
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*

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

International Standard ISO 17020 was prepared by the European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (CENELEC) as EN 45004, and was adopted, under a special "fast-track procedure", by the ISO Committee on Conformity Assessment (ISO/CASCO) in parallel with its approval by the ISO member bodies and the IEC National Committees.

The ISO Committee on Conformity Assessment (ISO/CASCO), now mandated to produce International Standards, chose EN 45004 to meet a perceived market need for an international consensus-based normative document on requirements for inspection bodies, replacing ISO/IEC Guide 39:1988, *General requirements for the acceptance of inspection bodies*, and ISO/IEC Guide 57:1991, *Guidelines for the presentation of inspection results*.

Throughout the text of this standard, read "... this European Standard ..." to mean "... this International Standard ...".

Annexes A to C form an integral part of this International Standard. Annexes D and ZZ are for information only.

Annex ZZ provides a list of corresponding International and European Standards for which equivalents are not given in the text.

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.

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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 organizations, 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 xxxx¹⁾, 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

1) In preparation.

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

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 recognizing 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 EN 45000 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 organization, or part of an organization.

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

3 Administrative requirement

3.1 The inspection body, or the organization of which it forms a part, shall be legally identifiable.

3.2 An inspection body that is part of an organization involved in functions other than inspection shall be identifiable within that organization.

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 organization 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 organization and provides inspection services only to that organization.

3.6 The inspection body, or the organization 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 organizations 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.

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 organization 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 organization 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 organization 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 Organization and management

6.1 The inspection body shall have an organization 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 organization. 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 deputize 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 organization.

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.

7.6 The inspection body shall maintain a system for control of all documentation relating to its activities. It shall ensure that:

- a) the current issues of the appropriate documentation are available at all relevant locations and to all relevant staff;
- b) all changes of documents or amendments to documents are covered by the correct authorization and processed in a manner which will ensure timely availability at the appropriate location;
- c) superseded documents are removed from use throughout the organization, but one copy is filed for a determined period;
- d) other parties, as necessary, are notified of changes.

7.7 The inspection body shall carry out a system of planned and documented internal quality audits to verify compliance with the criteria of this standard and the effectiveness of the quality system. The personnel performing the audits shall be suitably qualified and independent from the functions being audited.

7.8 The inspection body shall have documented procedures for dealing with feedback and corrective action whenever discrepancies are detected in the quality system and/or in the performance of inspections.

7.9 The management of the inspection body shall review the quality system at appropriate intervals to ensure its continuing suitability and effectiveness. The results of such reviews shall be recorded.

8 Personnel

8.1 The inspection body shall have a sufficient number of permanent personnel with the range of expertise to carry out its normal functions.

8.2 The staff responsible for inspection shall have appropriate qualifications, training, experience and a satisfactory knowledge of the requirements of the inspections to be carried out. They shall have the ability to make professional judgements as to conformity with general requirements using examination results and to report there on.

They shall also have relevant knowledge of the technology used for the manufacturing of the products inspected, of the way in which products or processes submitted to their inspections are used or are intended to be used, and of the defects which may occur during use or in service.

They shall understand the significance of deviations found with regard to the normal use of the products or processes concerned.

8.3 The inspection body shall establish a documented training system to ensure that the training of its personnel, in the technical and administrative aspects of the work in which they will be involved, is kept up-to-date in accordance with its policy.

The training required shall depend upon the ability, qualifications and experience of persons involved. The inspection body shall establish the necessary stages of training for each of its personnel. These may include:

- a) an induction period;
- b) a supervised working period with experienced inspectors;
- c) continuation training, throughout employment, to keep pace with developing technology.

8.4 Records of academic or other qualifications, training and experience of each member of its personnel shall be maintained by the inspection body.

8.5 The inspection body shall provide guidance for the conduct of its staff.

8.6 The remuneration of persons engaged in inspection activities shall not directly depend on the number of inspections carried out and in no case on the results of such inspections.

9 Facilities and equipment

9.1 The inspection body shall have available to it suitable and adequate facilities and equipment to permit all activities associated with the inspection services to be carried out.

