SLOVENSKI STANDARD
SIST EN 45011:1998

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Nadomešča:
SIST EN 45011:1996

Splošna merila za certifikacijske organe za področje certificiranja sistemov proizvodov (ISO/IEC Vodilo 65:1996)

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

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

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

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03.120.20	Certificiranje proizvodov in podjetij. Ugotavljanje skladnosti	Product and company certification. Conformity assessment

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Descriptors: testing laboratories, certification, approval organizations, specifications

English version

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

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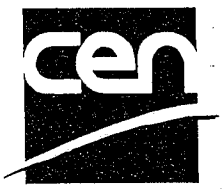
This European Standard was approved by CEN/CENELEC on 8 August 1997.

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 and national electrotechnical committees, respectively, 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 Commitee 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).

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.

4 Certification body

4.1 General provisions

4.1.1 The policies and procedures under which the certification body operates and their administration shall be non-discriminatory and shall be administered in a non-discriminatory manner. Procedures shall not be used to impede or inhibit access by applicants, other than as provided for in this standard.

4.1.2 The certification body shall make its services accessible to all applicants whose activities fall within its declared field of operation. There shall not be undue financial or other conditions. Access shall not be conditional upon the size of the supplier or membership of any association or group, nor shall certification be conditional upon the number of certificates already issued.

4.1.3 The criteria against which the products of a supplier are evaluated shall be those outlined in specified standards. Requirements for standards suitable for this purpose are contained in ISO/IEC Guide 7. If explanation is required as to the application of these documents for a specific certification system, it shall be formulated by relevant and impartial committees or persons possessing the necessary technical competence, and published by the certification body.

4.1.4 The certification body shall confine its requirements, evaluation and decision on certification to those matters specifically related to the scope of the certification being considered.

4.2 Organization

The structure of the certification body shall be such as to foster confidence in its certifications. In particular, the certification body shall

a) be impartial;

b) be responsible for decisions relating to its granting, maintaining, extending, suspending and withdrawing of certification;

c) identify the management (committee, group or person) which shall have overall responsibility for all of the following:

  1) performance of testing, inspection, evaluation and certification as definied in this standard,

  2) formulation of policy matters relating to the operation of the certification body,

  3) decisions on certification,

  4) supervision of the implementation of its policies,

  5) supervision of the finances of the body,

  6) delegation of authority to committees or individuals as required to undertake defined activities on its behalf,

  7) technical basis for granting certification;

d) have documents which demonstrate it is a legal entity;

e) have a documented structure which safeguards impartiality including provisions to ensure the impartiality of the operations of the certification body; this structure shall enable the participation of all parties significantly concerned in the development of policies and principles regarding the content and functioning of the certification system;

f) ensure that each decision on certification is taken by a person(s) different from those who carried out the evaluation;

g) have rights and responsibilities relevant to its certification activities;

h) have adequate arrangements to cover liabilities arising from its operations and/or activities;

i) have the financial stability and resources required for the operation of a certification system;

j) employ a sufficient number of personnel having the necessary education, training, technical knowledge and experience for performing certification functions relating to the type, range and volume of work performed, under a responsible senior executive;

k) have a quality system giving confidence in its ability to operate a certification system for products;

l) have policies and procedures that distinguish between product certification and any other activities in which the certification body is engaged;

m) together with its senior executive and staff, be free from any commercial, financial and other pressures which might influence the results of the certification process;

n) have formal rules and structures for the appointment and operation of any committees which are involved in the certification process; such committees shall be free from any commercial, financial and other pressures that might influence decisions; a structure where members are chosen to provide a balance of interests where no single interest predominates will be deemed to satisfy this provision;

o) ensure that activities of related bodies do not affect the confidentiality, objectivity and impartiality of its certifications, and it shall not

  1) supply or design products of the type it certifies,

  2) give advice or provide consultancy services to the applicant as to methods of dealing with matters which are barriers to the certification requested,

  3) provide any other products or services which could compromise the confidentiality, objectivity or impartiality of its certification process and decisions;

p) have policies and procedures for the resolution of complaints, appeals and disputes received from suppliers or other parties about the handling of certification or any other related matters.

