# GUIDE 58

# Calibration and testing laboratory accreditation systems — General requirements for operation and recognition



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## Foreword

ISO (the International Organization for Standardization) and IEC (the International Electrotechnical Commission) together form a system for worldwide standardization as a whole. National bodies that are members of ISO or IEC participate in the development of International Standards through technical committees established by the respective organization to deal with particular fields of technical activity. ISO and IEC technical committees collaborate in fields of mutual interest. Other international organizations, governmental and non-governmental, in liaison with ISO and IEC, also take part in the work.

This Guide replaces ISO/IEC Guide 54:1988, *Testing laboratory accreditation systems — General recommendations for the acceptance of accreditation bodies*, and ISO/IEC Guide 55:1988, *Testing laboratory accreditation systems — General recommendations for operation*. It was drawn up by the ISO Council Committee on conformity assessment, ISO/CASCO, on the basis of a draft transmitted by the International Laboratory Accreditation Conference (ILAC '90) and in collaboration with laboratory experts.

Its object is to provide guidance for the setting up and operation of a laboratory accreditation body and to facilitate agreements between such bodies on mutual recognition of accreditation of testing laboratories.

Whilst ISO/IEC Guides such as this are intended to provide guidance, it is hoped that any changes from the documents made in introducing systems nationally would be minimal. In recognition of the fact that some countries may choose to adopt the Guides directly, they are written to enable this to be done by including words such as "shall" to indicate those aspects which desirably would be mandatory. The overriding basis that the document is intended to provide guidance holds good.

It is only in recent years that national accreditation bodies have developed on a large scale because of the necessity to make available testing services of an assessed level of quality to all sectors of the economy and also to facilitate mutual acceptance of calibration and test results.

This Guide was approved by the ISO Council Committee on conformity assessment (ISO/CASCO) in September 1992 and by the IEC Council in October 1992.

# Calibration and testing laboratory accreditation systems — General requirements for operation and recognition

## 1 Scope

This document sets out the general requirements for the operation of a system for accreditation of calibration and/or testing laboratories 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 the services of an accreditation body, other than the laboratories accredited by that accreditation body, may require compliance with requirements additional to those specified in this document.

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

NOTE – It is recognized that agreements on mutual recognition of accreditations 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 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 laboratories accredited by it, and it should be prepared to exchange information on accreditation procedures and practices with other accreditation bodies.

## 2 References

ISO/IEC Guide 2:1991, *General terms and their definitions concerning standardization and related activities.*

ISO/IEC Guide 25:1990, *General requirements for the competence of calibration and testing laboratories.*

ISO/IEC Guide 43:1984, *Development and operation of laboratory proficiency testing.*

ISO 8402, *Quality management and quality assurance — Vocabulary.*

ISO 10011-1:1990, *Guidelines for auditing quality systems — Part 1: Auditing.*

ISO 10011-2:1991, *Guidelines for auditing quality systems — Part 2: Qualification criteria for quality systems auditors.*

## 3 Definitions

The relevant definitions contained in ISO/IEC Guide 2 are applicable.

In addition, the following definitions apply for the purposes of this document:

**3.1 laboratory:** Body that calibrates and/or tests.

[3.1 of ISO/IEC Guide 25:1990]

**3.2 accreditation:** Procedure by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks.

NOTE – 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.

[13.7 of ISO/IEC Guide 2:1991, with the addition of a note]

For the purposes of this document the term "client" refers to any organization or person that engages the services of a calibration or testing laboratory.

## 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 laboratory 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 laboratory shall be assessed by the accreditation body against all of the requirements of ISO/IEC Guide 25.

**4.1.3** The requirements of ISO/IEC Guide 25 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.

**4.1.4** The accreditation body shall require accredited laboratories to maintain impartiality and integrity.

**4.1.5** 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.

## 4.2 Organization of the accreditation body

**4.2.1** The accreditation body shall

a) be a legally identifiable, public or private entity;

b) have rights and responsibilities relevant to its accreditation activities;

c) have adequate arrangements to cover liabilities arising from its operations and/or activities;

d) have the financial stability and resources required for the operation of an accreditation system;

e) have and make available on request a description of the means by which it receives its financial support;

f) 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 a senior executive who is responsible to the organization, body or board to which it reports;

g) have a quality system, including an organizational structure, that enables it to give confidence in its ability to operate a laboratory accreditation system satisfactorily;

h) 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 any other activities in which the body is engaged;

— 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;

i) 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;

j) 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;

k) 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;

l) not offer consultancies or other services which may compromise the objectivity of its accreditation process and decisions;

m) 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.

