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Standard Guide for Calibration and Testing Laboratory Accreditation Systems General Requirements for Operation and Recognition

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1. Scope

1.1 This guide covers the general requirements for the operation of a system for accreditation of calibration and testing laboratories so that the accreditation 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 a national or international level as competent and reliable.

1.2 Users of the services of an accreditation body, other than the laboratories accredited by that accreditation body, may require compliance with additional requirements to those specified in this guide.

1.3 The object of this guide is to provide guidance for the set-up and operation of an accreditation body and to facilitate agreement on mutual recognition of accreditation of laboratories between such bodies.

NOTE 1—It is recognized that agreements on mutual recognition of accreditation aiming at the removal of barriers to across-border trade may have to cover other aspects not explicitly specified in these general requirements, such as proficiency testing or other interlaboratory comparisons, 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 laboratories accredited by it, and it should be prepared to exchange information on accreditation procedures and practices with other accreditation bodies.

1.4 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsiblity of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.* [1]

2. Referenced Documents

2.1 *ASTM Standards:*

E 548 Guide for Generic Criteria Used for Evaluating Laboratory Competence[2]

E 1187 Terminology Related to Laboratory Accreditation[2]

E 1301 Guide for Development and Operation of Proficiency Testing Programs[2]

2.2 *ISO Standards:*

ISO/IEC Guide 2, General Terms and Their Definitions Concerning Standardization and Related Activities

ISO/IEC Guide 25, General Requirements for the Competence of Calibration and Testing Laboratories[3]

ISO/IEC Guide 43, Development and Operation of Laboratory Proficiency Testing[3]

ISO Standard 10011-1 Guidelines for Auditing Quality Systems—Part 1: Auditing[3]

ISO Standard 10011-2 Guidelines for Auditing Quality Systems—Part 2: Qualification Criteria for Quality Systems Auditors[3]

ISO Standard 10011-3 Guidelines for Auditing Quality Systems—Part 3: Management of Audit Programmes[3]

3. Terminology

3.1 *Definitions:*

3.1.1 The relevant definitions contained in ISO/IEC Guide 2 and Terminology E 1187 are applicable. In addition, the following descriptions of terms apply for the purpose of this guide:

3.2 *Definitions of Terms Specific to This Standard:*

3.2.1 *accreditation*—procedure by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks.

3.2.2 *client*—an organization or person that engages the services of a calibration or testing laboratory.

3.2.3 *laboratory*—body that calibrates or tests, or both.

4. Significance and Use

4.1 The object of this guide is to provide guidance for the set-up and operation of an accreditation body and to facilitate agreements on mutual recognition of accreditation of laboratories between such bodies.

5. Accreditation Body

5.1 *General Provisions*:

5.1.1 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

[1] This guide is under the jurisdiction of ASTM Committee E-36 on Laboratory and Inspection Agency Evaluation and Accreditation and is the direct responsibility of Subcommittee E36.10 on Generic Criteria.

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[2] *Annual Book of ASTM Standards*, Vol 14.02.

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

body shall not be conditional upon membership of any association or group, nor shall there be undue financial conditions to restrict participation.

5.1.2 The competence of an applicant laboratory shall be assessed by the accreditation body against all of the requirements outlined in Guide E 548.

5.1.3 The requirements of Guide E 548 may have to be interpreted for a specific calibration, test or type of calibration or test by the accreditation body. These interpretations shall be formulated by relevant and impartial committees or persons possessing the necessary technical competence. They shall be published by the accreditation body.

5.1.4 The accreditation body shall require accredited laboratories to maintain impartiality, independence, and integrity.

5.1.5 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.

5.1.6 Accreditation does not, of itself, qualify the laboratory to approve any particular product. However, accreditation may be relevant to approval and certification authorities when they decide whether or not to accept data produced by a given laboratory in connection with their own activities.

5.2 *Organization of the Accreditation Body*:

5.2.1 The accreditation body shall:

5.2.1.1 Be a legally identifiable, public or private entity;

5.2.1.2 Have rights and responsibilities relevant to its accreditation activities;

5.2.1.3 Have adequate arrangements to cover liabilities arising from its operations or activities, or both;

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

5.2.1.5 Employ a sufficient number of personnel having the necessary education, training, technical knowledge, and experience for the type, range, and volume of work performed under a senior executive who is responsible to the organization, body, or board to which it reports;

5.2.1.6 Have a quality system including an organizational structure that enables it to give confidence in its ability to operate a laboratory accreditation system satisfactorily;

5.2.1.7 Have documented policies and procedures for the operation of the quality system that include policies and decision-making procedures that distinguish between laboratory accreditation and other activities in which the body is engaged; and policies and procedures for the resolution of complaints and appeals received from laboratories about the handling of accreditation matters, or from users of services about accredited laboratories or any other matters;

5.2.1.8 Together with its senior executive and staff, be free from any commercial, financial, or other pressures that might influence the results of the accreditation process;

5.2.1.9 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, or other pressures that might influence decisions or shall have a structure where members are chosen to provide impartiality through a balance of interest where no single interest predominates;

5.2.1.10 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. Criteria for these committees should be defined to ensure that adequate expertise and diversity of experience is considered. Public hearings may be necessary to ensure fair representation.

