
General requirements for bodies providing accreditation of inspection bodies

*Exigences générales relatives aux organismes procédant à l'accréditation
d'organismes d'inspection*

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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.

The main task of technical committees is to prepare International Standards, but in exceptional circumstances a technical committee may propose the publication of a Technical Report of one of the following types:

- type 1, when the required support cannot be obtained for the publication of an International Standard, despite repeated efforts;
- type 2, when the subject is still under technical development or where for any other reason there is the future but not immediate possibility of an agreement on an International Standard;
- type 3, when a technical committee has collected data of a different kind from that which is normally published as an International Standard ("state of the art", for example).

Technical Reports of types 1 and 2 are subject to review within three years of publication, to decide whether they can be transformed into International Standards. Technical Reports of type 3 do not necessarily have to be reviewed until data they provide are considered to be no longer valid or useful.

ISO/IEC TR 17010, which is a Technical Report of type 2, was prepared by CASCO, ISO Committee on Conformity Assessment, in collaboration with IEC.

This document is being issued in the Technical Report (type 2) series of publications (according to subclause G.3.2.2 of part 1 of the ISO/IEC Directives, 1995) as a "prospective standard for provisional application" in the field of accreditation of inspection bodies because there is an urgent need for guidance on how standards in this field should be used to meet an identified need.

This document is not to be regarded as an "International Standard". It is proposed for provisional application so that information and experience of its use in practice may be gathered. Comments on the content of this document should be sent to the ISO Central Secretariat.

A review of this Technical Report (type 2) will be carried out not later than three years after its publication with the options of: extension for another three years; conversion into an International Standard or a Guide; or withdrawal.

ISO/IEC TR 17010 was based on EAC-EAL *General requirements for bodies providing accreditation of inspection bodies*, prepared by the European Accreditation of Certification (EAC) and the European Accreditation of Laboratories (EAL). These two organizations merged into the European Co-operation for Accreditation (EA) in November 1997.

General requirements for bodies providing accreditation of inspection bodies

1 Scope

This Technical Report gives general requirements for bodies providing accreditation of inspection bodies so that the accreditations granted and the services covered by the accreditations may be recognized at a national or an international level and the body operating the accreditation system may be recognized at national or international level as competent and reliable. Users of accreditation, other than the inspection body, may require compliance with requirements additional to those specified in this Technical Report.

The object of this Technical Report is to provide the basis for the setting up and operation of an accreditation body and to facilitate agreements, between such bodies, on mutual recognition of accreditation of inspection bodies.

NOTE 1 It is recognized that agreements on mutual recognition of accreditations aimed at the removal of barriers to cross-border trade may have to cover other aspects not explicitly specified in these general requirements, such as exchange of any relevant information between inspection bodies and exchange of staff or training programmes. In particular, with a view to creating confidence and harmonizing the interpretation and implementation of standards, each accreditation body should encourage technical cooperation and exchange of experience among inspection bodies accredited by it, and should be prepared to exchange information on accreditation procedures and practices with other accreditation bodies.

NOTE 2 This Technical Report is based on ISO/IEC Guide 58:1993, and on ISO/IEC Guide 61:1996. To facilitate a comparison between requirements on bodies that accredit inspection bodies, testing laboratories and certification bodies, an extensive cross-reference table between the clauses of this Technical Report and the corresponding clauses of the two above-mentioned Guides has been prepared and is available on request.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this Technical Report. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this Technical Report are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO/IEC 17020, *General criteria for the operation of various types of bodies performing inspection*.

ISO/IEC Guide 2, *Standardization and related activities — General vocabulary*.

3 Terms and definitions

For the purposes of this Technical Report, the terms and definitions given in ISO/IEC Guide 2 apply, with the exception of the terms *inspection* and *inspection body*, for which the definitions given in ISO/IEC 17020 apply.

4 Accreditation body

4.1 General provisions

4.1.1 The procedures under which the accreditation body operates shall be administered in a non-discriminatory manner.

Access to an accreditation system operated by an accreditation body shall not be conditional upon the size of the inspection body, the number of inspection bodies already accredited, or membership of any association or group, nor shall there be undue financial conditions to restrict participation.

4.1.2 The competence of an applicant inspection body shall be assessed by the accreditation body against the requirements of ISO/IEC 17020.

4.1.3 The requirements of ISO/IEC 17020 may have to be interpreted for specific fields of inspection by the accreditation body. These interpretations shall be formulated by relevant and impartial committees [see 4.2.1 m) and n)] possessing the necessary technical competence. They shall be published by the accreditation body.

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

4.2 Organization of the accreditation body

4.2.1 The accreditation body shall:

- a) be impartial;
- b) be responsible for its decisions relating to accreditation, including the granting, maintaining, extending, reducing, suspending and withdrawing of accreditation;
- c) be a legally identifiable entity;
- d) ensure that each decision on accreditation is taken by a person or by persons different from those who carried out the assessment;
- e) have rights and responsibilities relevant to its accreditation activities;
- f) have adequate arrangements to cover liabilities arising from its operations and/or activities;
- g) have the financial stability and resources required for the operation of an accreditation system;
- h) have and make available on request a description of the means by which it receives its financial support;
- i) employ a sufficient number of personnel having the necessary education, training, technical knowledge and experience for handling the type, range and volume of work performed, under the responsibility of a senior executive;
- j) have a quality system, including an organizational structure, that enables it to give confidence in its ability to satisfactorily operate a system of accreditation of inspection bodies;
- k) have documented policies and procedures for the operation of the quality system that include:
 - policies and decision-making procedures that distinguish between accreditation activities and any other activities in which the body is engaged,
 - policies and procedures for the resolution of complaints and appeals received from inspection bodies about the handling of accreditation matters, or from users of services about accredited inspection bodies or any other matters;
- l) 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;
- m) have formal rules and structures for the appointment and operation of committees involved in the accreditation process; such committees shall be free from any commercial, financial and other pressures that might influence decisions or shall have a structure where members are chosen to provide impartiality through a balance of interests where no single interest predominates;

- n) establish one or more technical committees, each responsible, within its scope, for advising the accreditation body on the technical matters relating to the operation of its accreditation system;
- o) not offer consultancies or other services such as inspection which may compromise the objectivity of its accreditation process and decisions;
- p) have arrangements to preserve confidentiality at all times in accordance with 4.3.9 of this Technical Report.

4.2.2 The accreditation body shall have arrangements for controlling the ownership, use and display of the accreditation documents and/or controlling the manner in which an accredited inspection body may refer to its accredited status, in accordance with clause 7 of this Technical Report.

4.3 Quality system

4.3.1 Policy for quality

The top management of the accreditation body shall define and document its policy for quality, including objectives for quality and its commitment to quality. The management shall ensure that this policy is understood, implemented and maintained at all levels of the organization.

4.3.2 Availability, implementation and responsibility

The accreditation body shall operate a quality system appropriate to the type, range and volume of work performed. This system shall be documented and the documentation shall be available for use by the accreditation body staff. The accreditation body shall ensure effective implementation of the documented quality system procedures and instructions. The accreditation body shall designate a person having direct access to its highest executive level to take responsibility for the quality system and its improvement and the maintenance of the quality documentation.

4.3.3 Documentation of the quality system

The quality system shall be documented in a quality manual and associated quality procedures, and the quality 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 accreditation body;
- c) the names, qualifications, experience and terms of reference of the senior executive and other accreditation personnel who could affect the quality of the accreditation function;
- d) a description of the organizational structure of the accreditation body, including an organization chart showing lines of authority, responsibility and allocation of functions stemming from the senior executive and, in particular, the relationship between those responsible for the assessment and those taking decisions regarding accreditation;
- e) the operational and functional duties and services pertaining to quality, so that each person concerned will know the extent and the limits of their responsibility;
- f) administrative procedures including document control;
- g) policies and procedures to implement the accreditation process;
- h) arrangements for feedback and corrective actions whenever discrepancies are detected;
- i) the policy and procedures for dealing with appeals, complaints and disputes;
- j) the policy and procedures for conducting internal audits;
- k) the policy and procedures for conducting management reviews of the quality system;

- l) the policy and procedures for the recruitment and training of assessors and accreditation body personnel and for monitoring their performances.

4.3.4 Internal audits

The person designated as having responsibility for the quality system shall ensure that internal audits are conducted covering all procedures in a planned and systematic manner, to verify that the quality system is being implemented and is effective. This person shall ensure that:

- a) personnel responsible for the area audited are informed of the outcome of the audit;
- b) corrective and, when necessary, preventive action is taken in a timely and appropriate manner;
- c) the results of the audit are documented.

