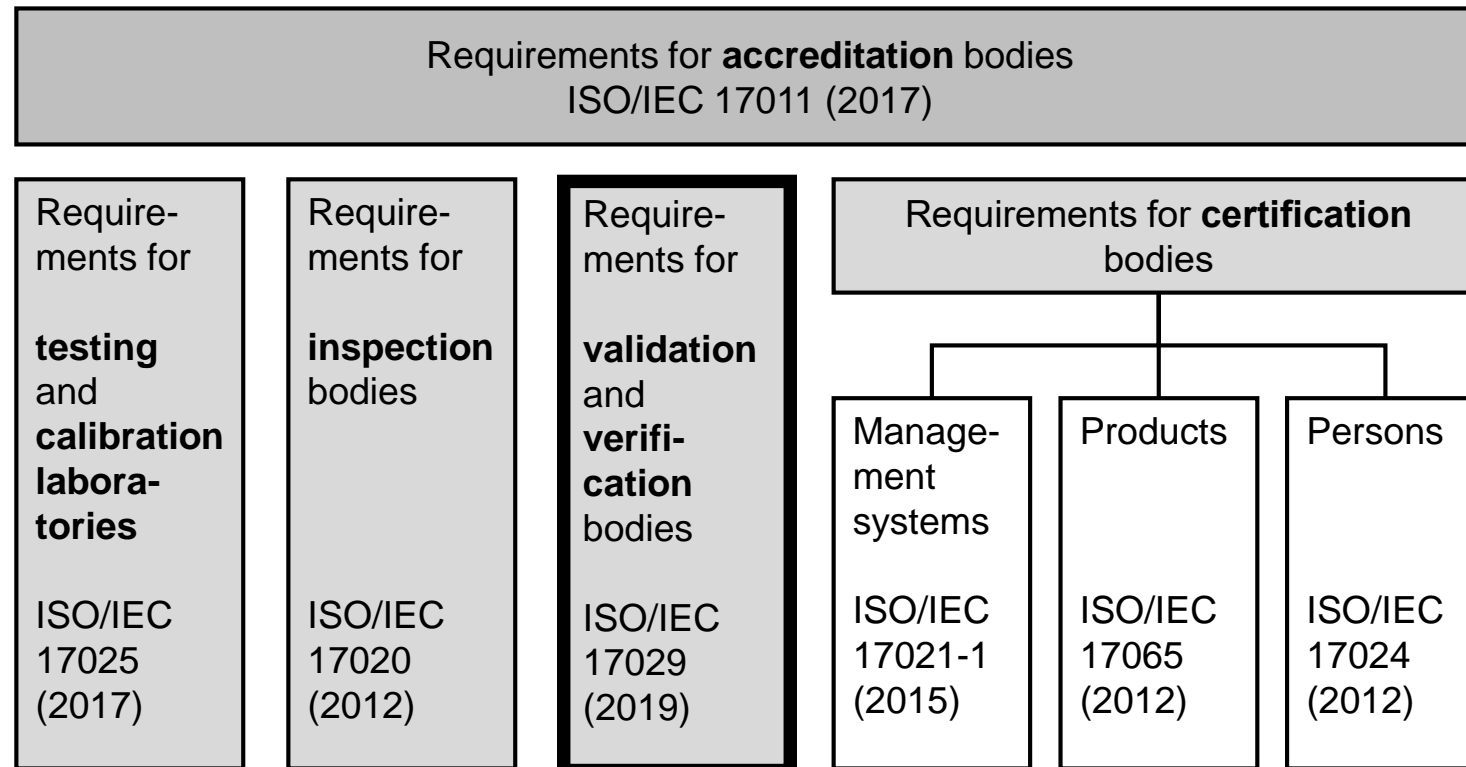
Validation/verification as conformity assessment

Characterisation with regards to other CASCO tools:

- The **claim** can represent a situation at a point in time or could cover a period of time.
- The validation/verification outcome reflects only the situation at the **point in time** it is issued as **validation/verification statement**.
- Review and decision shall be **made by personnel different from** those who carried out the validation/verification execution.