5.2.1.11 Not offer consultancies or other services that may compromise the objectivity of its accreditation process and decisions; and

5.2.1.12 Have arrangements that are consistent with applicable laws to safeguard, at all levels of its organization (including committees), confidentiality of the information obtained relating to applications, assessment, and accreditation of laboratories.

5.2.2 The accreditation body shall have arrangements for either controlling the ownership, use, and display of the accreditation documents or controlling the manner in which an accredited laboratory may refer to its accredited status, or both.

5.3 *Quality System*:

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

5.3.2 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:

5.3.2.1 A quality policy statement;

5.3.2.2 The organizational structure of the accreditation body;

5.3.2.3 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;

5.3.2.4 Administrative procedures, including documentation control;

5.3.2.5 Policies and procedures to implement the accreditation process;

5.3.2.6 Arrangements for feedback and corrective actions whenever discrepancies are detected;

5.3.2.7 The policy and procedure for dealing with appeals, complaints, and disputes;

5.3.2.8 The policy and procedures for conducting internal audits;

5.3.2.9 The policy and procedures for conducting quality system reviews; and

5.3.2.10 The policy and procedures for recruitment and training of assessors and monitoring their performance.

5.3.3 The activities of the accreditation body be audited to verify that they comply with the requirements of the quality system. The quality system shall also be reviewed to ensure its continued effectiveness. Audits and reviews shall be carried out systematically and periodically and recorded together with details of any corrective action taken. Criteria for the auditing program and the selection of the auditor(s) should be defined.

NOTE 2—Guidance on auditing programs and auditors may be obtained from ISO 10011-1, 10011-2, and 10011-3.

5.3.4 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 should form part of the record.

5.3.5 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 5.2.1 of this guide.

5.4 Granting, maintaining, extending, suspending, and withdrawing accreditation.

5.4.1 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 laboratory's scope of accreditation.

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

5.4.3 The accreditation body shall have arrangements relating to the transfer of accreditation when the legal status (for example, ownership) of the accredited laboratory changes.

5.5 *Documentation*:

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

5.5.1.1 Information about the authority under which accreditation systems operated by the accreditation body were established and specifying whether they are mandatory or voluntary;

5.5.1.2 A document containing its requirements for accreditation in accordance with this guide;

5.5.1.3 A document stating the arrangement for granting, maintaining, extending, suspending and withdrawing accreditation;

5.5.1.4 Information about the assessment and accreditation process;

5.5.1.5 General information on the fees charged to applicant and accredited laboratories;

5.5.1.6 A description of the rights and duties of accredited laboratories as specified in 8.1, 8.2, and 8.3 of this guide, including requirements, restrictions, or limitations on the use of the accrediting body's logo and on the ways of referring to the accreditation granted.

6. Laboratory Assessors

6.1 *Requirements for Assessors*—The assessor or assessment team appointed to assess a laboratory shall:

6.1.1 Be familiar with the relevant legal regulations, accreditation procedures, and accreditation requirements;

6.1.2 Have a thorough knowledge of the relevant assessment method and assessment documents;

6.1.3 Have appropriate technical knowledge of the specific calibrations, tests or types of calibrations or tests for which accreditation is sought and, where relevant, with the associated sampling procedures;

6.1.4 Be able to communicate effectively, both in writing and orally;

6.1.5 Be free of any commercial, financial, or other pressures or conflicts of interest that might cause an assessor(s) to act in other than an impartial or non-discriminatory manner.

6.1.6 Not have offered consultancies to laboratories that might compromise their impartiality in the accreditation process and decisions.

NOTE 3—Guidance on personal attributes of assessors may be obtained from ISO 10011-2, Clause 7.

6.2 *Qualification Procedures*—The accreditation body shall have an adequate procedure for:

6.2.1 Qualifying assessors, comprising an assessment of their competence and training, attendance at one or more actual assessments with a qualified assessor, and

6.2.2 Monitoring the performance of assessors.

6.3 *Contracting of Assessors*—The accreditation body shall require the assessors to sign a contract or other document by which they commit themselves to comply with the rules defined by the accreditation body, including those relating to confidentiality and those relating to independence from commercial and other interests, and any prior association with laboratories to be assessed.

6.4 *Assessor Records*—The accreditation body shall possess and maintain up-to-date records on assessors consisting of:

6.4.1 Name and address;

6.4.2 Organization affiliation and position held;

6.4.3 Educational qualification and professional status;

6.4.4 Work experience;

6.4.5 Training in quality assurance, assessment, and calibration;

6.4.6 Experience in laboratory assessment, together with field of competence; and

6.4.7 Date of most recent updating of record.

6.5 *Procedures for Assessors*—Assessors shall be provided with an up-to-date set of procedures giving assessment instructions and all relevant information on accreditation arrangements.

7. Accreditation Process

7.1 *Application for Accreditation*:

7.1.1 A detailed description of the assessment and accreditation procedure, the documents containing the requirements for accreditation and documents describing the rights and duties of accredited laboratories (including fees to be paid by applicant and accredited laboratories) shall be maintained up-to-date and given to applicant laboratories.

7.1.2 Additional relevant information shall be provided to applicant laboratories on request.

7.1.3 A duly authorized representative of the applicant laboratory shall be required to sign an official application form, in which or attached to which: