SLOVENSKI STANDARD
oSIST prEN ISO/IEC 17029:2018

01-november-2018

Ugotavljanje skladnosti - Splošna načela in zahteve za organe, ki izvajajo validacijo in verifikacijo (ISO/IEC/DIS 17029:2018)

Conformity Assessment - General principles and requirements for validation and verification bodies (ISO/IEC/DIS 17029:2018)

Konformitätsbewertung - Allgemeine Grundsätze und Anforderungen an Stellen, die Validierungs- und Verifizierungstätigkeiten durchführen (ISO/IEC/DIS 17029:2018)

Évaluation de la conformité - Exigences et principes généraux pour les organismes de validation et de vérification (ISO/IEC/DIS 17029:2018)

Ta slovenski standard je istoveten z: **prEN ISO/IEC 17029**

ICS:

03.120.20	Certificiranje proizvodov in podjetij. Ugotavljanje skladnosti	Product and company certification. Conformity assessment

oSIST prEN ISO/IEC 17029:2018 **en,fr,de**

DRAFT INTERNATIONAL STANDARD

ISO/IEC DIS 17029

ISO/CASCO

Secretariat: **ISO**

Voting begins on:
2018-09-17

Voting terminates on:
2018-12-10

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

Évaluation de la conformité — Titre manque

ICS: 03.120.20

This document is circulated as received from the committee secretariat.

This draft is submitted to a parallel vote in ISO and in IEC.

ISO/CEN PARALLEL PROCESSING

Reference number
ISO/IEC DIS 17029:2018(E)

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Published in Switzerland

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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 ISO documents 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 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).

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

For an explanation on 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 the following URL: www.iso.org/iso/foreword.html.

The committee responsible for this document is ISO Policy Committee on Conformity Assessment (ISO/CASCO).

This is the first edition of this document.

Introduction

A growing need has been felt for providing validation and verification activities beyond their specific applications established in the greenhouse gas sector. The development of this document, specifying generic requirements for bodies performing validation or verification activities as conformity assessment in different sectors, i.e. beyond the established sectors, is therefore a response to this need.

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

Both activities are distinguished according to the perspective of each assessment with regard to the timeline of the assessed claim. Validation is applied to claims regarding an intended use or projected effect (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).

Assurance is provided and is serving as a confidence building element for stakeholders and parties interested in the claim. The operated programme can define varied levels of assurance, e.g. a reasonable or limited level of assurance.

The functional approach according to ISO/IEC 17000 to the demonstration that specified requirements are fulfilled specifies conformity assessment as a series of the three functions (1) selection, (2) determination and (3) review and attestation. According to this functional approach, validation and verification as conformity assessment include a decision on issuing a validation/verification statement. The validation/verification body issues the confirmation of the claim as a validation/verification statement that the claim conforms with the initially specified requirements, whether they are general or detailed and free from material misstatements operated programme can define additional steps within the validation/verification process.

When determining whether a claim made by the client can be confirmed, validation/verification activities have to gather information and develop 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.

Since the requirements in this document are generic in nature, a programme for the particular validation/verification is to be operated. These programmes further specify 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.

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

Validation/verification bodies, as specified by this document, 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).

The validation/verification bodies described in this document are primarily expected to be third party validation/verification bodies that have no user interest. The requirements specified in this standard may also be applied to bodies that have a user interest in the claim (second party) or bodies that are internal to the organization that provides the claim (first party).

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

conformity assessment activity. Likewise, results of other conformity assessment activities can be used when performing validation/verification activities.

Statements of conformity themselves, issued as result of another conformity assessment activity, e.g. supplier's declaration of conformity regarding product specifications according to ISO/IEC 17050 or certificates or design examination and verification in the context of inspection activities according to ISO/IEC 17020, are not considered to be objects of validation/verification.

Furthermore, this document does not apply to situations where validation/verification activities are being undertaken 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 are to be applied for structuring and performing these processes. Examples are method validation as a step of a testing activity 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 greenhouse gas (GHG) emissions (e.g. according to ISO 14064-3), environmental labelling, declarations and footprints (e.g. according to ISO 14020 series, such as the environmental product declaration or EPD), 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:

(CASCO Secretariat to insert the link at a later stage.)

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

1 Scope

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

1.2 Bodies operating according to this document can be first party, second party as well as third party bodies. Bodies can be validation bodies only, verification bodies only, or provide both activities.

1.3 This document is applicable to validation/verification bodies in any sector, providing confirmation that claims are either plausible with regards to the intended purpose (validation) or correctly stated (verification). However, statements of conformity themselves, issued as result of another conformity assessment activity (e.g. testing, inspection and certification), are not considered to be subject to validation/verification according to this document.

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

1.5 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 operated validation or verification programme. 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 http://www.iso.org/obp

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

3.1
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/verification body.

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”, “openmindedness”, “even-handedness”, “detachment”, “balance”.

[SOURCE: ISO/IEC 17021-1:2015, modified - 3.2, replacement of *certification body* by *validation/ verification body*]

3.2
validation
confirmation of a claim (3.11), through the provision of objective evidence, that the requirements for a specific intended 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).

[SOURCE: ISO 9000:2015, 3.8.13, modified – “of a claim” added; notes 1-2 deleted, Note 3 “the use of conditions for validation can be” replaced with “objective evidence can come from”; new Notes 2 and 3 added]

3.3
validation body
body that performs validation

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

3.4
validation programme
rules, procedures and management for carrying out validation activities in a specific sector or field

Note 1 to entry: Validation programmes may 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.

[SOURCE: ISO/IEC 17000:2004, 2.8 *conformity assessment system*, modified to make validation specific.]

3.5
verification
confirmation of a claim (3.11), 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).

[SOURCE: ISO 9000:2015, 3.8.12, modified - “of a claim” added, Notes 1-3 deleted and new Notes 1-2 added]