



Guide for General Requirements for Assessment and Accreditation of Certification/Registration Bodies¹

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INTRODUCTION

The requirements contained in this guide are written, above all, to be considered as general requirements for bodies operating accreditation systems. This guide, however, is in three sections so that if used by organizations other than accreditation bodies concerned with recognition of competence, Sections 1–3 and 5 apply, and users need simply replace *accreditation* by *recognition*.

1. Scope

1.1 This guide 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 guide will promote equivalence of national systems and facilitate agreements on mutual recognition of accreditations between such bodies.

1.2 The primary objective of this guide 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, also may use it by replacing *accreditation* by *recognition*.

1.3 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 guide always refers to such bodies as *bodies*. This should not be understood to be limiting, as this guide also may 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 the exchange of staff or training programs. 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 nonspecific requirements, such as “staff shall be competent”. Mutual recognition of accreditation requires harmonization of interpretation of such clauses.

2.1 *ISO Standards:*
ISO 8402:1994, Quality Management and Quality Assurance—Vocabulary²
ISO 1001 1–1: 1990, Guidelines for Auditing Quality Systems—Part 1: Auditing²
ISO 1001 1–2: 1991, Guidelines for Auditing Quality Systems—Part 2: Qualification Criteria for Quality Systems Auditors²

2. Referenced Documents

2.1 ISO Standards:

ISO 8402:1994, Quality Management and Quality Assurance—Vocabulary²

ISO 1001 1–1: 1990, Guidelines for Auditing Quality Systems—Part 1: Auditing²

ISO 1001 1–2: 1991, Guidelines for Auditing Quality Systems—Part 2: Qualification Criteria for Quality Systems Auditors²

2.2 ISO/IEC Standards:

ISO/IEC Guide 2:1996, General Terms and Their Definitions Concerning Standardization and Related Activities²

ISO/IEC Guide 25:1990, General Requirements for the Competence of Calibration and Testing Laboratories²

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 Conformity²

ISO/IEC Guide 28:1982, General Rules for a Model Third-Party Certification System for Products²

ISO/IEC Guide 40:1, General Requirements for Bodies Operating Product Certification Systems²

ISO/IEC Guide 62:1996, General Requirements for Bodies

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² Available from American National Standards Institute, 11 W. 42nd St., 13th Floor, New York, NY 10036.



Operating Assessment and Certification/Registration of Quality Systems²

3. Terminology

3.1 *Definitions*— For the purposes of this guide, the relevant definitions provided in **ISO/IEC Guide 2** and ISO 8402 apply.

4. Requirements for Accreditation Bodies

4.1 *Accreditation Body—General Provisions:*

4.1.1 The policies and procedures under which the accreditation body operates shall be nondiscriminatory and they shall be administered in a nondiscriminatory manner. Procedures shall not be used to impede or inhibit access by applicant bodies other than as specified in this guide.

4.1.2 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.

4.1.3 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 program, it shall be formulated by relevant and impartial committees or persons possessing the necessary technical competence, and published by the accreditation body.

4.1.4 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.

4.2 *Organization*— The structure of the accreditation body shall be such as to give confidence in its accreditations. In particular, the accreditation body shall do the following:

4.2.1 Be impartial;

4.2.2 Be responsible for its decisions relating to the granting, maintaining, extending, reducing, suspending, and withdrawing of accreditation;

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

4.2.3.1 Performance of assessment and accreditation as defined in this guide;

4.2.3.2 Formulation of policy matters relating to the operation of the accreditation body;

4.2.3.3 Decisions on accreditation;

4.2.3.4 Supervision of the implementation of its policies;

4.2.3.5 Supervision of the finances of the accreditation body; and,

4.2.3.6 Delegation of authority to committees or individuals, as required, to undertake defined activities on its behalf;

4.2.4 Have documents, which demonstrate that it is a legal entity;

4.2.5 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;

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

4.2.7 Have rights and responsibilities relevant to its accreditation activities;

4.2.8 Have adequate arrangements to cover liabilities arising from its operations and/or activities;

4.2.9 Have the financial stability and resources required for the operation of an accreditation system;

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

4.2.11 Have a quality system, as outlined in **4.4**, giving confidence in its ability to operate an accreditation system for certification/registration bodies;

4.2.12 Have policies and procedures that distinguish between accreditation and any other activities in which the accreditation body is engaged;

4.2.13 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;

4.2.14 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**);

NOTE 2—A structure where members are chosen to provide a balance of interests, where no single interest predominates, will be deemed to satisfy this provision.

4.2.15 Ensure that activities of related bodies do not affect the confidentiality, objectivity, or impartiality of its accreditations and shall not offer or provide, directly or, indirectly, the following:

4.2.15.1 Those services that it accredits others to perform;

4.2.15.2 Consulting services to obtain or maintain accreditation;

4.2.15.3 Services to design, implement or maintain a certification scheme (see **Note 3**);

NOTE 3—Other products, processes, or services may be offered, directly or indirectly, provided they do not compromise confidentiality or the objectivity or impartiality of its accreditation process and decisions.