**4.2.2** 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.

## 4.3 Quality system

**4.3.1** 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 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.

**4.3.2** 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:

a) a quality policy statement;

b) the organizational structure of the accreditation body;

c) 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;

d) administrative procedures including document control;

e) policies and procedures to implement the accreditation process;

f) arrangements for feedback and corrective actions whenever discrepancies are detected;

g) the policy and procedures for dealing with appeals, complaints and disputes;

h) the policy and procedures for conducting internal audits;

i) the policy and the procedures for conducting quality system reviews;

j) the policy and the procedures for the recruitment and training of assessors and monitoring their performance.

**4.3.3** The accreditation body shall audit its activities 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 actions taken.

**4.3.4** The accreditation body shall maintain records to demonstrate that accreditation procedures have been ef-

fectively 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.

**4.3.5** 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 4.2.1 m) of this document.

### 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 laboratory'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 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.



**4.4.3** The accreditation body shall have arrangements relating to the transfer of accreditation when the legal status (e.g. ownership) of the accredited laboratory changes.



### 4.5 Documentation

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

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

b) a document containing its requirements for accreditation in accordance with the present document;

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 applicant and accredited laboratories;

f) a description of the rights and duties of accredited laboratories as specified in 7.1, 7.2 and 7.3 of this document, including requirements, restrictions or limitations on the use of the accrediting body's logo and on the ways of referring to the accreditation granted.

## 5 Laboratory assessors

### 5.1 Requirements for assessors

The assessor or assessment team appointed to assess a laboratory shall

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

b) have a thorough knowledge of the relevant assessment method and assessment documents;

c) 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;

d) be able to communicate effectively, both in writing and orally;

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

f) not have offered consultancies to laboratories which might compromise their impartiality in the accreditation process and decisions.

NOTE – Guidance on personal attributes of assessors may be obtained from ISO 10011-2:1991, clause 7.

### 5.2 Qualification procedures for assessors

The accreditation body shall have an adequate procedure for

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

b) monitoring the performance of assessors.

### 5.3 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.

### 5.4 Assessor records

The accreditation body shall possess and maintain up-to-date records on assessors consisting of

a) name and address;

b) organization affiliation and position held;

c) educational qualification and professional status;

d) work experience;

e) training in quality assurance, assessment and calibration and testing;

f) experience in laboratory assessment, together with field of competence;

g) date of most recent updating of record.

### 5.5 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.

## 6 Accreditation process

### 6.1 Application for accreditation

**6.1.1** 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.

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

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

a) the scope of the desired accreditation is clearly defined;

b) the applicant's representative agrees to fulfil the accreditation procedure, especially to receive the assessment team, to pay the fees charged to the applicant laboratory whatever the result of the assessment may be, and to accept the charges of subsequent maintenance of the accreditation of the laboratory;

c) the applicant agrees to comply with the requirements for accreditation and to supply any information needed for the evaluation of the laboratory.

**6.1.4** The following minimum information shall be provided by the applicant laboratory prior to the on-site assessment:

a) the general features of the applicant laboratory (corporate entity: name, address, legal status, human and technical resources);

b) general information concerning the laboratory covered by the application, such as primary function, relationship in a larger corporate entity and, if applicable, physical location of laboratories involved;

c) a definition, for the calibrations concerned, of the type of measurement performed, the measurement range and best measurement capability, and for tests, of the materials or products tested, the methods used and the tests performed;

d) a copy of the laboratory's quality manual and, where required, the associated documentation.

The information gathered shall be used for the preparation of on-site assessment and shall be treated with appropriate confidentiality.

