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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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Contents

Page

Foreword iv

Introduction v

1 Scope 1

2 Normative references 1

3 Terms and definitions 1

4 General requirements 4
4.1 Legal and contractual matters 4
4.2 Management of impartiality 6
4.3 Liability and financing 7
4.4 Non-discriminatory conditions 7
4.5 Confidentiality 7
4.6 Publicly available information 8

5 Structural requirements 8
5.1 Organizational structure and top management 8
5.2 Mechanism for safeguarding impartiality 9

6 Resource requirements 10
6.1 Certification body personnel 10
6.2 Resources for evaluation 11

7 Process requirements 12
7.1 General 12
7.2 Application 13
7.3 Application review 13
7.4 Evaluation 14
7.5 Review 15
7.6 Certification decision 15
7.7 Certification documentation 16
7.8 Directory of certified products 16
7.9 Surveillance 17
7.10 Changes affecting certification 17
7.11 Termination, reduction, suspension or withdrawal of certification 18
7.12 Records 18
7.13 Complaints and appeals 19

8 Management system requirements 19
8.1 Options 19
8.2 General management system documentation (Option A) 20
8.3 Control of documents (Option A) 20
8.4 Control of records (Option A) 21
8.5 Management review (Option A) 21
8.6 Internal audits (Option A) 22
8.7 Corrective actions (Option A) 22
8.8 Preventive actions (Option A) 23

Annex A (informative) **Principles for product certification bodies and their certification activities** 24

Annex B (informative) **Application of this International Standard for processes and services** 26

Bibliography 27

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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. 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.

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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 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.

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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.

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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

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