
**Conformity assessment — General
requirements for accreditation bodies
accrediting conformity assessment
bodies**

*Évaluation de la conformité — Exigences générales pour les organes
d'accréditation procédant à l'accréditation des organes d'évaluation de
la conformité*

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Foreword

ISO (the International Organization for Standardization) and IEC (the International Electrotechnical Commission) form the specialized system for worldwide standardization. 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 or technical activity. ISO and IEC technical committees collaborate in fields of mutual interest. Other International Organization, governmental and non-governmental, in liaison with ISO and IEC, also take part in the work. In the field of conformity assessment, the ISO Committee on conformity assessment (CASCO) is responsible for the development of International Standards and Guides.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. 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.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO/IEC 17011 was prepared by the ISO, *Committee on conformity assessment (CASCO)*.

This first edition of ISO/IEC 17011 cancels and replaces ISO/IEC Guide 58, ISO/IEC Guide 61, and ISO/IEC/TR 17010. Many accreditation bodies requested this revision because, for quite similar activities, they have had to comply with three sets of largely repetitious but slightly differing, requirements for the same attributes.

Introduction

In the regulatory sector, government authorities implement laws covering the approval of products (including services) for reasons of safety, health, environmental protection, fraud prevention or market fairness. In the voluntary sector, many lines of industry have, both within an economy as well as globally, set up systems for conformity assessment and approval, aiming at achieving a minimum technical level, enabling comparability, and also ensuring competition on equal terms.

A prerequisite for trade on equal terms is that any product (including services), accepted formally in one economy, must also be free to circulate in other economies without having to undergo extensive re-testing, re-inspection, re-certification, etc. This should be the case regardless of whether the product (including services) falls wholly or partly under the regulatory sector.

In today's society it is often required to state objectively conformity of products (including services) to specified requirements. Conformity assessment bodies (CABs) can objectively state such conformity. These CABs perform conformity assessment activities that include certification, inspection, testing and, in the context of this International Standard, calibration.

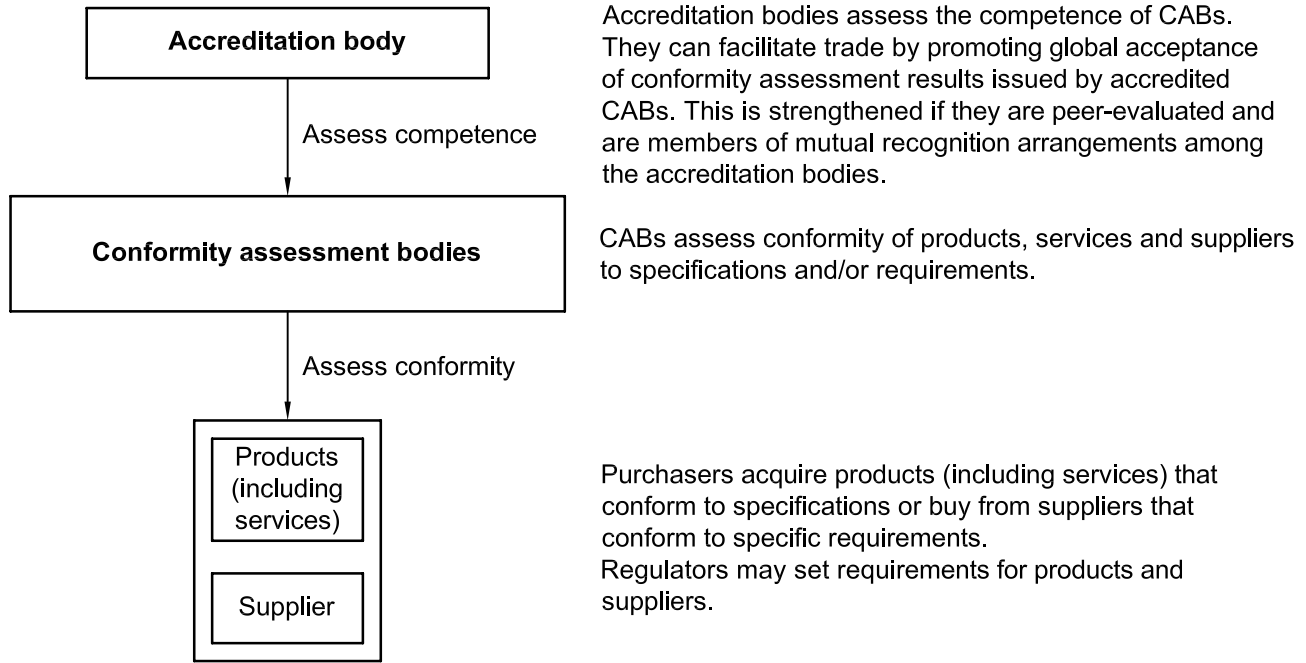
It is important for the purchaser, regulator and the public to know that these CABs are competent to perform their tasks. For that reason there is an increasing demand for impartial verification of their competence. Such verification is done by authoritative accreditation bodies that are impartial in relation to both the CABs and their clients, and which normally operate in a non-profit distributing manner (see Figure 1).

