DRAFT International Standard

ISO/IEC DIS 42007

Information technology — Artificial intelligence — High-level framework and guidance for the development of conformity assessment schemes for AI systems

ICS: 35.240.01

ISO/IEC JTC **1**/SC **42**

Secretariat: **ANSI**

Voting begins on:
2026-08-11

Voting terminates on:
2026-11-03

Member bodies are requested to consult relevant national interests in ISO/CASCO before casting their ballot to the e-Balloting application.

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Reference number
ISO/IEC DIS 42007:2026(en)

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Published in Switzerland

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Foreword

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This document was prepared by Joint Technical Committee ISO/IEC JTC 1, *Information technology*, Subcommittee SC 42, *Artificial Intelligence* and ISO Committee on Conformity Assessment (CASCO) within Joint Working Group 6. This document is intended to be used in conjunction with ISO/IEC FDIS 17067.

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

Artificial Intelligence (AI) systems can differ from traditional programmed systems in many ways, including the capability to automatically adapt to different training data and operational environments. The conformity assessment of AI systems can therefore be more challenging. This is the reason why it is important to enable the quality infrastructure to support trusted market access through the conformity assessment of AI systems. This document provides guidance for the development and operation of conformity assessment schemes, including those which utilize certification, for AI systems.

This document is intended to be used in conjunction with ISO/IEC FDIS 17067 — *Conformity assessment — Fundamentals of and guidelines for conformity assessment schemes*. This document has the same structure and clause numbering as ISO/IEC FDIS 17067 so they can be applied concurrently. Unless explicitly stated otherwise, for ease of comprehension of this document, the term "conformity assessment scheme" is sometimes referred to in this document by the short-term "scheme".

The scheme owner chooses when to require a self-declaration of conformity or assessment by a third-party. Third-party assessment and attestation that fulfilment of specified requirements has been demonstrated is referred to as certification.

This document outlines how conformity assessment schemes for AI systems can be structured, developed, deployed, operated, and managed. It identifies common activities that are used for conformity assessment including but not limited to auditing, certification, inspection and testing.

The intended audience for this document is primarily conformity assessment scheme owners, or those considering become scheme owners. Conformity assessment scheme for AI systems owners can include:

a) product certification bodies;

b) regulatory authorities;

c) purchasing agencies;

d) non-governmental organizations;

e) industry and retail associations;

f) civil society organizations;

g) AI system providers and users.

This document is also useful for organizations and people that are not scheme owners, such as conformity assessment practitioners and AI system interested parties including AI system developers, providers, customers, partners, users and other affected parties (including consumers, citizens, tax payers) and regulatory authorities.

Conformity assessment schemes for AI systems can include management system requirements which can be applicable to all or only specifically identified parties related to the AI system. Conformity assessment schemes for AI systems can describe AI systems as objects of conformity assessment and identify specified requirements related to them. Such schemes can also describe the type of management systems, if any, under which AI systems are developed or used as objects of conformity assessment, and identify specified requirements related to them (e.g. ISO/IEC 42001 [1] and ISO/IEC 27001 [2]). Conformity assessment in accordance with such schemes provides assurance about AI systems by demonstrating that an AI system fulfils the relevant specified requirements and, in addition, by demonstrating that the type of management system, if any, under which AI systems are developed or used fulfils the relevant specified requirements. Other combinations of objects of conformity assessment and related specified requirements in aconformity assessment scheme for AI systems can be useful for providing assurance regarding AI systems.

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Information technology — Artificial intelligence — High-level framework and guidance for the development of conformity assessment schemes for AI systems

1 Scope

This document provides a high-level framework and guidance for the development and operation of conformity assessment schemes, including certification schemes, for artificial intelligence systems (AI systems).

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*

ISO/IEC DIS 17067, *Conformity assessment — Fundamentals of and guidelines for conformity assessment schemes*

ISO/IEC 22989, *Information technology — Artificial intelligence — Artificial intelligence concepts and terminology*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO/IEC 17000, ISO/IEC 22989, and ISO/IEC FDIS 17067 and the following applies.

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

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

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

3.1
artificial intelligence system
AI system
engineered system that generates outputs such as content, forecasts, recommendations, or decisions for a given set of human-defined objectives

Note 1 to entry: The engineered system can use various techniques and approaches related to artificial intelligence to develop a model to represent data, knowledge, processes, etc. which can be used to conduct tasks.

Note 2 to entry: AI systems are designed to operate with varying levels of automation.

