



**SLOVENSKI STANDARD
SIST EN 45004:199)**

01-maj-1995

Splošna merila za delovanje različnih organov, ki izvajajo kontrolo

General criteria for the operation of various types of bodies performing inspection

Allgemeine Kriterien für den Betrieb verschiedener Typen von Stellen, die Inspektionen durchführen

Criteres généraux pour le fonctionnement de différents types d'organismes procédant à l'inspection

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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

General criteria for the operation of various types of bodies performing inspection

Critères généraux pour le fonctionnement de
différents types d'organismes procédant à
l'inspection

Allgemeine Kriterien für den Betrieb
verschiedener Typen von Stellen, die
Inspektionen durchführen

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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.

The European Standards exist 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, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

CEN/CENELEC

Central Secretariat: rue de Stassart, 36 B-1050 Brussels

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Foreword

This European Standard has been drawn up by CEN/CENELEC/TC 1 "Criteria for conformity assessment bodies", whose secretariat is held by the CEN Central Secretariat.

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of an identical text or by endorsement, at the latest by September 1995, and conflicting national standards shall be withdrawn at the latest by September 1995.

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

Introduction

This European Standard has been drawn up with the objective of promoting confidence in those bodies performing inspection which conform to it.

It has been drawn up in the light of experience of European bodies performing inspections taking into account requirements and recommendations of European and international documents such as the ISO 9000 (EN/ISO 9000) series of standards and ISO/IEC Guide 39.

Inspection bodies have carried out assessments on behalf of private clients, their parent organisations, and/or official authorities with the objective of providing information to those parties relative to conformity with regulations, standards, or specifications. Inspection parameters may include matters of quantity, quality, safety, fitness for use, and continued safety compliance of plant or systems in operation. The general criteria, with which these bodies are required to comply in order that their services be accepted by clients and by supervisory authorities, need to be harmonized in a European standard.

This standard, therefore, covers the functions of bodies whose work may include the examination of materials, products, installations, plant, processes, work procedures, or services, and the determination of their conformity with requirements, and the subsequent reporting of results of these activities to clients and, when required, to supervisory authorities. Inspection of a product an installation or plant may concern all stages during the lifetime of these items, including the design stage. Such work normally requires the exercise of professional judgement in providing the service, in particular when assessing conformity.

The requirement for the independence of inspection bodies varies according to legislation and market needs. This standard therefore includes, in annexes A, B and C, criteria for independence.

This standard has also been produced to support the introduction of the conformity assessment procedures specified in the EC Council decision concerning the modules for the various phases of the conformity assessment procedures which are intended to be used in the technical harmonization directives.

The relevant requirements of the EN/ISO 9000 series of standards applying to the quality systems for inspection bodies are incorporated in this standard.

This standard forms part of the following series of standards covering testing, inspection, certification and accreditation:

- EN 45001 General criteria for the operation of testing laboratories
- EN 45002 General criteria for the assessment of testing laboratories
- EN 45003 General criteria for the laboratory accreditation bodies
- EN 45004 General criteria for the operation of bodies performing inspection
- EN xxxx* General criteria for the accreditation of various types of bodies performing inspection
- EN 45011 General criteria for certification bodies operating product certification
- EN 45012 General criteria for certification bodies operating quality system certification
- EN 45013 General criteria for certification bodies operating certification of personnel
- EN 45014 General criteria for suppliers' declaration of conformity
- EN 45020 General terms and their definitions concerning standardisation and related activities.

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1 Scope

- 1.1 This European standard specifies general criteria for the competence of impartial bodies performing inspection irrespective of the sector involved. It also specifies independence criteria.
- 1.2 This standard is intended for the use of inspection bodies and their accreditation bodies as well as other bodies concerned with recognising the competence of inspection bodies.
- 1.3 This set of criteria may have to be interpreted when applied to particular sectors, or to in-service inspection.
- 1.4 This standard does not cover testing laboratories, certification bodies or the suppliers' declaration of conformity, the criteria for which are contained in other European Standards of the EN45000 series.