A system to accredit CAB conformity assessment services should provide confidence to the purchaser and regulator. Such a system should facilitate cross-border trade, as pursued by trade authorities and organizations. The ultimate goal is to achieve one-stop accreditation and one-stop conformity assessment.

A "cross border" trade facilitating system can work well if accreditation bodies and CABs all operate to globally accepted requirements in an equivalent manner and take into account the interests of all parties concerned.

This International Standard specifies the general requirements for accreditation bodies. Peer evaluation mechanisms have been created at regional and international levels, through which assurance is provided that accreditation bodies are operating in accordance with this International Standard. Those who have passed such an evaluation can become members of mutual recognition arrangements. Through regular re-evaluations, the continued adherence to this International Standard is assured.

These mutual recognition arrangement members facilitate the one-stop process, through recognition, promotion and acceptance of each other's accredited conformity assessments. This means that a CAB in an economy should not need to be accredited more than once for the same scope by different accreditation bodies.



NOTE The word supplier is used to mean provider of products (including services).

Figure 1 — Flowchart

Conformity assessment — General requirements for accreditation bodies accrediting conformity assessment bodies

1 Scope

This International Standard specifies general requirements for accreditation bodies assessing and accrediting conformity assessment bodies (CABs). It is also appropriate as a requirements document for the peer evaluation process for mutual recognition arrangements between accreditation bodies.

Accreditation bodies operating in accordance with this International Standard do not have to offer accreditation to all types of CABs.

For the purposes of this International Standard, CABs are organizations providing the following conformity assessment services: testing, inspection, management system certification, personnel certification, product certification and, in the context of this International Standard, calibration.

NOTE General requirements for these bodies have been established, for example in International Standards and Guides (examples of which are given in the Bibliography).

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 9000:2000, *Quality management systems — Fundamentals and vocabulary*

ISO/IEC 17000:2004, *Conformity assessment — Vocabulary and general principles*

VIM:1993, *International vocabulary of basic and general terms in metrology*, issued by BIPM, IEC, IFCC, ISO, IUPAC, IUPAP and OIML

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO/IEC 17000 and the following apply. Where the terms and definitions are neither included in this document nor in ISO/IEC 17000, the terms and definitions of ISO 9000 or the International vocabulary of basic and general terms in metrology (VIM) apply. If different definitions for specific metrological terms are given, the definitions of VIM have preference.

3.1

accreditation

third-party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks

3.2

accreditation body

authoritative body that performs accreditation

NOTE The authority of an accreditation body is generally derived from government.

3.3

accreditation body logo

logo used by an accreditation body to identify itself

3.4

accreditation certificate

formal document or a set of documents, stating that accreditation has been granted for the defined scope

3.5

accreditation symbol

symbol issued by an accreditation body to be used by accredited CABs to indicate their accredited status

NOTE "Mark" is to be reserved to indicate direct conformity of an entity against a set of requirements.

3.6

appeal

request by a CAB for reconsideration of any adverse decision made by the accreditation body related to its desired accreditation status

NOTE Adverse decisions include

- refusal to accept an application,
- refusal to proceed with an assessment,
- corrective action requests,
- changes in accreditation scope,
- decisions to deny, suspend or withdraw accreditation, and
- any other action that impedes the attainment of accreditation .

3.7

assessment

process undertaken by an accreditation body to assess the competence of a CAB, based on particular standard(s) and/or other normative documents and for a defined scope of accreditation

NOTE Assessing the competence of a CAB involves assessing the competence of the entire operations of the CAB, including the competence of the personnel, the validity of the conformity assessment methodology and the validity of the conformity assessment results.