[SOURCE: ISO/IEC 17000:2020, 3.1.4]

3.2
conformity assessment
demonstration that *specified requirement* (3.6) are fulfilled

Note 1 to entry: The process of conformity assessment as described in the functional approach in ISO/IEC 17000:2020, Annex A can have a negative outcome, i.e. demonstrating that the specified requirements are not fulfilled.

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[SOURCE: ISO/IEC 17000:2020, 4.1, modified – Notes to entry not copied]

3.3
object of conformity assessment
object
entity to which *specified requirements* (3.6) apply

EXAMPLE Product, process, service, management system, system, design, project, data, information, programme, material, installation, claim, person, body or organization, or any combination thereof.

[SOURCE: ISO/IEC 17000:2020, 4.2, modified – original Note 1 to entry not copied. New Note 1 to entry added.]

3.4
conformity assessment scheme for AI systems
conformity assessment programme for AI systems
set of rules and *procedures* (3.7) that describes the *objects of conformity assessment* (3.3), identifies the *specified requirements* (3.6) and provides the *methodology* (3.5) for performing *conformity assessment* (3.2) related to AI systems

[SOURCE: ISO/IEC 17000:2020, 4.9, modified – original Notes to entry (Note to entry 1-3) not copied]

3.5
methodology
systematic collection of methods

Note 1 to entry: In *conformity assessment* (3.2), a systematic approach, or collection of methods, for performing activities contributing to the functions described in ISO/IEC 17000;2020, Annex A, (the functional approach) is one part of a conformity assessment scheme. Individual demonstrations performed in accordance with the same conformity assessment scheme follow the same methodology.

Note 2 to entry: A method or procedure for a specific individual conformity assessment activity within the functional approach (e.g. a sampling protocol, test method, calibration method, inspection procedure, a general plan for an audit of a management system, a general plan for validation or verification of a type of claim, the formatting of a statement of conformity) can be included or referenced in the methodology provided in a conformity assessment scheme. However, a method or procedure for a specific individual conformity assessment activity is not by itself a methodology for demonstrating the fulfilment of *specified requirements* (3.6).

[SOURCE: ISO/IEC FDIS 17067, 3.22]

3.6
specified requirement
need or expectation that is stated

Note 1 to entry: Specified requirements can be stated in normative documents such as regulations, standards and technical specifications.

Note 2 to entry: Specified requirements can be detailed or general.

[SOURCE: ISO/IEC 17000:2020, 5.1]

3.7
procedure
specified way to carry out an activity or a process

Note 1 to entry: In the context of this document, a process is defined as a set of interrelated or interacting activities that use inputs to deliver an intended result.

[SOURCE: ISO/IEC 17000:2020, 5.2, modified — original Note to entry was modified.]

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3.8
attestation
issue of a statement, based on a decision, that fulfilment of *specified requirements* (3.6) has been demonstrated

Note 1 to entry: The resulting statement, referred to in this document as a "statement of conformity", is intended to convey the assurance that the *specified requirements* (3.6) have been fulfilled. Such an assurance does not, of itself, provide contractual or other legal guarantees.

Note 2 to entry: First-party attestation and third-party attestation are distinguished by the terms *declaration* (3.9), *certification* (3.10) and *accreditation* (3.11), but there is no corresponding term applicable to second-party attestation.

[SOURCE: ISO/IEC 17000:2020, 7.3]

3.9
declaration
first-party *attestation* (3.8)

[SOURCE: ISO/IEC 17000:2020, 7.5]

3.10
certification
third-party *attestation* (3.8) related to an *object of conformity assessment* (3.3) with the exception of *accreditation* (3.11)

[SOURCE: ISO/IEC 17000:2020, 7.6]

3.11
accreditation
third-party *attestation* (3.8) related to a *conformity assessment body* (3.12), conveying formal demonstration of its competence, impartiality and consistent operation in performing specific conformity assessment activities

[SOURCE: ISO/IEC 17000:2020, 7.7]

3.12
conformity assessment body
body that performs conformity assessment activities, excluding *accreditation* (3.11)

EXAMPLE Testing facility or laboratory, inspection body, certification body.

[SOURCE: ISO/IEC 17000:2020,4.6, modified – example added]

3.13
surveillance
systematic iteration of conformity assessment activities as a basis for maintaining the validity of the statement of conformity

[SOURCE: ISO/IEC 17000:2020, 8.1]

4 Conformity assessment schemes (programmes) and systems

ISO/IEC FDIS 17067, Clause 4 applies.

5 Functional approach to conformity assessment

ISO/IEC FDIS 17067, Clause 5 applies.

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