### 6.2 Assessment

**6.2.1** The accreditation body shall appoint qualified assessor(s) to evaluate all material collected from the applicant and to conduct the assessment on its behalf at the laboratory and any other sites where activities to be covered by the accreditation are performed.

**6.2.2** To ensure that a comprehensive and correct assessment is carried out, each assessor shall be provided with the appropriate working documents.

**6.2.3** The date of assessment shall be mutually agreed with the applicant laboratory. The latter shall be informed of the name(s) of the qualified assessor(s) nominated to carry out the assessment, with sufficient notice so that the laboratory is given an opportunity to appeal against the appointment of any particular assessor.

**6.2.4** The assessor(s) shall be formally appointed. A lead assessor shall be appointed, if relevant. The mandate given to the assessor(s) shall be clearly defined and made known to the applicant laboratory.

NOTE – Guidance on procedures for assessment may be obtained in ISO 10011-1:1990, clause 5.



### 6.3 Sub-contracting of assessment

**6.3.1** If an accreditation body decides to delegate fully or partially the assessment of a laboratory to another body, then the accreditation body shall take full responsibility for such an assessment made on its behalf.

**6.3.2** The accreditation body shall ensure that any body to which assessment has been delegated is competent and complies with the applicable provisions of this document.

### 6.4 Assessment report

**6.4.1** The accreditation body may adopt reporting procedures that suit its needs but as a minimum these procedures shall ensure that:

a) a meeting takes place between the assessor or assessment team and the laboratory management prior to leaving the laboratory, at which the assessment team provides a written or oral report on the compliance of the applicant laboratory with the accreditation requirements;

b) the assessor or assessment team provides the accreditation body with a detailed assessment report containing all relevant information concerning the ability of the applicant laboratory to comply with all of the accreditation requirements, including any which may come about from the results of proficiency testing;

c) a report on the outcome of the assessment is promptly brought to the applicant laboratory's notice by the accreditation body, identifying any non-compliances that have to be discharged in order to comply with all of

the accreditation requirements. The laboratory shall be invited to present its comments on this report and to describe the specific actions taken, or planned to be taken within a defined time, to remedy any non-compliances with the accreditation requirements identified during the assessment.

**6.4.2** The final report authorized by the accreditation body and submitted to the laboratory, if it is different, shall include as a minimum:

a) date(s) of assessment(s);

b) the name(s) of the person(s) responsible for the report;

c) the names and addresses of all the laboratory sites assessed;

d) the assessed scope of accreditation or reference thereto;

e) comments of the assessor(s) or assessment team on the compliance of the applicant laboratory with the accreditation requirements.

**6.4.3** The reports should take into consideration:

a) the technical qualification, experience and authority of the staff encountered, especially the persons responsible for the technical validity of calibration certificates, test reports or test certificates;

b) the adequacy of the internal organization and procedures adopted by the applicant laboratory to give confidence in the quality of its services, and of the physical facilities, i.e. the environment and the calibration/test equipment of the laboratory, including maintenance and calibration, having regard to the volume of work undertaken;

c) any proficiency testing or other interlaboratory comparison performed by the applicant laboratory, the results of this proficiency testing, and the use of these results by the laboratory;

d) the actions taken to correct any non-compliances identified at previous assessments.

### 6.5 Decision on accreditation

**6.5.1** The decision whether or not to accredit a laboratory shall be taken by the accreditation body on the basis of the information gathered during the accreditation process according to 4.2.1.

**6.5.2** The accreditation body shall not delegate its responsibility for granting, maintaining, extending, suspending or withdrawing accreditation.

### 6.6 Granting accreditation

**6.6.1** The accreditation body shall transmit to each accredited laboratory formal accreditation documents such as a letter or a certificate signed by an officer who has been assigned such responsibility. These formal accreditation documents shall permit identification of

a) the name and address of the laboratory that has been accredited;

b) the scope of the accreditation, including:

1) the calibrations or tests, or types of calibration or test, for which accreditation has been granted;

2) for calibrations, the type of measurement performed, the measurement range and best measurement capability;

3) for tests, the materials or products tested, the methods used and the tests performed;

4) for specific calibrations and tests for which accreditation has been granted, the methods used defined by written standards or reference documents that have been accepted by the accreditation body;

c) where appropriate, the persons recognized by the accreditation body as being responsible for the calibration certificates, test certificates or test reports;

d) the effective date of accreditation, and the term of the accreditation if applicable;

e) the accredited laboratory by a unique number.

