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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 ut ISO's adherence to the e (TBT) see www.iso.org/

nt (CASCO).

national standards body. A

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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:

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— selection;

— determination;

— review and attestatio

The relationship between
concepts defined by this d

According to this function
decision on the confirmati
the initially specified requ
verification statement. T
free from material missta
validation/verification pr

When determining wheth
to gather information an
requirements. This can in
performing alternative cal

The requirements specifi
verification. Wherever a r

Validation/verification bo
party), bodies that have a
person or organization th

By defining validation/ve
conformity assessment t
examination (inspection)
validation/verification is
as test reports from a lab
management system can
statements can be used a

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.

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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.

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es, peer assessment within
ion bodies by international
owners, industry bodies,

to the validation/verification
al to the requirements of this

me or all of their content
edition cited applies. For
any amendments) applies.

ISO/IEC 17000 and the

the following addresses:

/*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.
have been fulfilled

Note 1 to entry: Verification
information to determine wh

Note 2 to entry: Verification i
already been obtained (confi

Note 3 to entry: Figure C.2 ill

[SOURCE: ISO 9000:2015,
and the Notes to entry hav

3.4
validation body
body that performs *validat*

Note 1 to entry: A validation

3.5
verification body
body that performs *verific*

Note 1 to entry: A verificatio

3.6
validation statement
declaration by the *validati*

Note 1 to entry: Validation
"decisions", "opinions" or "re

Note 2 to entry: The validati

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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

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es in a specific sector

nal, national, sub-national or

nt can serve as a programme.

ific *validation programme*

ification body (3.5) itself, a fication bodies, an external

r" has been replaced with replaced with "validation

cluding the boundaries of

and

publication, to which the

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.

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Note 3 to entry: Arranging
that, where the course relat
provision of generic informa

Note 4 to entry: The provisi
that will be the object of v
include:

— explaining the meaning

— explaining associated th

— sharing non-confidentia

3.15
level of assurance
degree of confidence in th

Note 1 to entry: The levels of
absolute, reasonable, limited

3.16
material
significant to intended use

Note 1 to entry: Materiality
reliability of the *claim* (3.1) o

Note 2 to entry: Materiality c

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

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self-interest.

done by themselves.

o familiar with or trusting
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