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International Standard

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Conformity assessment — Requirements for bodies certifying products, processes and services

Évaluation de la conformité — Exigences pour les organismes certifiant les produits, les procédés et les services

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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), in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/CLC/JTC 1, *Criteria for conformity assessment bodies,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO/IEC 17065:2012), which has been technically revised.

The main changes are as follows:

— updated to reflect terminology in ISO/IEC 17000;

— in subclause 8.8, replaced of “Preventive actions” with a new clause “Actions to address risks and opportunities”;

— updated and corrected bibliographic references.

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

The overall aim of certifying products, processes or services is to give confidence to all interested parties that a product, process or service fulfils specified requirements. The value of certification is the degree of confidence and trust that is established by an impartial and competent demonstration of fulfilment of specified requirements through third-party attestation. Parties that have an interest in certification include, but are not limited to:

a) the clients of the certification bodies;

b) the customers of the organizations whose products, processes or services are certified;

c) governmental authorities;

d) non-governmental organizations; and

e) consumers and other members of the public.

Interested parties can expect or require the certification body to meet all the requirements of this document and perform certification in accordance with a certification scheme.

Certification of products, processes or services is a means of providing assurance that they comply with specified requirements in standards and other normative documents. Some product, process or service certification schemes can include initial testing or inspection and assessment of its suppliers' quality management systems, followed by surveillance that takes into account the quality management system and the testing or inspection of samples from the production and the open market. Other schemes rely on initial testing and surveillance testing, while still others comprise type testing only.

This document specifies requirements, the observance of which is intended to ensure that certification bodies operate certification schemes in a competent, consistent and impartial manner, thereby facilitating the recognition of such bodies and the acceptance of certified products, processes and services on a national and international basis and so furthering international trade. This document can be used as a criteria document for accreditation or peer assessment or designation by governmental authorities, scheme owners and others.

The requirements contained in this document are written, above all, to be considered as general criteria for certification bodies operating product, process or service certification schemes; they can have to be amplified when specific industrial or other sectors make use of them, or when particular requirements such as health and safety have to be taken into account. Annex A contains principles relating to certification bodies and certification activities that they provide.

This document does not set requirements for schemes and how they are developed and is not intended to restrict the role or choice of scheme owners, however scheme rules and procedures, including those identifying the certification requirements, should not contradict or exclude any of the requirements of this document.

Statements of conformity to the applicable standards or other normative documents can be in the form of certificates and/or marks of conformity. Schemes for certifying particular products or product groups, processes and services to specified standards or other normative documents can, in many cases, necessitate their own explanatory documentation.

While this document is concerned with bodies providing certification (third party attestation) for a product, process or service, many of its provisions can also be useful for bodies performing first- and second-party product, process or service conformity assessment activities.

In this document, the following verbal forms are used:

— “shall” indicates a requirement;

— “should” indicates a recommendation;

— “may” indicates a permission;

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— “can” indicates a possibility or a capability.

Further details can be found in the ISO/IEC Directives, Part 2.

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Conformity assessment — Requirements for bodies certifying products, processes and services

1 Scope

This document contains requirements for the competence, consistent operation and impartiality of product, process and service certification bodies. Certification bodies operating to this document need not offer all types of products, processes and services certification. Certification of products, processes and services is a third-party conformity assessment activity (see ISO/IEC 17000:2020, 4.5).

In this document, the term "product" can be read as "process" or "service", except in those instances where separate provisions are stated for "processes" or "services" (see Annex B).

2 Normative references

The following referenced documents are indispensable for the application 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 17020, *Conformity assessment — Requirements for bodies performing inspection*

ISO/IEC 17021-1, *Conformity assessment — Requirements for bodies providing audit and certification of management systems — Part 1: Requirements*

ISO/IEC 17025, *General requirements for the competence of testing and calibration laboratories*

ISO/IEC 17029, *Conformity assessment — General principles and requirements for validation and verification bodies*

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
client
organization or person responsible to a certification body for ensuring that *certification requirements* (3.7), including *product requirements* (3.8), are fulfilled

Note 1 to entry: Whenever the term "client" is used in this document, it applies to both the "applicant" and the "client", unless otherwise specified.

3.2
consultancy
participation in

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a) the designing, manufacturing, installing, maintaining or distributing of a certified product or a product to be certified, or

b) the designing, implementing, operating or maintaining of a certified process or a process to be certified, or

c) the designing, implementing, providing or maintaining of a certified service or a service to be certified

Note 1 to entry: In this document, the term “consultancy” is used in relation to activities of certification bodies, personnel of certification bodies and organizations related or linked to certification bodies.

3.3
evaluation
combination of the selection and determination functions of conformity assessment activities

Note 1 to entry: The selection and determination functions are specified in ISO/IEC 17000:2020, Clauses A.2 and A.3.

3.4
product
result of a process

Note 1 to entry: Four generic product categories are noted in ISO 9000:2005[1)]:

— services (e.g. transport) (see 3.6);

— software (e.g. computer program, dictionary);

— hardware (e.g. engine, mechanical part);

— processed materials (e.g. lubricant).

