Technical Specification

# ISO/IEC TS 17035

# Conformity assessment — Guidelines for validation and verification programmes

*Évaluation de la conformité — Lignes directrices pour les programmes 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 or www.iec.ch/members_experts/refdocs).

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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. In the IEC, see www.iec.ch/understanding-standards.

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 and www.iec.ch/national-committees.

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# Introduction

This document is aligned with ISO/IEC 17029 which provides principles and requirements for bodies providing validation/verification services. ISO/IEC 17029 is a generic standard that can apply to validation/verification bodies in any economic sector or industry. It is distinct from other standards for conformity assessment bodies in that it requires the object of conformity to be a claim, and for this to be validated and/or verified in accordance with a validation or verification programme. Validation/verification bodies operating in accordance with ISO/IEC 17029 can provide services as first-, second- or third-party activities.

This document is also aligned with sector-specific applications of ISO/IEC 17029, such as ISO 14065 which references the requirements of ISO/IEC 17029 and includes specific requirements related to bodies that validate or verify environmental information.

To validate or verify a claim, validation/verification bodies must often review large amounts of data and information, including aspects such as the suitability of the boundaries of the claim; the way data has been defined, collected and recorded; how quantification and calculation methods that support the claim have been undertaken; and provision of a professional judgement on matters that are material or significant to the claim.

The issuance of a validation or verification statement will normally be a one-off attestation based on the information available at that point in time. Validation/verification statements normally do not have a period of validity associated with them. Each subsequent validation/verification is a new separate conformity assessment and is not considered to be a surveillance activity that supports an original or previous validation/verification statement.

The result of validation or verification activities will frequently be a validation or verification statement. These statements normally provide an opinion from the validation or verification body on the plausibility of a claim that is made about the future based on projected data (validation), or the truthfulness of the claim based on historical data (verification). The results from a validation and verification programme can sometimes be combined to support a claim (e.g. a mixed engagement or in the management of similar or related programmes). Validation/verification bodies can also be asked to undertake a validation/verification process and issue a report of their findings, but without any formal statement or opinion on the plausibility or truthfulness of the claim being made.

NOTE This is often referred to undertaking validation or verification activities on the basis of Agreed Upon Procedures (AUP).

Within ISO/IEC 17029, there is a requirement for validation/verification bodies to operate within the context of at least one validation or verification programme. Within ISO/IEC 17029 requirements, there are many references to validation/verification programmes, and it is expected that validation/verification programmes give direction to the validation/verification body. The importance of appropriate validation/verification programmes when undertaking validation/verification activities in accordance with ISO/IEC 17029 is critical to the correct operation of this type of conformity assessment.

ISO/IEC 17029:2019, Annex A also provides a comprehensive informative list of elements to be considered in the development and operation of validation/verification programmes. The content of ISO/IEC 17029:2019, Annex A has been included and amplified in this document.

To assist in the development, operation and recognition of validation/verification programmes suitable for use with ISO/IEC 17029, this document covers the following:

a) an overview of validation/verification programmes in the context of ISO/IEC 17029;

b) development of validation/verification programmes;

c) recognition of validation/verification programmes.

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# Conformity assessment — Guidelines for validation and verification programmes

## 1 Scope

This document provides guidance to validation/verification programme owners, validation/verification bodies and interested parties on the development, content and operation of validation/verification programmes.

When implemented by validation/verification bodies, this document is intended to be used in conjunction with ISO/IEC 17029 and sector-specific applications of ISO/IEC 17029.

## 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 terminology databases for use in standardization at the following addresses:

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

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

**3.1**
**claim**
information declared by the client

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.

[SOURCE: ISO/IEC 17029:2019, 3.1]

**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.

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