INTERNATIONAL STANDARD

ISO/IEC 17065

First edition
2012-09-15

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

Reference number
ISO/IEC 17065:2012(E)

COPYRIGHT PROTECTED DOCUMENT

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

Contents

Page

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. In the field of conformity assessment, the ISO Committee on conformity assessment (CASCO) is responsible for the development of International Standards and Guides.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

Draft International Standards are circulated to the national bodies for voting. Publication as an International Standard requires approval by at least 75 % of the national bodies casting a vote.

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.

ISO/IEC 17065 was prepared by the ISO Committee on conformity assessment (CASCO).

It was circulated for voting to the national bodies of both ISO and IEC, and was approved by both organizations.

This first edition of ISO/IEC 17065 cancels and replaces ISO/IEC Guide 65:1996, which has been technically revised.

The following major changes have been made compared with ISO/IEC Guide 65:1996:

— restructuring of this International Standard based on the common structure adopted by ISO/CASCO;

— modifications based on ISO/PAS 17001, ISO/PAS 17002, ISO/PAS 17003, ISO/PAS 17004 and ISO/PAS 17005;

— introduction of the ISO/IEC 17000 functional approach in the process requirements of Clause 7;

— information on the application of this International Standard for processes and services in Annex B;

— revision of the terms and definitions in Clause 3;

— improvement of the impartiality requirements (mechanism);

— consolidation of the management system requirements in Clause 8;

— inclusion of principles for product certification bodies and their activities in Annex A;

— improvement by taking into account IAF GD 5;

— inclusion of a reference to certification schemes, for which further information is provided in ISO/IEC 17067.

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 by a third party. 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 International Standard as well as when relevant, those of the 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 may 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 International Standard 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 International Standard 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 International Standard are written, above all, to be considered as general criteria for certification bodies operating product, process or service certification schemes; they may 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 International Standard 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 requirements should not contradict or exclude any of the requirements of this International Standard.

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 will, in many cases, require their own explanatory documentation.

While this International Standard is concerned with third parties providing product, process or service certification, many of its provisions may also be useful in first- and second-party product conformity assessment procedures.

In this International Standard, 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.

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

1 Scope

This International Standard contains requirements for the competence, consistent operation and impartiality of product, process and service certification bodies. Certification bodies operating to this International Standard 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 17000:2004, definition 5.5).

In this International Standard, 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 the operation of various types of bodies performing inspection*

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

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

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO/IEC 17000 and the following apply.

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 Whenever the term “client” is used in this International Standard, it applies to both the “applicant” and the “client”, unless otherwise specified.

3.2
consultancy
participation in

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 In this International Standard, 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 The selection and determination functions are specified in ISO/IEC 17000:2004, Clauses A.2 and A.3.

3.4
product
result of a process

NOTE 1 Four generic product categories are noted in ISO 9000:2005:

— services (e.g. transport) (see definition in 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 Products include results of natural processes, such as growth of plants and formation of other natural resources.

NOTE 3 Adapted from ISO/IEC 17000:2004, definition 3.3.

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

EXAMPLES 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 Adapted from ISO 9000:2005, definition 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 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 Adapted from ISO 9000:2005, definition 3.4.2.

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

NOTE Certification requirements include requirements imposed on the client by the certification body [usually via the certification agreement (see 4.1.2)] to meet this International Standard, and can also include requirements imposed on the client by the certification scheme. “Certification requirements”, as used in this International Standard, do not include requirements imposed on the certification body by the certification scheme.

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.

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

NOTE Product requirements can be specified in normative documents such as regulations, standards and technical specifications.

3.9
certification scheme
certification system related to specified products, to which the same specified requirements, specific rules and procedures apply

NOTE 1 Adapted from ISO/IEC 17000:2004, definition 2.8.

NOTE 2 A “certification system” is a “conformity assessment system”, which is defined in ISO/IEC 17000:2004, definition 2.7.

NOTE 3 The rules, procedures and management for implementing product, process and service certification are stipulated by the certification scheme.

NOTE 4 General guidance for the development of schemes is given in ISO/IEC 17067, in combination with ISO/IEC Guide 28 and ISO/IEC Guide 53.

3.10
scope of certification
identification of

— 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 The scheme owner can be the certification body itself, a governmental authority, a trade association, a group of certification bodies or others.

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

NOTE A certification body can be non-governmental or governmental (with or without regulatory authority).

3.13
impartiality
presence of objectivity

NOTE 1 Objectivity is understood to mean that conflicts of interest do not exist, or are resolved so as not to adversely influence the activities of the body.

NOTE 2 Other terms that are useful in conveying the element of impartiality are independence, freedom from conflicts of interest, freedom from bias, freedom from prejudice, neutrality, fairness, open-mindedness, even-handedness, detachment and balance.

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 may 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;

g) if the client provides copies of the certification documents to others, the documents shall be reproduced in their entirety or as specified in the certification scheme;

h) in making reference to its product certification in communication media such as documents, brochures or advertising, the client complies with the requirements of the certification body or as specified by the certification scheme;

i) the client complies with any requirements that may be prescribed in the certification scheme relating to the use of marks of conformity, and on information related to the product;

NOTE See also ISO/IEC 17030, ISO/IEC Guide 23 and ISO Guide 27.

j) the client keeps a record of all complaints made known to it relating to compliance with certification requirements and makes these records available to the certification body when requested, and

1) takes appropriate action with respect to such complaints and any deficiencies found in products that affect compliance with the requirements for certification;

2) documents the actions taken;

NOTE Verification of item j) by the certification body can be specified in the certification scheme.

k) the client informs the certification body, without delay, of changes that may affect its ability to conform with the certification requirements.

NOTE Examples of changes can include the following:

— the legal, commercial, organizational status or ownership,

— organization and management (e.g. key managerial, decision-making or technical staff),

— modifications to the product or the production method,

— contact address and production sites,

— major changes to the quality management system.

4.1.3 Use of license, certificates and marks of conformity

4.1.3.1 The certification body shall exercise the control as specified by the certification scheme over ownership, use and display of licenses, certificates, marks of conformity, and any other mechanisms for indicating a product is certified.

NOTE 1 Guidance on the use of certificates and marks permitted by the certification body can be obtained from ISO/IEC Guide 23.

NOTE 2 ISO/IEC 17030 provides requirements for the use of third-party marks.

4.1.3.2 Incorrect references to the certification scheme, or misleading use of licenses, certificates, marks, or any other mechanism for indicating a product is certified, found in documentation or other publicity, shall be dealt with by suitable action.

NOTE Such actions are addressed in ISO Guide 27 and can include corrective actions, withdrawal of certificate, publication of the transgression and, if necessary, legal action.