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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.

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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

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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

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

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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).

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