Validation/verification as conformity assessment

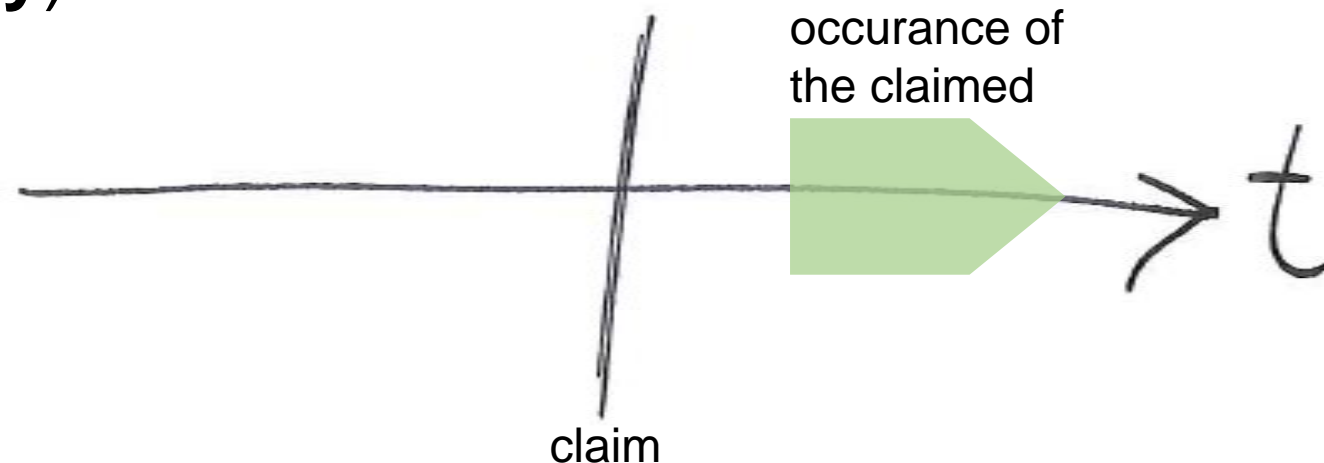
CASCO toolbox:



Validation/verification as conformity assessment

Differentiation from each other:

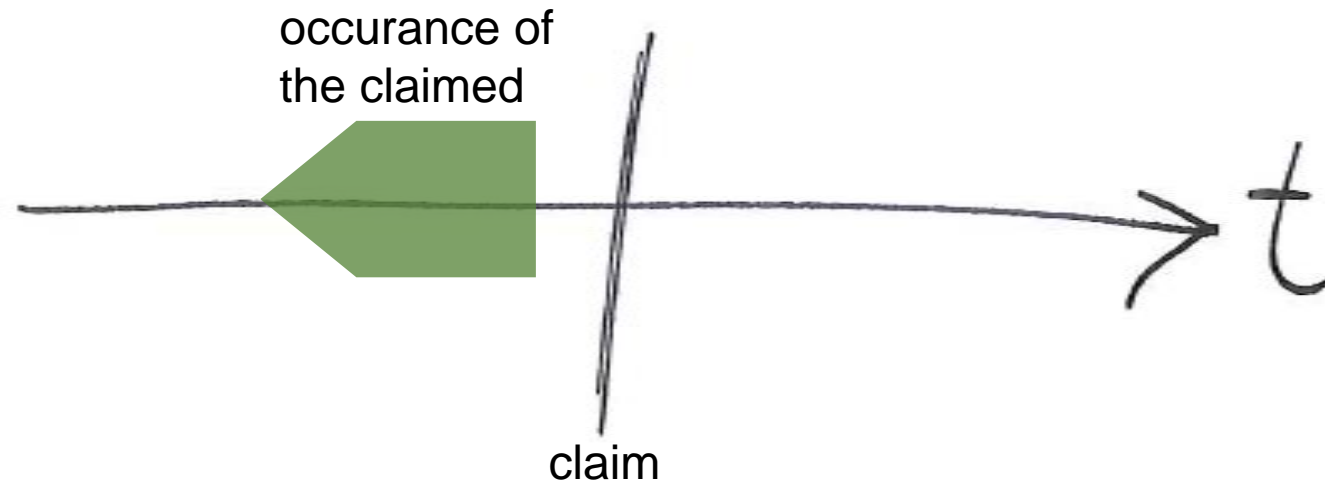
- **validation** – confirmation of a claim through the provision of objective evidence, that the requirements for a specific intended future use or application have been fulfilled (confirmation of **plausibility**)