4.2.16 Have policies and procedures for the resolution of complaints, appeals, and disputes received from bodies or other parties about the handling of accreditation or any related matters.

4.3 *Subcontracting*— When an accreditation body decides to subcontract work related to accreditation, for example, audits, to an external body or person, a properly documented agreement covering the arrangements, including confidentiality and conflict of interests, shall be drawn up. The accreditation body shall do the following:



4.3.1 Take full responsibility for such subcontracted work and maintain its responsibility for granting, maintaining, extending, reducing, suspending, or withdrawing accreditation;

4.3.2 Ensure that the subcontracted body or person is competent and complies with the applicable provisions of this guide and is not involved, either directly or through its employer, with the design, implementation or maintenance of a certification or certification/registration scheme in such a way that impartiality could be compromised; and,

4.3.3 Obtain the consent of the applicant or accredited body.

NOTE 4—Requirements as stated in 4.3.1 and 4.3.2 also are relevant, by extension, when an accreditation body uses, for granting its own accreditation, work provided by another accreditation body with which it has signed an agreement.

4.4 *Quality System:*

4.4.1 The management of the accreditation body with executive responsibility for quality 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.

4.4.2 The accreditation body shall operate a quality system in accordance with the relevant elements of this guide and appropriate to the type, range, and volume of work performed. This quality system shall be documented and the documentation shall be available for use by the staff of the accreditation body. The accreditation body shall ensure effective implementation of the documented quality system procedures and instructions. The accreditation body shall designate a person with direct access to its highest executive level, who irrespective of other responsibilities, shall have defined authority to do the following:

4.4.2.1 Ensure that a quality system is established, implemented, and maintained in accordance with this guide;

4.4.2.2 Report on the performance of the quality system to the management of the accreditation body for review and as a basis for improvement of the quality system.

4.4.3 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:

4.4.3.1 A quality policy statement;

4.4.3.2 A brief description of the legal status of the accreditation body, including the names of its owners, if applicable, and if different, the names of the persons who control it;

4.4.3.3 The names, qualifications, experience, and terms of reference of the senior executive and other accreditation personnel influencing the quality of the accreditation function;

4.4.3.4 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;

4.4.3.5 A description of the rights and duties of applicants and accredited bodies, as specified, including requirements, restrictions, or limitations on the use of the accreditation body's logo and on the ways of referring to the accreditation granted;

4.4.3.6 Information on procedures for handling complaints, appeals, and disputes;

4.4.3.7 A directory of accredited bodies including their locations, describing the scope of accreditation granted to each;

4.4.3.8 The operational and functional duties and services pertaining to quality, so that the extent and limits of each person's responsibility are known to all concerned;

4.4.3.9 The policy and procedures for the recruitment and training of accreditation body personnel (including auditors) and monitoring their performance;

4.4.3.10 A list of its subcontractors and details of the procedures for assessing, recording, and monitoring their competence;

4.4.3.11 Its procedures for handling nonconformities and for assuring the effectiveness of any corrective actions taken;

4.4.3.12 The policy and procedures for implementing the accreditation process, including:

(a) (a) The conditions for issue, retention and withdrawal of accreditation documents;

(b) (b) Checks of the use and application of documents used in the accreditation;

(c) (c) The procedures for assessing and accrediting applicants;

(d) (d) The procedures for surveillance and reassessment of accredited bodies;

4.4.3.13 The policy and procedures for dealing with appeals, complaints, and disputes; and,

4.4.3.14 The procedures for conducting internal audits based on the provisions of ISO 1 001 1–1.

4.5 *Conditions for Granting, Maintaining, Extending, Reducing, Suspending and Withdrawing Accreditation:*

4.5.1 The accreditation body shall specify the conditions for granting, maintaining, extending, and reducing accreditation, and the conditions under which accreditation may be suspended or withdrawn, partially or in total, for all or part of the accredited body's scope of accreditation. In particular, the accreditation body shall require the body to notify it promptly of any intended changes to the quality system or other changes, which may affect conformity.

4.5.2 The accreditation body shall have procedures to do the following:

4.5.2.1 Grant, maintain, withdraw, and suspend accreditation;

4.5.2.2 Extend or reduce the scope of accreditation; and,

4.5.2.3 Conduct reassessment in the event of changes significantly affecting the activity and operation of the accredited body, such as change of ownership, changes in personnel or equipment, or if analysis of a complaint or any other information indicates that the accredited body no longer complies with the requirements of the accreditation body.

4.6 *Internal Audits and Management Reviews:*

4.6.1 The accreditation body shall conduct periodic internal audits covering all procedures in a planned and systematic manner to verify that the quality system is being implemented and is effective. The accreditation body shall ensure the following:

4.6.1.1 Personnel responsible for the area audited are informed of the outcome of the audit;