9.2 The inspection body shall have clear rules for the access to and the use of specified facilities and equipment.

9.3 The inspection body shall ensure the continued suitability of the facilities and the equipment mentioned in 9.1 for their intended use.

9.4 All such equipment shall be properly identified.

9.5 The inspection body shall ensure that all such equipment is properly maintained, in accordance with documented procedures and instructions.

9.6 The inspection body shall ensure that, where appropriate, equipment is calibrated before being put into service and thereafter according to an established programme.

9.7 The overall programme of calibration of equipment shall be designed and operated so as to ensure that wherever applicable measurements made by the inspection body are traceable to national and International Standards of measurement where available. Where traceability to national or International Standards of

measurement is not applicable, the inspection body shall provide satisfactory evidence of correlation or accuracy of inspection results.

9.8 Reference standards of measurement held by the inspection body shall be used for calibration only and for no other purpose. Reference standards of measurement shall be calibrated by a competent body that can provide traceability to a national or International Standard of measurement.

9.9 Where relevant, equipment shall be subjected to in-service checks between regular recalibrations.

9.10 Reference materials shall where possible be traceable to national or International Standard reference materials.

9.11 Where relevant to the quality of inspection services, the inspection body shall have procedures for:

- a) selection of qualified suppliers;
- b) issuing appropriate purchasing documents;
- c) inspection of received materials;
- d) ensuring appropriate storage facilities.

9.12 Where applicable the condition of stored items shall be assessed at appropriate intervals to detect deterioration.

9.13 If the inspection body uses computers or automated equipment in connection with inspections, it shall ensure that:

- a) computer software is tested in order to confirm that it is adequate for use;
- b) procedures are established and implemented for protecting the integrity of data;
- c) computer and automated equipment is maintained in order to ensure proper functioning; and
- d) procedures are established and implemented for maintenance of security of data.

9.14 The inspection body shall have documented procedures for dealing with defective equipment. Defective equipment shall be removed from service by segregation, prominent labelling or marking. The inspection body shall examine the effect of defects on previous inspections.

9.15 Relevant information on the equipment shall be recorded. This will normally include identification, calibration and maintenance.

10 Inspection methods and procedures

10.1 The inspection body shall use the methods and procedures for inspection which are defined in the requirements, against which conformity is to be determined.

10.2 The inspection body shall have and use adequate documented instructions on inspection planning and on standard sampling and inspection techniques, where the absence of such instructions could jeopardize the efficiency of the inspection process. Where applicable, this requires sufficient knowledge of statistical techniques to ensure statistically sound sampling procedures and the correct processing and interpretation of results.

10.3 When the inspection body has to use inspection methods or procedures which are non-standard, such methods and procedures shall be appropriate and fully documented.

10.4 All instructions, standards or written procedures, worksheets, check lists and reference data relevant to the work of the inspection body shall be maintained up-to-date and be readily available to the staff.

10.5 The inspection body shall have a contract or work order control system which ensures that:

- a) work to be undertaken is within its expertise and that the organization has adequate resources to meet the requirements;
- b) the requirements of those seeking the inspection body's services are adequately defined and that special conditions are understood so that unambiguous instructions can be issued to staff performing the duties to be required;
- c) work being undertaken is controlled by regular review and corrective action;
- d) completed work is reviewed to confirm that requirements have been met.

10.6 Observations and/or data obtained in the course of inspections shall be recorded in a timely manner to prevent loss of relevant information.

10.7 All calculations and data transfers shall be subject to appropriate checks.

10.8 The inspection body shall have documented instructions for carrying out inspection safely.

11 Handling inspection samples and items

11.1 The inspection body shall ensure that samples and items to be inspected are uniquely identified to avoid confusion regarding the identity of such items at any time.

11.2 Any apparent abnormalities notified to, or noticed by, the inspector shall be recorded before commencement of the inspection. Where there is any doubt as to the item's suitability for the inspection to be carried out, or where the item does not conform to the description provided, the inspection body shall consult the client before proceeding.

11.3 The inspection body shall establish whether the item has received all necessary preparation, or whether the client requires preparation to be undertaken or arranged by the inspection body.

