SLOVENSKI STANDARD
SIST EN 45012:1998

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Nadomešča:
SIST EN 45012:1996

Splošne zahteve za organe za področje ocenjevanja in certificiranja/registracije sistemov kakovosti (ISO/IEC Vodilo 62)

General requirements for bodies operating assessment and certification/registration of quality systems (ISO/IEC Guide 62:1996)

Allgemeine Anforderungen an Stellen, die Qualitätsmanagementsysteme begutachten und zertifizieren (ISO/IEC Guide 62:1996)

Exigences générales relatives aux organismes gérant l'évaluation et la certification/enregistrement des systemes qualité (Guide ISO/IEC 62:1996)

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

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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 62:1996 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 45012:1989.

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/registration of a supplier's quality system is one means of providing assurance that the certified/registered supplier is capable of supplying products or services that meet specified requirements.

This standard specifies requirements, the observance of which is intended to ensure that certification/registration bodies operate third-party certifi-cation/registration systems in a consistent and reliable manner, thereby facilitating their acceptance on a national and international basis. This standard should serve as a foundation for the recognition of relevant national systems in the interests of international trade.

This standard is intended for use by bodies, however described, which carry out the functions of assessment and certification/registration of quality systems. For convenience of drafting, such bodies are referred to as "certification/registration bodies". This wording should not be an obstacle to the use of this standard by bodies with other designations which undertake activities which it covers. Indeed, this standard should be usable by any body involved in quality system assessment.

The requirements contained in this standard are written, above all, to be considered as general requirements for organizations operating quality system certification/registration programmes, therefore the requirements may have to be supplemented when specific industrial or other sectors (e.g. health and safety) make use of it.

Quality system certification/registration involves only the assessment of a supplier's quality system and not the certification of products, processes or services. Evidence of conformity to the appropriate quality system standard and any supplementary documentation will be in the form of a certification/registration document or a quality system certificate.

While this standard is intended for use by bodies concerned with recognizing the competence of certification/registration bodies, many provisions contained herein may be useful in second-party assessment procedures.

Section 1 : General

1.1 Scope

1.1.1 Scope

This European Standard specifies general requirements for a third-party body operating quality system certification/registration to meet if it is to be recognized as competent and reliable in the operation of quality system certification/registration.

NOTE 1 In some countries, the bodies which verify conformity of quality systems to specified standards are called "certification bodies", in others "registration bodies", in others "assessment and registration bodies" or "certification/registration bodies", and in still others "registrars". For ease of understanding, this European Standard always refers to such bodies as "certification/registration bodies". This should not be understood to be limiting.

The requirements contained in this European Standard are written, above all, to be considered as general requirements for any body operating certification/registration of quality systems.

1.2 References

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

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

ISO 9000-1:1994, *Quality management and quality assurance standards - Part 1: Guidelines for selection and use.*

ISO 9000-2:1993, *Quality management and quality assurance standards - Part 2: Generic guidelines for the application of ISO 9001, ISO 9002 and ISO 9003.*

ISO 9000-3:1991, *Quality management and quality assurance standards - Part 3: Guidelines for the application of ISO 9001 to the development, supply and maintenance of software.*

ISO 9000-4:1993, *Quality management and quality assurance standards - Part 4: Guide to dependability programme management.*

ISO 9001:1994, *Quality systems - Model for quality assurance in design, development, production, installation and servicing.*

ISO 9002:1994, *Quality systems - Model for quality assurance in production, installation and servicing.*

ISO 9003:1994, *Quality systems - Model for quality assurance in final inspection and test.*

ISO 9004-1:1994, *Quality management and quality system elements - Part 1: Guidelines.*

ISO 9004-2:1991, *Quality management and quality system elements - Part 2: Guidelines for services.*

ISO 9004-3:1993, *Quality management and quality system elements - Part 3: Guidelines for processed materials.*

ISO 9004-4:1993, *Quality management and quality system elements - Part 4: Guidelines for quality improvement.*

ISO 10005:1995, *Quality management - Guidelines for quality plans.*

ISO 10007:1995, *Quality management - Guidelines for configuration management.*

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.*

ISO 10011-3:1991, *Guidelines for auditing quality systems - Part 3: Management of audit programmes.*

ISO 10012-1:1992, *Quality assurance requirements for measuring equipment - Part 1: Metrological confirmation system for measuring equipment.*

ISO 10013:1995, *Guidelines for developing quality manuals.*

1.3 Definitions

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

1.3.1 supplier: The party that is responsible for the product, process or service and is able to ensure that quality assurance is exercised.

This definition may apply to manufacturers, distributors, importers, assemblers, service organizations, etc.

1.3.2 certification/registration body: A third party that assesses and certifies/registers the quality system of suppliers with respect to published quality system standards and any supplementary documentation required under the system.

1.3.3 certification/registration document: Document indicating that a supplier's quality system conforms to specified quality system standards and any supplementary documentation required under the system.

1.3.4 certification/registration system: System having its own rules of procedure and management for carrying out the assessment leading to the issuance of a certification/registration document and its subsequent maintenance.

Section 2: Requirements for certification/registration bodies

2.1 Certification/registration body

2.1.1 General provisions

2.1.1.1 The policies and procedures under which the certification/registration 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 applicants other than as specified in this standard.

2.1.1.2 The certification/registration body shall make its services accessible to all applicants. 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/registration be conditional upon the number of suppliers already certified/registered.

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

2.1.1.4 The certification/registration body shall confine its requirements, assessment and decision on certification/registration to those matters specifically related to the scope of the certification/registration being considered.

2.1.2 Organization

The structure of the certification/registration body shall be such as to give confidence in its certifications/registrations.

In particular, the certification/registration body shall

a) be impartial;

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

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

1) performance of assessment and certification / registration as defined in this standard,

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

3) decisions on certification / registration,

4) supervision of the implementation of its policies,

5) supervision of the finances of the certification / registration 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 certification / registration 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/registration system;

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

g) have rights and responsibilities relevant to its certification/registration 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/registration system;

j) employ a sufficient number of personnel having the necessary education, training, technical knowledge and experience for performing certification/registration 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 a certification / registration system for suppliers;

l) have policies and procedures that distinguish between supplier certification/registration and any other activities in which the 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/registration process;

n) have formal rules and structures for the appointment and operation of any committees which are involved in the certification /