

General requirements for bodies operating product certification systems

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British Standard

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National foreword

This British Standard is identical with EN 45011, General requirements for bodies operating product certification systems. It is a revision of BS 7511:1989, which is withdrawn.

The EN 45000 series of standards will assist the process of mutual recognition between bodies engaged in conformity assessment, the development of national accreditation on a harmonized basis and the notification of such bodies by Governments to perform the relevant functions under European Community directives.

The UK participation in its preparation was entrusted to Technical Committee QS/3, Assessment, testing, certification and inspection, which has the responsibility to:

- aid enquirers to understand the text;
- present to the responsible European committee any enquiries on the interpretation, or proposals for change, and keep the UK interests informed;
- monitor related international and European developments and promulgate them in the UK.

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

Cross-references

The British Standards which implement international or European publications referred to in this document may be found in the BSI Standards Catalogue under the section entitled “International Standards Correspondence Index”, or by using the “Find” facility of the BSI Standards Electronic Catalogue.

A British Standard does not purport to include all the necessary provisions of a contract. Users of British Standards are responsible for their correct application.

Compliance with a British Standard does not of itself confer immunity from legal obligations.

Summary of pages

This document comprises a front cover, an inside front cover, the EN title page, pages 2 to 10, an inside back cover and a back cover.

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English version

**General requirements for bodies operating product
certification systems**
(ISO/IEC Guide 65:1996)

Exigences générales relatives aux organismes
procédant à la certification de produits
(Guide ISO/IEC 65:1996)

Allgemeine Anforderungen an Stellen, die
Produktertifizierungssysteme betreiben
(ISO/IEC Guide 65:1996)

This European Standard was approved by CEN/CENELEC on 8 August 1997.
CEN/CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN/CENELEC member.

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/CENELEC member into its own language and notified to the Central Secretariat has the same status as the official versions.

CEN/CENELEC members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

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Foreword

The text of the ISO/IEC Guide 65:1996 of the Committee on Conformity Assessment (CASCO) has been taken over as a European Standard by Technical Committee CEN/CLC/TC 1, Criteria for conformity assessment bodies, the secretariat of which is held by NSF, and approved by CEN and CENELEC.

This European Standard supersedes EN 45011:1989.

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 August 1998, and conflicting national standards shall be withdrawn at the latest by August 1998.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

NOTE Normative references to International Standards are listed in annex ZA (normative).

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Introduction

Certification of a product (a term used to include a process or service) is a means of providing assurance that it complies with specified standards and other normative documents. Some product certification systems may include initial testing of a product and assessment of its suppliers' quality systems, followed by surveillance that takes into account the factory quality system and the testing of samples from the factory and the open market. Other systems rely on initial testing and surveillance testing, while still others comprise type testing only.

This standard specifies requirements, the observance of which is intended to ensure that certification bodies operate third-party certification systems in a consistent and reliable manner, thereby facilitating their acceptance on a national and international basis and so furthering international trade.

The requirements contained in this standard are written, above all, to be considered as general criteria for organizations operating product certification systems; 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.

Assertion of conformity to the appropriate standards or other normative documents will be in the form of certificates or marks of conformity. Systems for certifying particular products or product groups to specified standards or other normative documents will, in many cases, require their own explanatory documentation.

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

The diversity in certification systems may at first seem unnecessary and even confuse newcomers in the field, clients and operators alike. The ISO/IEC publication *Certification and related activities* is available for background reading and will help to answer questions regarding the practices of the worldwide conformity assessment community.

1 Scope

1.1 This European Standard specifies general requirements that a third-party operating a product certification system shall meet if it is to be recognized as competent and reliable.

In this European Standard the term "certification body" is used to cover any body operating a product certification system. The word "product" is used in its widest sense and includes processes and services; the word "standard" is used to include other normative documents such as specifications or technical regulations.

1.2 The certification system used by the certification body may include one or more of the following, which could be coupled with production surveillance or assessment and surveillance of the supplier's quality system or both, as described in ISO/IEC Guide 53:

- type testing or examination;
- testing or inspection of samples taken from the market or from supplier's stock or from a combination of both;
- testing or inspection of every product or of a particular product, whether new or already in use;
- batch testing or inspection;
- design appraisal.

NOTE 1 ISO/IEC Guide 28 may be consulted for a model of one form of a third-party product certification system.

2 References

- ISO 8402:1994, *Quality management and quality assurance — Vocabulary*.
- ISO 10011-1:1990, *Guidelines for auditing quality systems — Part 1: Auditing*.
- ISO/IEC Guide 2:1996, *Standardization and related activities — General vocabulary*.
- ISO/IEC Guide 7:1994, *Guidelines for drafting of standards suitable for use for conformity assessment*.
- ISO/IEC Guide 23:1982, *Methods of indicating conformity with standards for third-party certification systems*.
- ISO/IEC Guide 25:1990, *General requirements for the competence of calibration and testing laboratories*.
- ISO/IEC Guide 27:1983, *Guidelines for corrective action to be taken by a certification body in the event of misuse of its mark of conformity*.
- ISO/IEC Guide 28:1982, *General rules for a model third-party certification system for products*.
- ISO/IEC Guide 39:1988, *General requirements for the acceptance of inspection bodies*.
- ISO/IEC Guide 53:1988, *An approach to the utilization of a supplier's quality system in third-party product certification*.
- ISO/IEC Guide 62:1996, *General requirements for bodies operating assessment and certification/registration of quality systems*.

3 Definitions

For the purposes of this standard, the relevant definitions given in ISO/IEC Guide 2 and ISO 8402 apply, together with the following definition.

3.1

supplier

the party that is responsible for ensuring that products meet and, if applicable, continue to meet, the requirements on which the certification is based