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

Évaluation de la conformité — Principes généraux et exigences pour les organismes de validation et de vérification

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Foreword

ISO (the International Organization for Standardization) and IEC (the International Electrotechnical Commission) form the specialized system for worldwide standardization. National bodies that are members of ISO or IEC participate in the development of International Standards through technical committees established by the respective organization to deal with particular fields of technical activity. ISO and IEC technical committees collaborate in fields of mutual interest. Other international organizations, governmental and non-governmental, in liaison with ISO and IEC, also take part in the work.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of document should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO and IEC shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents) or the IEC list of patent declarations received (see http://patents.iec.ch).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html.

This document was prepared by the ISO Committee on Conformity Assessment (CASCO).

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

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

Both activities are distinguished according to the timeline of the assessed claim. Validation is applied to claims regarding an intended future use or projected outcome (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).

Since the requirements in this document are generic in nature, a programme for the particular validation/verification needs to be operated. Such a programme further specifies definitions, principles, rules, processes and requirements for validation/verification process steps, as well as for the competence of validators/verifiers for a specific sector. 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.

Assurance is provided by validation/verification and gives confidence to stakeholders and parties interested in the claim. The programme can define levels of assurance, e.g. a reasonable or limited level of assurance.

According to ISO/IEC 17000, the functional approach to the demonstration that specified requirements are fulfilled describes conformity assessment as a series of the three functions:

— selection;

— determination;

— review and attestation.

The relationship between the generic terms and concepts defined by ISO/IEC 17000 and the terms and concepts defined by this document is given in Table B.1.

According to this functional approach, validation and verification as conformity assessment include a decision on the confirmation of the claim. The decision as to whether (or not) the claim conforms with the initially specified requirements is then issued by the validation/verification body as the validation/verification statement. The specified requirements can be general or detailed, e.g. the claim being free from material misstatements. The applicable programme can define additional steps within the validation/verification process.

When determining whether the claim by a client can be confirmed, validation/verification bodies need to gather information and develop a complete understanding regarding fulfilment of the specified requirements. This can include an appropriate evaluation of data and plans, reviewing documentation, performing alternative calculations, visiting sites or interviewing people.

The requirements specified by this document are common to both activities, validation as well as verification. Wherever a requirement applies only to one activity it is identified.

Validation/verification bodies can be internal bodies of the organization that provides the claim (first party), bodies that have a user interest in the claim (second party) or bodies that are independent of the person or organization that provides the claim and have no user interests in that claim (third party).

By defining validation/verification as confirmation, these activities are differentiated from other conformity assessment tools as neither resulting in a characterization (testing) nor providing examination (inspection) or an attestation of conformity for a defined period (certification). However, validation/verification is intended to match applications of the conformity assessment system. Just as test reports from a laboratory can be included for inspection purposes, or auditing the producer’s management system can be used as an input for product certification, validation/verification statements can be used as an input for another conformity assessment activity. Likewise, results of

other conformity assessment activities can be used as an input when performing validation/verification activities.

Statements of conformity themselves, issued as a result of another conformity assessment activity, are not considered to be objects of validation/verification according to this document. This includes, for example, a supplier's declaration of conformity regarding product specifications according to ISO/IEC 17050, certificates according to ISO/IEC 17021-1 or design examination and verification in the context of inspection according to ISO/IEC 17020.

Furthermore, this document does not apply to situations where validation/verification activities are undertaken as steps within the process of testing (ISO/IEC 17025, ISO 15189), inspection (ISO/IEC 17020) or certification (ISO/IEC 17021-1, ISO/IEC 17065) and where specific requirements need to be applied for structuring and performing these processes. Examples are method validation as a step of a testing performed in accordance with ISO/IEC 17025 and design validation/verification in the context of implementing a management system according to ISO 9001.

Current examples for validation/verification as conformity assessment activities include claims related to greenhouse gas emissions (e.g. according to ISO 14064-3), environmental labelling, product declarations and footprints (e.g. according to ISO 14020 and ISO 14040, such as the environmental product declaration), sustainability or environmental reporting (e.g. according to ISO 14016). Potential new applications can include claims relating to construction technology, energy management, financial management, industrial automation systems, software and systems engineering, artificial intelligence, information technology, healthcare products and medical devices, machine safety, safety and design engineering, and social responsibility. However, in sector applications where validation/verification are not performed as conformity assessment activities as defined by this document, these activities are not within the scope of this document.

In this document, the following verbal forms are used:

— "shall" indicates a requirement;

— "should" indicates a recommendation;

— "may" indicates a permission;

— "can" indicates a possibility or a capability.

Further details can be found in the ISO/IEC Directives, Part 2.