2 Definitions

For the purpose of this standard the following definitions apply:

- 2.1 **Inspection** Examination of a product design, product, service, process or plant, and determination of their conformity with specific requirements or, on the basis of professional judgement, general requirements.

Note 1: Inspection of processes includes personnel, facilities, technology and methodology.

Note 2: The results of inspection may be used to support certification.

2.2 Inspection body

Body that performs Inspection.

Note: A body can be an organisation, or part of an organisation.

For other definitions those given in EN 45020: 1993 are applicable.

3 Administrative requirements

- 3.1 The inspection body, or the organisation of which it forms a part, shall be legally identifiable.
- 3.2 An inspection body that is part of an organisation involved in functions other than inspection shall be identifiable within that organisation.
- 3.3 The inspection body shall have documentation which describes its functions and the technical scope of activity for which it is competent.

The precise scope of an inspection will be determined by the terms of the individual contract or work order.

- 3.4 The inspection body shall have adequate liability insurance unless its liability is assumed by the State in accordance with national laws or by the organisation of which it forms a part.
- 3.5 The inspection body shall have documentation describing the conditions on which it does business unless it is part of an organisation and provides inspection services only to that organisation.
- 3.6 The inspection body, or the organisation of which it forms a part, shall have independently audited accounts.

4 Independence, impartiality and integrity

4.1 General

The personnel of the inspection body shall be free from any commercial, financial and other pressures which might affect their judgement. Procedures shall be implemented to ensure that persons or organisations external to the inspection body, cannot influence the results of inspections carried out.

4.2 Independence

The inspection body shall be independent to the extent that is required with regard to the conditions under which it performs its services.

Depending on these conditions it shall meet the minimum criteria stipulated in one of the normative Annexes A, B or C. EN 45004:1997

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4.2.1 Type A inspection body

The inspection body providing "third party" services shall meet the criteria of Annex A (normative).

4.2.2 Type B inspection body

The inspection body which forms a separate and identifiable part of an organisation involved in the design, manufacture, supply, installation, use or maintenance of the items it inspects and has been established to supply inspection services to its parent organisation shall meet the criteria of Annex B (normative).

4.2.3 Type C inspection body

The inspection body which is involved in the design, manufacture, supply, installation, use or maintenance of the items it inspects or of similar competitive items and may supply inspection services to other parties not being its parent organisation shall meet the criteria of Annex C (normative).

5 Confidentiality

The inspection body shall ensure confidentiality of information obtained in the course of its inspection activities. Proprietary rights shall be protected.

6 Organisation and management

- 6.1 The inspection body shall have an organisation that enables it to maintain the capability to perform its technical functions satisfactorily.
- 6.2 The inspection body shall define and document the responsibilities and reporting structure of the organisation. Where the inspection body also supplies certification and/or testing services, the relationship between its functions must be clearly defined.
- 6.3 The inspection body shall have a technical manager however named, who is qualified and experienced in the operation of the inspection body and who has overall responsibility that the inspection activities are carried out in accordance with this standard. He shall be a permanent employee.

Note:

Where an inspection body consists of several divisions with different scopes of activity, there may be one technical manager per division.

- 6.4 The inspection body shall provide effective supervision by persons familiar with the inspection methods and procedures, the objectives of the inspection and the assessment of the examination results.
- 6.5 The inspection body shall have named persons who will deputise in the absence of any manager, however named, responsible for inspection services.
- 6.6 Each position category affecting the quality of the inspection services shall be described. These job descriptions shall include the requirements for education, training, technical knowledge and experience.

7 Quality system

- 7.1 The inspection body's management shall define and document its policy and objectives for, and commitment to, quality, and shall ensure that this policy is understood, implemented and maintained at all levels in the organisation.
- 7.2 The inspection body shall operate an effective quality system appropriate to the type, range and volume of work performed.
- 7.3 The quality system shall be fully documented. There shall be a Quality Manual, which shall contain the information required by this standard and as listed in Annex D (informative).
- 7.4 The management of the inspection body shall designate a person who, irrespective of other duties, shall have defined authority and responsibility for quality assurance within the inspection body. This person shall have direct access to top management.
- 7.5 The quality system shall be maintained relevant and current under the responsibility of the same person.