Validation/verification as conformity assessment

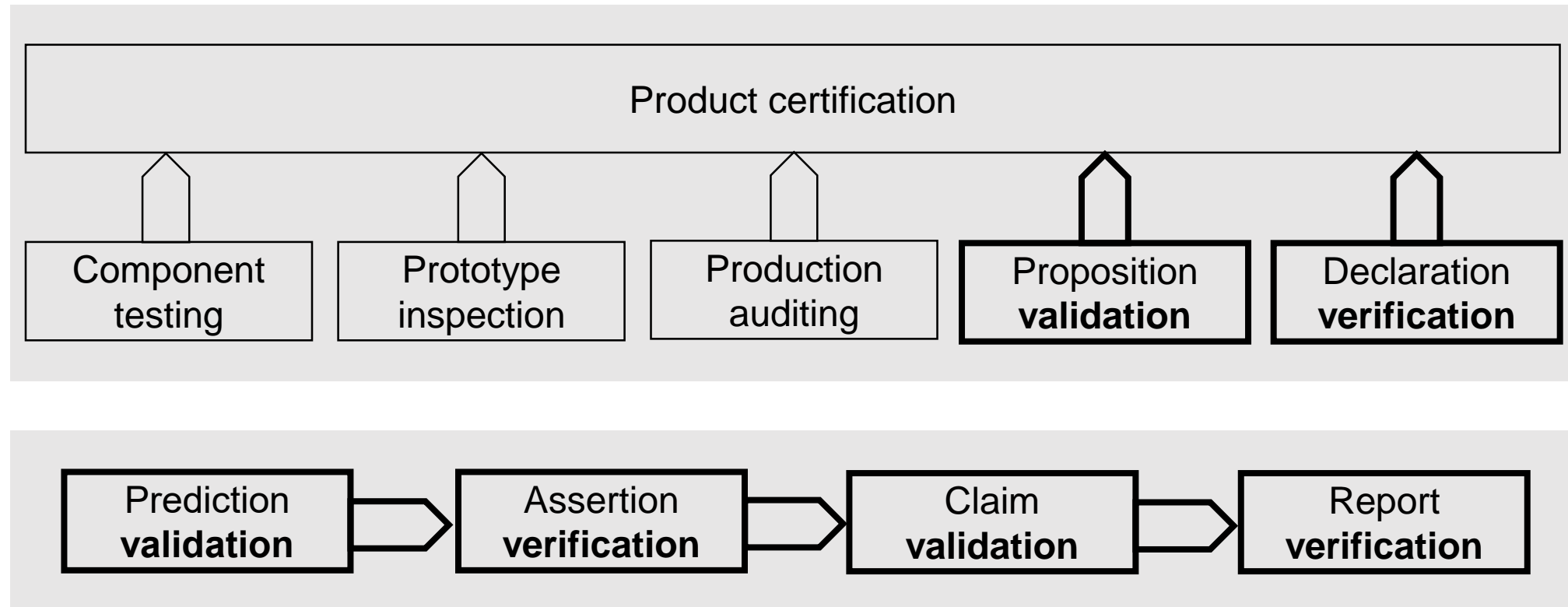
Differentiation from each other:

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



Validation/verification as conformity assessment

Application with other CASCO tools:



ISO/IEC 17029 as CASCO tool

Exclusions from application as CASCO tool:

- **Statements of conformity** themselves, issued as result of another conformity assessment activity, e.g. supplier's declaration of conformity regarding product specifications, certificates, design examination and verification in the context of inspection
- Validation/verification activities as **steps within the process** of another conformity assessment activity, e.g. testing, inspection or certification

ISO/IEC 17029 as CASCO tool

Application:

- Application to validation/verification bodies in **any sector**, in conjunction with sector specific **programmes** that contain requirements for validation/verification processes and procedures
- Validation/verification bodies can provide validation/verification as **first party, second party as well as third party activity**.
- Bodies can be validation bodies only, verification bodies only, or provide both activities.