4.3.5 Management reviews

The accreditation body's top management shall review its quality system at defined intervals sufficient to ensure its continuing suitability and effectiveness in satisfying the requirements of this Technical Report and the stated quality policy and objectives. Records of such reviews shall be maintained.

4.3.6 Document control

The accreditation body shall establish and maintain procedures to control all documents and data that relate to its accreditation functions. These documents shall be reviewed and approved for adequacy by appropriately authorized and competent personnel prior to issuing any documents following initial development or any subsequent amendment or change being made. A listing of all appropriate documents with the respective issue and/or amendment status identified shall be maintained. The distribution of all such documents shall be controlled to ensure that the appropriate documentation is made available to personnel of the accreditation body, applicants and accredited bodies.

4.3.7 Maintenance of records

The accreditation body shall maintain records to demonstrate that accreditation procedures have been effectively fulfilled, particularly with respect to application forms, assessment reports, and reports relating to granting, maintaining, extending, suspending or withdrawing accreditation. These accreditation documents shall form part of the record.

4.3.8 Retention and access to records

The accreditation body shall have a policy and procedures for retaining records for a period consistent with its contractual and legal obligations. The accreditation body shall have a policy and procedures concerning access to these records consistent with 4.2.1 p) of this Technical Report.

4.3.9 Confidentiality

The accreditation body shall have adequate arrangements, consistent with applicable laws, to safeguard the confidentiality of the information obtained in the course of its accreditation activities at all levels of its organization, including committees and external bodies or individuals acting on its behalf. Except as required in this Technical Report, information about a particular inspection body shall not be disclosed to a third party without the written consent of the body. Where the law requires information to be disclosed to a third party, the inspection body shall be informed of the information provided.

4.3.10 Appeals, complaints and disputes

The accreditation body shall have documented procedures for dealing with appeals, complaints and disputes brought before the accreditation body by inspection bodies or other parties. In particular, the accreditation body shall:

- a) keep a record of all appeals, complaints and disputes;

- b) take appropriate corrective and preventive action;
- c) document the actions taken and assess their effectiveness.

4.4 Granting, maintaining, extending, suspending and withdrawing accreditation

4.4.1 The accreditation body shall specify the conditions for granting, maintaining and extending accreditation and the conditions under which accreditation may be suspended or withdrawn, partially or in total for all or part of the inspection body's scope of accreditation.

4.4.2 The accreditation body shall have arrangements to grant, maintain, suspend or withdraw accreditation, increase or reduce the scope of accreditation, or require re-assessment in the event of changes affecting the activity and operation of the inspection body, such as changes in personnel or equipment, or if analysis of a complaint or any other information indicates that the inspection body no longer complies with the requirements of the accreditation body.

4.4.3 The accreditation body shall have arrangements relating to the transfer of accreditation when significant changes in the status of the accredited inspection body occur.

4.5 Documentation

4.5.1 The accreditation body shall provide (through publications, electronic media or other means), update at adequate intervals, and make available the following, on request:

- a) information about the authority under which the accreditation body operates;
- b) a document containing its requirements for accreditation;
- c) a document stating the arrangements for granting, maintaining, extending, suspending and withdrawing accreditation;
- d) information about the assessment and accreditation process;
- e) general information on the fees charged to the applicant and accredited inspection bodies;
- f) a description of the rights and duties of accredited inspection bodies as specified in 8.1, 8.2 and 8.3 of this Technical Report, including requirements, restrictions or limitations on the use of the accrediting body's logo and on the ways of referring to the accreditation granted;
- g) information on procedures for handling complaints, appeals and disputes.

4.5.2 The accreditation body shall publish periodically a directory of accredited inspection bodies describing the accreditations granted.

5 Personnel involved in the accreditation process

5.1 General

5.1.1 The personnel involved in the accreditation process shall be competent for the functions they perform.

5.1.2 Information on the relevant qualifications, training and experience of each member of the personnel involved in the accreditation process shall be maintained by the accreditation body. Records of training and experience shall be kept up to date.

5.2 Requirements for assessors

5.2.1 The assessor(s) appointed to assess an inspection body shall:

- a) be familiar with the relevant legal regulations, accreditation procedures and accreditation requirements;