SLOVENSKI STANDARD
SIST EN 45010:1998

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Splošne zahteve za ocenjevanje in akreditacijo cerifikacijskih/registracijskih organov (ISO/IEC Vodilo 61:1996)

General requirements for assessment and accreditation of certification/registration bodies (ISO/IEC Guide 61:1996)

Allgemeine Anforderungen an die Begutachtung und Akkreditierung von Zertifizierungsstellen (ISO/IEC Guide 61:1996)

Exigences générales pour l'évaluation et l'accréditation d'organismes de certification/d'enregistrement (Guide ISO/IEC 61:1996)

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

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English version

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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 61:1996 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 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of an identical text or by endorsement, at the latest by August 1998, and conflicting national standards shall be withdrawn at the latest by August 1998.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

The requirements contained in this standard are written, above all, to be considered as general requirements for bodies operating accreditation systems. This standard, however, is in three sections so that if used by organizations other than accreditation bodies concerned with recognition of competence, Sections 1 and 3 apply, and users need simply replace "accreditation" by "recognition".

Section 1 : General

1.1 Scope

This European Standard specifies general requirements for a body to follow if it is to be recognized at a national or international level as competent and reliable in assessing and subsequently accrediting certification bodies or registration bodies. Conformity to the requirements of this European Standard will promote equivalence of national systems and facilitate agreements on mutual recognition of accreditations between such bodies.

The primary objective of this European Standard is to describe accreditation as providing, by means of assessment and subsequent surveillance, an assurance that the market can rely on certificates issued by the accredited bodies. However, organizations other than accreditation bodies, concerned with recognition of competence, may also use it by replacing "accreditation" by "recognition".

In some countries, bodies which verify conformity of products, processes, services or systems to specified standards are called "certification bodies", in other countries "registration bodies", and in still others "assessment bodies". For ease of understanding, this European Standard always refers to such bodies as "bodies". This should not be understood to be limiting, as this European Standard may also be applicable to the assessment and accreditation of conformity assessment bodies other than certification or registration bodies, such as inspection bodies.

NOTE 1 It is recognized that agreements on mutual recognition of accreditations aiming at the removal of barriers to cross-border trade may have to cover other aspects not explicitly specified in these general requirements, such as th e exchange of staff or training programmes. In particular, with a view to create confidence and harmonize the interpretation and implementation of standards, each accreditation body should encourage technical cooperation and exchange of experience among bodies accredited by it, and it should be prepared to exchange information on accreditation procedures and practices with other accreditation bodies. Certification and certification/registration body standards often contain non-specific requirements such as "staff shall be competent". Mutual recognition of accreditation requires harmonization of interpretation of such clauses.

1.2 References

ISO/IEC Guide 2:1996, Standardization and related activities - General vocabulary.

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 62:1996, *General requirements for bodies operating assessment and certification/registration of quality systems.*

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

ISO 8402:1994, *Quality management and quality assurance — Vocabulary.*

ISO 10011-1:1990, *Guidelines for auditing quality systems — Part 1: Auditing.*

ISO 10011-2:1991, *Guidelines for auditing quality systems — Part 2: Qualification criteria for quality systems auditors.*

1.3 Definitions

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

Section 2 : Requirements for accreditation bodies

2.1 Accreditation body

2.1.1 General provisions

2.1.1.1 The policies and procedures under which the accreditation body operates shall be non-discriminatory, and they shall be administered in a non-discriminatory manner. Procedures shall not be used to impede or inhibit access by applicant bodies other than as specified in this standard.

2.1.1.2 The accreditation 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 applicant body or membership of any association or group, nor shall accreditation be conditional upon the number of bodies already accredited.

2.1.1.3 The accreditation criteria against which the competence of an applicant body is assessed shall be those outlined in the ISO/IEC Guides 40 and 62 or other normative documents relevant to the function performed. If an explanation is required as to the application of these documents to a specific accreditation programme, it shall be formulated by relevant and impartial committees or persons possessing the necessary technical competence, and published by the accreditation body.

2.1.1.4 The accreditation body shall confine its requirements, assessment and decisions on accreditation to those matters specifically related to the scope of the accreditation being considered.

2.1.2 Organization

The structure of the accreditation body shall be such as to give confidence in its accreditations.

In particular, the accreditation body shall

a) be impartial;

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

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

   1) performance of assessment and accreditation as defined in this standard,

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

   3) decisions on accreditation,

   4) supervision of the implementation of its policies,

   5) supervision of the finances of the accreditation body,

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

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

e) have a documented structure which safeguards impartiality, including provisions to assure the impartiality of the operations of the accreditation 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 accreditation system;

f) ensure that each decision on accreditation is taken by a person or persons different from those who carried out the assessment;

g) have rights and responsibilities relevant to its accreditation 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 an accreditation system;

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

k) have a quality system, as outlined in 2.1.4, giving confidence in its ability to operate an accreditation system for certification/registration bodies;

l) have policies and procedures that distinguish between accreditation and any other activities in which the accreditation 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 accreditation process;

n) have formal rules and structures for the appointment and operation of any committees which are involved in the accreditation process; such committees shall be free from any commercial, financial and other pressures that might influence decisions (see note 2);

o) ensure that activities of related bodies do not affect the confidentiality, objectivity or