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

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The UK participation in its preparation was entrusted to Technical Committee CAS/1, Conformity assessment.

A list of organizations represented on this committee can be obtained on request to its secretary.

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Évaluation de la conformité - Exigences pour les organismes certifiant les produits, les procédés et les services (ISO/IEC 17065:2012)

Konformitätsbewertung - Anforderungen an Stellen, die Produkte, Prozesse und Dienstleistungen zertifizieren (ISO/IEC 17065:2012)

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This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN and CENELEC member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN and CENELEC members are the national standards bodies and national electrotechnical committees of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

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Foreword

This document (EN ISO/IEC 17065:2012) has been prepared by Technical Committee ISO/CASCO "Committee on conformity assessment" in collaboration with Technical Committee CEN/CLC/TC 1 "Criteria for conformity assessment bodies" the secretariat of which is held by BSI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by March 2013, and conflicting national standards shall be withdrawn at the latest by March 2013.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN 45011:1998.

According to the CEN/CENELEC Internal Regulations, the national standards organisations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO/IEC 17065:2012 has been approved by CEN as a EN ISO/IEC 17065:2012 without any modification.

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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.

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.

INTERNATIONAL STANDARD

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