SLOVENSKI STANDARD
oSIST prEN ISO/IEC 17007:2024

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Ugotavljanje skladnosti - Napotki za pripravo normativnih dokumentov, primernih za uporabo pri ugotavljanju skladnosti (ISO/IEC DIS 17007:2024)

Conformity assessment - Guidance for drafting normative documents suitable for use for conformity assessment (ISO/IEC DIS 17007:2024)

Konformitätsbewertung - Leitlinien zur Erarbeitung von geeigneten normativen Dokumenten für die Konformitätsbewertung (ISO/IEC DIS 17007:2024)

Évaluation de la conformité - Directives pour la rédaction de documents normatifs appropriés pour l'évaluation de la conformité (ISO/IEC DIS 17007:2024)

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Conformity assessment — Guidance for drafting normative documents suitable for use for conformity assessment

Évaluation de la conformité — Directives pour la rédaction de documents normatifs appropriés pour l'évaluation de la conformité

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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 Documents 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 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 and www.iec.ch/national-committees.

Introduction

This document provides principles and guidance on how to develop normative documents, such as standards, technical specifications, codes of practice and regulations, so that they are concise and clear, especially in the context of any subsequent conformity assessment activity.

Conformity assessment is a demonstration that specified requirements are fulfilled and includes activities such as but not limited to assessment, auditing, design review, evaluation, examination, inspection, testing, surveillance, validation, verification, and certification. The methods and procedures for performing specific individual conformity assessment activities can be combined under rules and methodology through which approvals, certificates, consents, licenses, labels, markings, marks of conformity, permissions, reports and various forms of statements are issued.

This document is intended for the following users:

— standards developers;

— industry associations and consortia;

— purchasers;

— regulatory authorities;

— consumers and non-government groups;

— accreditation bodies;

— conformity assessment bodies;

— conformity assessment scheme owners; and

— other interested parties, e.g. insurance organizations.

This document is intended to assist the above users in developing normative documents suitable for use in conformity assessment at national, regional or international levels, both in regulated or non-regulated applications.

Users of this document may also find useful information in the ISO/IEC Directives, ISO/IEC 17060 *Conformity assessment Code of good practice,* ISO/IEC 17067 *Conformity assessment — Fundamentals of product certification and guidelines for product certification schemes* and the WTO Agreement on Technical Barriers to Trade, Annex 3, *Code of Good Practice for the Preparation, Adoption and Application of Standards*.

ISO/IEC Directives, Part 2, also covers aspects for conformity assessment, mandatory for standards developers in ISO, IEC and ISO/IEC committees.

This document also includes reference to documents in the domain of conformity assessment, known as the CASCO toolbox. These are principally the work of CASCO in cooperation with IEC. Reference to these generic publications is included to emphasise that they contain internationally agreed, globally applied provisions covering conformity assessment. Reliance on these publications as requirements for conformity assessment facilitates acceptance of results around the world.

To make this document as usable as possible, technical terminology has been avoided as much as possible. However, in some cases, the use of some technical terminology was necessary. For example, the requirements in normative documents can relate to many different areas, e.g. a particular material, product, service, installation, data, information, process, system, person or body. In a conformity assessment context, these are all examples of an "object of conformity assessment"..

In the field of conformity assessment "object of conformity assessment" or "object" (see 3.3) is a generic term used to represent anything that can fulfil specified requirements. In a normative document suitable for use in conformity assessment, the term "object of conformity assessment" or "object" would not be used. A normative document should include a scope which either explicitly or implicitly defines the related object of conformity assessment, for example, a type of product, process, service, installation, design, land used

for a specific purpose, management system, conformity assessment body, etc. In this document, the term “object of conformity assessment” or “object” is used so that this document can be applied to any individual normative document regardless of the scope of the normative document.

Conformity assessment — Guidance for drafting normative documents suitable for use for conformity assessment

1 Scope

This document provides principles and guidance for developing normative documents that contain:

— specified requirements for the object of conformity assessment;

— specific methods and procedures for individual conformity assessment activity (e.g. test methods);

— rules and methodology for conformity assessment (as part of conformity assessment schemes, including provisions for organizations that undertake conformity assessment).

This document is intended for use by standards developers, industry associations and consortia, purchasers, regulatory authorities, consumers and non-government groups, accreditation bodies, conformity assessment bodies, conformity assessment scheme owners, and other interested parties, such as insurance organizations.

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 17000:2020, *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
specified requirements
need or expectation that is stated

Note 1 to entry: Specified requirements can be stated in *normative documents* (3.2).

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

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

3.2
normative document
<conformity assessment>
documents that provide:

a) specified requirements for the object of conformity assessment;

b) specific methods and procedures for individual conformity assessment activity (e.g. test methods); or

c) rules and methodology for conformity assessment (as part of conformity assessment schemes, including provisions for organizations that undertake conformity assessment).

Note 1 to entry: The term “normative document” is a generic term that covers such documents as standards, technical specifications, codes of practice and regulations.

Note 2 to entry: A “document” is to be understood as any medium with information recorded on or in it.

[SOURCE: ISO/IEC Guide 2:2004, 3.1, modified with Note 3 deleted]

3.3
object of conformity assessment
object
entity to which *specified requirements* (3.1) apply

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

Note 1 to entry: The term “body” is used in this document to refer to conformity assessment bodies and accreditation bodies. The term “organization” is used in its general meaning and may include bodies according to the context. The more specific ISO/IEC Guide 2 definition of an organization as a body based on membership is not applicable to the field of conformity assessment.

[SOURCE: ISO/IEC 17000:2020, 4.2]

3.4
conformity assessment
demonstration that specified requirements 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.

Note 2 to entry: Conformity assessment is explained in ISO/IEC 17000:2020 Annex A as a series of functions.

Note 3 to entry: This document does not include a definition of “conformity”. “Conformity” does not feature in the definition of “conformity assessment”. Nor does this document address the concept of compliance

[SOURCE: ISO/IEC 17000:2020, 4.1 modified NOTE 2 deleted]

3.5
conformity assessment activity
any activity contributing to any of the functions in the functional approach described in ISO/IEC 17000:2020 Annex A

Note 1 to entry: Conformity assessment activities include but are not limited to testing, auditing, examination, evaluation, inspection, validation, verification, certification, and accreditation.

3.6
conformity assessment body
body that performs conformity assessment activities, excluding accreditation

[SOURCE: ISO/IEC 17000:2020, 4.6]

3.7
accreditation
third-party attestation related to a conformity assessment body, conveying formal demonstration of its competence, impartiality and consistent operation in performing specific conformity assessment activities

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