3.8

assessor

person assigned by an accreditation body to perform, alone or as part of an assessment team, an assessment of a CAB

3.9

complaint

expression of dissatisfaction, other than appeal, by any person or organization, to an accreditation body, relating to the activities of that accreditation body or of an accredited CAB, where a response is expected

3.10

conformity assessment body

CAB

body that performs conformity assessment services and that can be the object of accreditation

NOTE Whenever the word "CAB" is used in the text, it applies to both the "applicant and accredited CABs" unless otherwise specified.

3.11**consultancy**

participation in any of the activities of a CAB subject to accreditation

EXAMPLES:

- preparing or producing manuals or procedures for a CAB;
- participating in the operation or management of the system of a CAB;
- giving specific advice or specific training towards the development and implementation of the management system and/or competence of a CAB;
- giving specific advice or specific training for the development and implementation of the operational procedures of a CAB.

3.12**expert**

person assigned by an accreditation body to provide specific knowledge or expertise with respect to the scope of accreditation to be assessed

3.13**extending accreditation**

process of enlarging the scope of accreditation

3.14**interested parties**

parties with a direct or indirect interest in accreditation

NOTE Direct interest refers to the interest of those who undergo accreditation; indirect interest refers to the interests of those who use or rely on accredited conformity assessment services.

3.15**lead assessor**

assessor who is given the overall responsibility for specified assessment activities

3.16**reducing accreditation**

process of cancelling accreditation for part of the scope of accreditation

3.17**scope of accreditation**

specific conformity assessment services for which accreditation is sought or has been granted

3.18**surveillance**

set of activities, except reassessment, to monitor the continued fulfilment by accredited CABs of requirements for accreditation

NOTE Surveillance includes both surveillance on-site assessments and other surveillance activities, such as the following:

- a) enquiries from the accreditation body to the CAB on aspects concerning the accreditation;
- b) reviewing the declarations of the CAB with respect to what is covered by the accreditation;
- c) requests to the CAB to provide documents and records (e.g. audit reports, results of internal quality control for verifying the validity of CAB services, complaints records, management review records);
- d) monitoring the performance of the CAB (such as results of participating in proficiency testing).

3.19

suspending accreditation

process of temporarily making accreditation invalid, in full or for part of the scope of accreditation

3.20

withdrawing accreditation

process of cancelling accreditation in full

3.21

witnessing

observation of the CAB carrying out conformity assessment services within its scope of accreditation

4 Accreditation body

4.1 Legal responsibility

The accreditation body shall be a registered legal entity.

NOTE Governmental accreditation bodies are deemed to be legal entities on the basis of their governmental status. Where the governmental accreditation body is part of a larger governmental entity, the government is responsible for identifying the accreditation body in a way that no conflict of interest with governmental CABs occur. This accreditation body is deemed to be the "registered legal entity" in the context of this International Standard.

4.2 Structure

4.2.1 The structure and operation of an accreditation body shall be such as to give confidence in its accreditations.

4.2.2 The accreditation body shall have authority and shall be responsible for its decisions relating to accreditation, including the granting, maintaining, extending, reducing, suspending and withdrawing of accreditation.

4.2.3 The accreditation body shall have a description of its legal status, including the names of its owners if applicable, and, if different, the names of the persons who control it.

4.2.4 The accreditation body shall document the duties, responsibilities and authorities of top management and other personnel associated with the accreditation body who could affect the quality of the accreditation.

4.2.5 The accreditation body shall identify the top management having overall authority and responsibility for each of the following:

- a) development of policies relating to the operation of the accreditation body;
- b) supervision of the implementation of the policies and procedures;
- c) supervision of the finances of the accreditation body;
- d) decisions on accreditation;
- e) contractual arrangements;
- f) delegation of authority to committees or individuals, as required, to undertake defined activities on behalf of top management.

4.2.6 The accreditation body shall have access to necessary expertise for advising the accreditation body on matters directly relating to accreditation.

NOTE Access to the necessary expertise may be obtained through one or more advisory committees (either ad-hoc or permanent), each responsible within its scope.

4.2.7 The accreditation body shall have formal rules for the appointment, terms of reference and operation of committees that are involved in the accreditation process, and shall identify the parties participating.

4.2.8 The accreditation body shall document its entire structure, showing lines of authority and responsibility.

4.3 Impartiality

4.3.1 The accreditation body shall be organized and operated so as to safeguard the objectivity and impartiality of its activities.