4.3 Operations

The certification body shall take all steps necessary to evaluate conformance with the relevant product standards according to the requirements of specific product certification system (see clause 3). The certification body shall specify the relevant standards or parts thereof and any other requirements such as sampling, testing and inspection requirements which form the basis for the applicable certification system.

In conducting its certification operations, the certification body shall observe, as appropriate, the requirements for the suitability and competence of body(ies) or person(s) carrying out testing, inspection and certification/registration as specified in ISO/IEC Guides 25, 39 and 62.

4.4 Subcontracting

When a certification body decides to subcontract work related to certification (e.g. testing or inspection) to an external body or person, a properly documented agreement covering the arrangements including confidentiality and conflict of interest shall be drawn up. The certification body shall

a) take full responsibility for such subcontracted work and maintain its responsibility for granting, maintaining, extending, suspending or withdrawing certification;

b) ensure that the subcontracted body or person is competent and complies with the applicable provisions of this standard and other standards and guides relevant to testing, inspection or other technical activities (see clause 2), and is not involved either directly or through the person's employer with the design or production of the product in such a way that impartiality would be compromised;

c) obtain the applicant's consent.

NOTES

2 Where work related to certification has been undertaken prior to the application for certification, the body may take account of it, provided it can take responsibility as detailed in 4.4 a) and satisfy itself regarding the matters detailed in 4.4 b).

3 The requirements given in 4.4 a) and b) are also relevant, by extension, when a certification body uses, for granting its own certification, work performed by another certification body with which it has signed an agreement.

4.5 Quality system

4.5.1 The management of the certification body having executive responsibility for quality shall define and document its policy for quality and its objectives for, and commitment to, quality. The management shall ensure that this policy is understood, implemented and maintained at all levels of the organization.

4.5.2 The certification body shall operate an effective quality system in accordance with the relevant elements of this standard and appropriate for the type, range and volume of work performed. This quality system shall be documented and the documentation shall be available for use by the certification body staff. The certification body shall ensure effective implementation of the documented quality system, procedures and instructions. The certification body shall designate a person having direct access to its highest executive level who, irrespective of other responsibilities, shall have defined authority for

a) ensuring that a quality system is established, implemented and maintained in accordance with this standard, and

b) reporting on the performance of the quality system to the body's management for review and as a basis for improvement of the quality system.

4.5.3 The quality system shall be documented in a quality manual and associated quality procedures, and the manual shall contain or refer to at least the following:

a) a quality policy statement;

b) a brief description of the legal status of the certification body, including the names of its owners and, if different, names of the persons who control it;

c) the names, qualifications, experience and terms of reference of the senior executive and other certification personnel, both internal and external;

d) an organization chart showing lines of authority, responsibility and allocation of functions stemming from the senior executive;

e) a description of the organization of the certification body, including details of the management (committee, group or person) identified in 4.2 c), its constitution, terms of reference and rules of procedure;

f) the policy and procedures for conducting management reviews;

g) administrative procedures including document control;

h) the operational and functional duties and services pertaining to quality, so that the extent and limits of each person's responsibility are known to all concerned;

i) the procedure for the recruitment, selection and training of certification body personnel and monitoring of their performance;

j) a list of its approved subcontractors and the procedures for assessing, recording and monitoring their competence;

k) its procedures for handling nonconformities and for assuring the effectiveness of any corrective and preventive actions taken;

l) the procedures for evaluating products and implementing the certification process, including

1) the conditions for issue, retention and withdrawal of certification documents,

2) controls over the use and application of documents employed in the certification of products;

m) the policy and procedure for dealing with appeals, complaints and disputes;

n) its procedures for conducting internal audits, based on the provisions of ISO 10011-1.