### 6.7 Surveillance and reassessment of accredited laboratories

**6.7.1** The accreditation body shall have an established documented programme consistent with the accreditation granted for carrying out periodic surveillance and reassessment at sufficiently close intervals to ensure that its accredited laboratories continue to comply with the accreditation requirements.

**6.7.2** Surveillance and reassessment procedures shall be consistent with those concerning the assessment of laboratories as described in this document.



### 6.8 Proficiency testing

**6.8.1** Laboratories shall be encouraged by the accreditation body to participate in proficiency testing or other interlaboratory comparisons.

**6.8.2** Proficiency testing or other interlaboratory comparisons may be organized by the accreditation body itself or by any other body judged competent. Proficiency testing should be consistent with the provisions contained in ISO/IEC Guide 43.

**6.8.3** Accredited laboratories shall participate in proficiency testing or other interlaboratory comparisons as required by the accreditation body. Their performance in such tests shall meet the requirements of the accreditation body.

### 6.9 Certificates or reports issued by accredited laboratories

**6.9.1** An accreditation body shall normally allow an accredited laboratory to refer to its accreditation in calibration certificates, test reports and test certificates that contain only the results of calibrations or tests, or types of calibration or test, for which accreditation is held.

**6.9.2** The accreditation body shall have a policy that defines the circumstances in which accredited laboratories are permitted to include, in calibration certificates, test reports or test certificates, the results of calibrations or

tests for which accreditation is not held and the results of sub-contracted calibrations or tests.

## 7 Relationship between accreditation body and laboratory

**7.1** The accreditation body shall have arrangements to ensure that the laboratory and its representatives afford such accommodation and cooperation as is necessary to enable the accreditation body to verify compliance with the requirements for accreditation. These arrangements shall include provision for examination of documentation and access to all calibration and testing areas, records and personnel for the purposes of assessment, surveillance, reassessment and resolution of complaints.

**7.2** The accreditation body shall require that an accredited laboratory

a) at all times complies with the relevant provisions of this document;

b) claims that it is accredited only in respect of services for which it has been granted accreditation and which are carried out in accordance with these conditions;

c) pays such fees as shall be determined by the accreditation body;

d) does not use its accreditation in such a manner as to bring the accreditation body into disrepute and does not make any statement relevant to its accreditation which the accreditation body may consider misleading or unauthorized;

e) upon suspension or withdrawal of its accreditation (however determined) forthwith discontinues its use of all advertising matter that contains any reference thereto and returns any certificates of accreditation to the accreditation body;

f) does not use its accreditation to imply product approval by the accreditation body;

g) endeavours to ensure that no certificate or report nor any part thereof is used in a misleading manner;

h) in making reference to its accreditation status in communication media such as advertising, brochures or other documents, complies with the requirements of the accreditation body.

### 7.3 Notification of change

**7.3.1** The accreditation body shall have arrangements to ensure that an accredited laboratory informs it without delay of changes in any aspect of the laboratory's status or operation that affects the laboratory's

a) legal, commercial or organizational status;

b) organization and management, e.g. key managerial staff;

c) policies or procedures, where appropriate;

d) premises;

e) personnel, equipment, facilities, working environment or other resources, where significant;

f) authorized signatories;

or other such matters that may affect the laboratory's capability, or scope of accredited activities, or compliance with the requirements in this document or any other relevant criteria of competence specified by the accreditation body.



**7.3.2** Upon receipt of due notice of any intended changes relating to the requirements of this document, the relevant criteria of competence and any other requirements prescribed by the accreditation body, the accreditation body shall ensure that the laboratory carries out the necessary adjustments to its procedures within such time as, in the opinion of the body, is reasonable. The laboratory shall notify the body when such adjustments have been made.



### 7.4 Directory of accredited laboratories

The accreditation body shall produce periodically a directory of accredited laboratories describing the accreditation granted.

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