For the purposes of research, users are encouraged to share their views on this document and their priorities for changes to future editions. Click on the link below to take part in the online survey:

https://fr.surveymonkey.com/r/NG3LYKD

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

1 Scope

This document contains general principles and requirements for the competence, consistent operation and impartiality of bodies performing validation/verification as conformity assessment activities.

Bodies operating according to this document can provide validation/verification as a first-party, second-party or third-party activity. Bodies can be validation bodies only, verification bodies only, or provide both activities.

This document is applicable to validation/verification bodies in any sector, providing confirmation that claims are either plausible with regards to the intended future use (validation) or truthfully stated (verification). However, results of other conformity assessment activities (e.g. testing, inspection and certification) are not considered to be subject to validation/verification according to this document. Neither are situations where validation/verification activities are performed as steps within another conformity assessment process.

This document is applicable to any sector, in conjunction with sector specific programmes that contain requirements for validation/verification processes and procedures.

This document can be used as a basis for accreditation by accreditation bodies, peer assessment within peer assessment groups, or other forms of recognition of validation/verification bodies by international or regional organizations, governments, regulatory authorities, programme owners, industry bodies, companies, clients or consumers.

NOTE This document contains generic requirements and is neutral with regard to the validation/verification programme in operation. Requirements of the applicable programmes are additional to the requirements of this document.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO/IEC 17000, *Conformity assessment — Vocabulary and general principles*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO/IEC 17000 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1
claim
information declared by the *client* (3.13)

Note 1 to entry: The claim is the object of conformity assessment by *validation* (3.2)/*verification* (3.3).

Note 2 to entry: The claim can represent a situation at a point in time or could cover a period of time.

Note 3 to entry: The claim should be clearly identifiable and capable of consistent evaluation or measurement against specified requirements by a *validation body* (3.4)/*verification body* (3.5).

Note 4 to entry: The claim can be provided in the form of a report, a statement, a declaration, a project plan, or consolidated data.

3.2
validation
confirmation of a *claim* (3.1), through the provision of objective evidence, that the requirements for a specific intended future use or application have been fulfilled

Note 1 to entry: Objective evidence can come from real or simulated sources.

Note 2 to entry: 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 to entry: Validation is applied to claims regarding an intended future use based on projected information (confirmation of plausibility).

Note 4 to entry: Figure C.1 illustrates the application of validation.

[SOURCE: ISO 9000:2015, 3.8.13, modified — The words "of a claim" and "future" have been added to the definition and the Notes to entry have been modified.]

3.3
verification
confirmation of a *claim* (3.1), through the provision of objective evidence, that specified requirements have been fulfilled

Note 1 to entry: 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 to entry: Verification is applied to claims regarding events that have already occurred or results that have already been obtained (confirmation of truthfulness).

Note 3 to entry: Figure C.2 illustrates the application of verification.

[SOURCE: ISO 9000:2015, 3.8.12, modified — The words "of a claim" have been added to the definition and the Notes to entry have been modified.]

3.4
validation body
body that performs *validation* (3.2)

Note 1 to entry: A validation body can be an organization, or part of an organization.

3.5
verification body
body that performs *verification* (3.3)

Note 1 to entry: A verification body can be an organization, or part of an organization.

3.6
validation statement
declaration by the *validation body* (3.4) of the outcome of the *validation* (3.2) process

Note 1 to entry: Validation statements can be referred to using specific programme terminology, such as "decisions", "opinions" or "reports".

Note 2 to entry: The validation statement reflects only the situation at the point in time it is issued.

Note 3 to entry: The validation statement can be confirming or not confirming the *claim* (3.1), with or without comments, according to the programme requirements.

3.7
verification statement
declaration by the *verification body* (3.5) of the outcome of the *verification* (3.3) process

Note 1 to entry: Verification statements can be referred to using specific programme terminology, such as "decisions", "opinions" or "reports".

Note 2 to entry: The verification statement reflects only the situation at the point in time it is issued.

Note 3 to entry: The verification statement can be confirming or not confirming the *claim* (3.1), with or without comments, according to the programme requirements.

3.8
validation programme
rules, procedures and management for carrying out *validation* (3.2) activities in a specific sector

Note 1 to entry: Validation programmes can be operated at international, regional, national, sub-national or sector-specific level.

Note 2 to entry: A programme can also be called a "scheme".

Note 3 to entry: A set of standards able to cover all the requirements of this document can serve as a programme.

3.9
verification programme
rules, procedures and management for carrying out *verification* (3.3) activities in a specific sector

Note 1 to entry: Verification programmes can be operated at international, regional, national, sub-national or sector-specific level.

Note 2 to entry: A programme can also be called a "scheme".

Note 3 to entry: A set of standards able to cover all the requirements of this document can serve as a programme.

3.10
programme owner
person or organization responsible for developing and maintaining a specific *validation programme* (3.8) or *verification programme* (3.9)

Note 1 to entry: The programme owner can be the *validation body* (3.4)/*verification body* (3.5) itself, a governmental authority, a trade association, a group of validation bodies/verification bodies, an external programme owner or others.

[SOURCE: ISO/IEC 17065:2012, 3.11, modified — The term "scheme owner" has been replaced with "programme owner" and the words "certification scheme" have been replaced with "validation programme or verification programme" in the definition.]

3.11
scope of validation/verification
identification of:

— the *claim* (3.1) to be the object of *validation* (3.2) or *verification* (3.3), including the boundaries of the claim,

— the applicable *validation programme* (3.8)/*verification programme* (3.9), and

— the standards and other normative documents, including their date of publication, to which the claim is validated/verified

3.12
impartiality
presence of objectivity

Note 1 to entry: Objectivity means that conflicts of interest do not exist, or are resolved so as not to adversely influence activities of the *validation body* (3.4)/*verification body* (3.5).

Note 2 to entry: Other terms that are useful in conveying the element of impartiality include "independence", "freedom from conflict of interests", "freedom from bias", "lack of prejudice", "neutrality", "fairness", "open-mindedness", "even-handedness", "detachment", "balance".

[SOURCE: ISO/IEC 17021-1:2015, 3.2, modified — The words "subsequent activities of the certification body" have been replaced with "activities of the validation body/verification body" in Note 1 to entry.]

3.13
client
organization or person requesting *validation* (3.2)/*verification* (3.3)

3.14
consultancy
participation in establishing the *claim* (3.1) that will be the object of *validation* (3.2)/*verification* (3.3)

Note 1 to entry: The term "consultancy" is used in relation to activities of *validation bodies* (3.4)/*verification bodies* (3.5), their personnel and organizations related or linked to the validation bodies/verification bodies.

Note 2 to entry: Participation in establishing the claim also includes involvement in design of the object leading to the claim or providing object specific expertise that supports the preparation of the claim.

Note 3 to entry: Arranging training and participating as a trainer is not considered as consultancy, provided that, where the course relates to the claim that will be the object of validation/verification, it is confined to the provision of generic information; i.e. the trainers should not provide *client* (3.13) specific solutions.

Note 4 to entry: The provision of generic information, but not client specific solutions for establishing the claim that will be the object of validation/verification, is not considered to be consultancy. Such information can include:

— explaining the meaning and intention of validation/verification requirements;

— explaining associated theories, methodologies, techniques, or tools;

— sharing non-confidential information on related best practices.

3.15
level of assurance
degree of confidence in the *claim* (3.1)

Note 1 to entry: The levels of assurance and the conditions to achieve them can be defined in the programme (e.g. absolute, reasonable, limited).

3.16
material
significant to intended users

Note 1 to entry: Materiality is the concept that misstatements, individually or aggregated, can influence the reliability of the *claim* (3.1) or decisions made by the intended user.

Note 2 to entry: Materiality can be qualitative or quantitative.

4 Principles

4.1 General

4.1.1 The principles described in this clause provide the basis for the requirements specified in this document. These principles should be applied as guidance for decisions that sometimes need to be made for unanticipated situations. Principles are not requirements.

4.1.2 The overall aim of validation/verification is to give confidence to all parties that a validated/verified claim fulfils the specified requirements. The value of validation/verification is the confidence that is established by an impartial evaluation by a competent validation/verification body.

4.1.3 Parties that have an interest in validation/verification include, but are not limited to:

a) clients of the validation/verification bodies;

b) programme owners;

c) users of the validated/verified claims;

d) regulatory authorities.

4.2 Principles for the validation/verification process

4.2.1 Evidence-based approach to decision making

The process deploys a method for reaching reliable and reproducible validation/verification conclusions and is based on sufficient and appropriate objective evidence. The validation/verification statement is based on evidence collected through an objective validation/verification of the claim.

4.2.2 Documentation

The validation/verification process is documented and establishes the basis for the conclusion and decision regarding conformity of the claim with the specified requirements.

4.2.3 Fair presentation

Validation/verification activities, findings, conclusions and statements, including significant obstacles encountered during the process, as well as unresolved, diverging views between the validation/verification body and the client are truthfully and accurately reflected.

4.3 Principles for validation/verification bodies

4.3.1 Impartiality

Decisions are based on objective evidence obtained through the validation/verification process and are not influenced by other interests or parties.

Threats to impartiality can include but are not limited to the following.

a) Self-interest: threats that arise from a person or body acting in their own interest. A concern related to validation/verification, as a threat to impartiality, is financial self-interest.

b) Self-review: threats that arise from a person or body reviewing the work done by themselves.

c) Familiarity (or trust): threats that arise from a person or body being too familiar with or trusting of another person instead of seeking evidence for validation/verification.