ISO/IEC 17029 as CASCO tool

Application as CASCO tool:

- General principles and requirements for the **competence**, **consistent operation** and **impartiality** of bodies performing validation/verification as conformity assessment activities
- Basis for **recognition**, e.g. accreditation by accreditation bodies, peer assessment within peer assessment groups, or other forms of recognition by international or regional organizations, governments, regulatory authorities, programme owners, industry bodies, companies, clients or consumers

ISO/IEC 17029 – Structure

- **Individual requirements** indicated, where applicable, for validation/verification and 1st/2nd/3rd party
- **Common elements** (QS-CAS-PROC-33)
- **Common structure** (QS-CAS-PROC-01)
- Clause 4 – **Principles**
- Clause 8, Annex A – Validation/verification **programmes**
- Clause 10 – Information requirements
- Annexes B, C – Relation to CASCO standards and tools

ISO/IEC 17029 – Definitions

- object of conformity assessment – **claim**
- statement of conformity – validation/verification **statement**
(confirming or not confirming the claim, with or without comments)
- conformity assessment scheme – validation/verification **programme**
(legal frameworks, international, regional or national standards, global initiatives, sector applications, individual agreements with clients)

ISO/IEC 17029 – Definitions

- **client** – organization or person requesting validation/verification
- **consultancy** – participation in establishing the claim that will be the object of validation/verification, including involvement in design of the object leading to the claim or providing object specific expertise that supports the preparation of the claim; training and provision of generic information are not considered to be consultancy

ISO/IEC 17029 – Impartiality

- **Review and decision** shall not be made by personnel who carried out the validation/verification **execution**.
- When providing both, **validation and verification, to the same client** the validation/verification body shall consider and manage the potential threat to impartiality (e.g. self-review and familiarity).
- The validation/verification body shall not offer or provide both **consultancy and validation/verification** for the same claim from the same client.
- Optional consultation with **committee of interested parties**

ISO/IEC 17029 – Process

- Clearly identifiable **claim**, capable of consistent evaluation or measurement against specified requirements
- Identification of the boundaries of the claim, the applicable programme and requirements (**scope** of validation/verification)
- **Evidence gathering** and development of complete understanding regarding fulfilment of the specified requirements, including appropriate evaluation of data and plans, reviewing documentation, performing alternative calculations, visiting sites or interviewing people

ISO/IEC 17029 – Process

- **Review** to confirm **completion** of all validation/verification activities in accordance with the agreement and the programme, sufficiency and appropriateness of **evidence** to support the decision, identification, resolution and documentation of significant **findings**
- **Decision** whether or not to confirm the claim
- Issue of **validation/verification statement**, including specifying the claim, scope of validation/verification, decision on confirmation, type of activity provided (1st, 2nd, 3rd party)
- **Facts discovered after** issue of validation/verification statement

ISO/IEC 17029 – Programmes

The **validation/verification body shall apply** one or more validation/verification programme(s) consistent with and not excluding the requirements of ISO/IEC 17029.

A programme is the set of rules, procedures and management for carrying out validation/verification activities in a specific sector or field, specifying the **scope** of validation/verification, **competence** criteria, **process** steps, **evidence gathering** activities, **reporting**.

ISO/IEC 17029 – Programmes

Further specification of

- level of assurance, materiality
- impartiality monitoring function
- monitoring and training needs for personnel
- facilities, equipment, systems, support services
- conditions for consultancy, outsourcing, accepting results
- wording of statements, agreements
- reference to validation/verification, use of marks
- confidentiality requirements

ISO/IEC 17029 – Outlook

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ISO/IEC **FDIS** 17029:201**98**(E)

ISO CASCO/WG46

Secretariat: ISO/CS

Conformity assessment — General principles and requirements for validation and verification
bodies

FDIS stage



ISO

Спасі́бо!

Merci!

Thank you!