11.4 The inspection body shall have documented procedures and appropriate facilities to avoid deterioration or damage to inspection items while under its responsibility.

12 Records

12.1 The inspection body shall maintain a record system to suit its particular circumstances and to comply with applicable regulations.

12.2 The records shall include sufficient information to permit satisfactory evaluation of the inspection.

12.3 All records shall be safely stored for a specified period, held secure and in confidence to the client, unless otherwise required by law.

13 Inspection reports and inspection certificates

13.1 The work carried out by the inspection body shall be covered by a retrievable inspection report and/or inspection certificate.

13.2 The inspection report and/or inspection certificate shall include all the results of examinations and the determination of conformity made from these results as well as all information needed to understand and interpret them. All this information shall be reported correctly, accurately, and clearly. Where the inspection report or inspection certificate contains results supplied by subcontractors, these results shall be clearly identified.

13.3 Inspection reports and inspection certificates shall be signed or otherwise approved by authorized staff members only.

13.4 Corrections or additions to an inspection report or inspection certificate after issue shall be recorded and justified in accordance with the relevant requirements of this section.

14 Subcontracting

14.1 The inspection body shall itself normally perform the inspections which it contracts to undertake.

14.2 When an inspection body subcontracts any part of the inspection, it shall ensure and be able to demonstrate that its subcontractor is competent to perform the service in question and where applicable complies with the criteria stipulated in the relevant standard of the EN 45000 series. The inspection body shall advise the client of its intention to subcontract any part of the inspection. The subcontractor shall be acceptable to the client.

14.3 The inspection body shall record and retain details of its investigation of the competence and compliance of its subcontractors. The inspection body shall maintain a register of all subcontracting.

14.4 Where the inspection body subcontracts certain specialized activities, it shall have access to a qualified and experienced person who is able to form an independent assessment of the results of these subcontracted activities. The responsibility for the determination of conformity with the requirements rests with the inspection body itself.

15 Complaints and appeals

15.1 The inspection body shall have documented procedures for dealing with complaints received from clients or other parties about the inspection body's activities.

15.2 The inspection body shall have documented procedures for the consideration and resolution of appeals against the results of its inspections, where these are carried out under legally delegated authority.

15.3 A record shall be maintained of all complaints and appeals and of the actions taken by the inspection body.

16 Cooperation

The inspection body is expected to participate in an exchange of experience with other inspection bodies and in the standardization processes as appropriate.

Annex A

(normative)

Independence criteria for Type A inspection body

The inspection body referred to in 4.2.1 shall meet the following criteria:

A.1 The inspection body shall be independent of the parties involved.

The inspection body, and its staff responsible for carrying out the inspection shall not be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of the items which they inspect, nor the authorized representative of any of these parties.

A.2 The inspection body and its staff shall not engage in any activities that may conflict with their independence of judgement and integrity in relation to their inspection activities. In particular they shall not become directly involved in the design, manufacture, supply, installation, use or maintenance of the items inspected, or similar competitive items.

A.3 All interested parties shall have access to the services of the inspection body. There shall not be undue financial or other conditions. The procedures under which the body operates shall be administered in a non-discriminatory manner.

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Annex B

(normative)

Independence criteria for Type B inspection body

The inspection body referred to in 4.2.2 shall meet the following criteria:

B.1 A clear separation of the responsibilities of the inspection personnel from those of the personnel employed in the other functions shall be established by organizational identification and the reporting methods of the inspection body within the parent organization.

B.2 The inspection body and its staff shall not engage in any activities that may conflict with their independence of judgement and integrity in relation to their inspection activities. In particular they shall not become directly involved in the design, manufacture, supply, installation, use or maintenance of the items inspected, or similar competitive items.

B.3 Inspection services shall only be supplied to the organization of which the inspection body forms a part.

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Annex C (normative)

Independence criteria for Type C inspection body

The inspection body referred to in 4.2.3 shall meet the following criterion:

C.1 The inspection body shall provide safeguards within the organization to ensure adequate segregation of responsibilities and accountabilities in the provision of inspection services by organization and/or documented procedures.

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