Many products comprise elements belonging to different generic product categories. Whether the product is then called service, software, hardware or processed material depends on the dominant element.

Note 2 to entry: Products include results of natural processes, such as growth of plants and formation of other natural resources.

3.5
process
set of interrelated or interacting activities which transforms inputs into outputs

EXAMPLE Welding engineering processes; heat treatment processes; manufacturing processes requiring confirmation of process capability (e.g. operating or producing product within specified tolerances); food production processes; plant growth processes.

Note 1 to entry: Adapted from ISO 9000:2005, 3.4.1.

3.6
service
result of at least one activity necessarily performed at the interface between the supplier and the customer, which is generally intangible

Note 1 to entry: Provision of a service can involve, for example, the following:

— an activity performed on a customer-supplied tangible product (e.g. automobile to be repaired);

— an activity performed on a customer-supplied intangible product (e.g. the income statement needed to prepare a tax return);

— the delivery of an intangible product (e.g. the delivery of information in the context of knowledge transmission);

— the creation of ambience for the customer (e.g. in hotels and restaurants).

Note 2 to entry: Adapted from ISO 9000:2005, 3.4.2.

1) Withdrawn.

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3.7
certification requirement
requirement, including *product requirements* (3.8), that is fulfilled by the *client* (3.1) as a condition of establishing or maintaining certification

EXAMPLE The following are certification requirements that are not product requirements:

— completing the certification agreement;

— paying fees;

— providing information about changes to the certified product;

— providing access to certified products for surveillance activities.

Note 1 to entry: Certification requirements include requirements imposed on the client by the certification body [usually via the certification agreement (see 4.1.2)] to meet this document, and can also include requirements imposed on the client by the certification scheme. Certification requirements, as used in this document, do not include requirements imposed on the certification body by the certification scheme.

3.8
product requirement
specified requirement that relates directly to a product, stated in standards or in other normative documents identified by the certification scheme

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

3.9
certification scheme
set of rules and procedures that describes the object of conformity assessment, identifies the specified requirements and provides the methodology for performing certification and the related conformity assessment activities

Note 1 to entry: The object of conformity assessment in this document is a product, process or service.

Note 2 to entry: General guidance on conformity assessment schemes which include product, process or services certification is given in ISO/IEC 17067.

[SOURCE: ISO/IEC 17000:2020, 4.9, modified — "Conformity assessment" has been replaced by "certification and the related conformity assessment activities"; the original notes to entry have been replaced by new ones.]

3.10
scope of certification

— information identifying the product(s), process(es) or service(s) for which the certification is granted,

— the applicable certification scheme, and

— the standard(s) and other normative document(s), including their date of publication, to which it is judged that the product(s), process(es) or service(s) comply

3.11
scheme owner
person or organization responsible for developing and maintaining a specific *certification scheme* (3.9)

Note 1 to entry: The scheme owner can be the certification body itself, a governmental authority, a trade association, a group of certification bodies or others.

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3.12
certification body
third-party conformity assessment body operating certification schemes

Note 1 to entry: A certification body can be non-governmental or governmental (with or without regulatory authority).

3.13
impartiality
objectivity with regard to the outcome of a conformity assessment activity

Note 1 to entry: Objectivity can be understood as freedom from bias or freedom from conflicts of interest.

[SOURCE: ISO/IEC 17000:2020, 5.3]

4 General requirements

4.1 Legal and contractual matters

4.1.1 Legal responsibility

The certification body shall be a legal entity, or a defined part of a legal entity, such that the legal entity can be held legally responsible for all its certification activities.

NOTE A governmental certification body is deemed to be a legal entity on the basis of its governmental status.

4.1.2 Certification agreement

4.1.2.1 The certification body shall have a legally enforceable agreement for the provision of certification activities to its clients. Certification agreements shall take into account the responsibilities of the certification body and its clients.

4.1.2.2 The certification body shall ensure its certification agreement requires that the client comply at least, with the following:

a) the client always fulfils the certification requirements (see 3.7), including implementing appropriate changes when they are communicated by the certification body (see 7.10);

b) if the certification applies to ongoing production, the certified product continues to fulfil the product requirements (see 3.8);

c) the client makes all necessary arrangements for

   1) the conduct of the evaluation (see 3.3) and surveillance (if required), including provision for examining documentation and records, and access to the relevant equipment, location(s), area(s), personnel, and client's subcontractors;

   2) investigation of complaints;

   3) the participation of observers, if applicable;

d) the client makes claims regarding certification consistent with the scope of certification (see 3.10);

e) the client does not use its product certification in such a manner as to bring the certification body into disrepute and does not make any statement regarding its product certification that the certification body can consider misleading or unauthorized;

f) upon suspension, withdrawal, or termination of certification, the client discontinues its use of all advertising matter that contains any reference thereto and takes action as required by the certification scheme (e.g. the return of certification documents) and takes any other required measure;

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