4.3.2 For safeguarding impartiality and for developing and maintaining the principles and major policies of operation of its accreditation system, the accreditation body shall have documented and implemented a structure to provide opportunity for effective involvement by interested parties. The accreditation body shall ensure a balanced representation of interested parties with no single party predominating.

4.3.3 The accreditation body's policies and procedures shall be non-discriminatory and shall be administered in a non-discriminatory way. The accreditation body shall make its services accessible to all applicants whose requests for accreditation fall within the activities (see 4.6.1) and the limitations as defined within its policies and rules. Access shall not be conditional upon the size of the applicant CAB or membership of any association or group, nor shall accreditation be conditional upon the number of CABs already accredited.

4.3.4 All accreditation body personnel and committees that could influence the accreditation process shall act objectively and shall be free from any undue commercial, financial and other pressures that could compromise impartiality.

4.3.5 The accreditation body shall ensure that each decision on accreditation is taken by competent person(s) or committee(s) different from those who carried out the assessment.

4.3.6 The accreditation body shall not offer or provide any service that affects its impartiality, such as

- a) those conformity assessment services that CABs perform, or
- b) consultancy.

The accreditation body's activities shall not be presented as linked with consultancy. Nothing shall be said or implied that would suggest that accreditation would be simpler, easier, faster or less expensive if any specified person(s) or consultancy were used.

4.3.7 The accreditation body shall ensure that the activities of its related bodies do not compromise the confidentiality, objectivity and impartiality of its accreditations. A related body may, however, offer consultancy or provide those conformity assessment services the accreditation body accredits, subject to the related body having (with respect to the accreditation body)

- a) different top management for the activities described in 4.2.5,
- b) personnel different from those involved in the decision-making processes of accreditation,
- c) no possibility to influence the outcome of an assessment for accreditation, and
- d) distinctly different name, logos and symbols.

The accreditation body, with the participation of the interested parties as described in 4.3.2, shall identify, analyse and document the relationships with related bodies to determine the potential for conflict of interest, whether they arise from within the accreditation body or from the activities of the related bodies. Where conflicts are identified, appropriate action shall be taken.

NOTE 1 A related body is a separate legal entity that is linked by common ownership or contractual arrangements to the accreditation body as described in 4.1.

NOTE 2 A separate part of the government, outside the governmental accreditation body as described in 4.1, is considered as a related body.

4.4 Confidentiality

The accreditation body shall have adequate arrangements to safeguard the confidentiality of the information obtained in the process of its accreditation activities at all levels of the accreditation body, including committees and external bodies or individuals acting on its behalf. The accreditation body shall not disclose confidential information about a particular CAB outside the accreditation body without written consent of the CAB, except where the law requires such information to be disclosed without such consent.

4.5 Liability and financing

4.5.1 The accreditation body shall have arrangements to cover liabilities arising from its activities.

4.5.2 The accreditation body shall have the financial resources, demonstrated by records and/or documents, required for the operation of its activities. The accreditation body shall have a description of its source(s) of income.

4.6 Accreditation activity

4.6.1 The accreditation body shall clearly describe its accreditation activities, referring to the relevant International Standards, Guides or other normative documents.

4.6.2 The accreditation body may adopt application or guidance documents and/or participate in the development of them. The accreditation body shall ensure that such documents have been formulated by committees or persons possessing the necessary competence and, where appropriate, with participation of interested parties. Where international application or guidance documents are available, these should be used.

4.6.3 The accreditation body shall establish procedures for extending its activities and to react to demands of interested parties. Possible elements to be included in the procedures are

- a) analysis of its present competence, suitability of extension, resources, etc. in the new field,
- b) accessing and employing expertise from other external sources,
- c) evaluating the need for application or guidance documents,
- d) initial selection and training of assessors, and
- e) training accreditation body's staff in the new field.

5 Management

5.1 General

5.1.1 The accreditation body shall establish, implement and maintain a management system and continually improve its effectiveness in accordance with the requirements of this International Standard. Requirements for the management system that take into account the particular nature of accreditation bodies are defined in 5.2 to 5.9.

5.1.2 Where this International Standard requires the accreditation body to have or establish procedures, this means that they shall be documented, implemented and maintained, and shall be based on formulated policies wherever suitable.

5.2 Management system

5.2.1 The accreditation body's top management shall define and document policies and objectives, including a quality policy, for its activities, and it shall provide evidence of commitment to quality and to compliance with the requirements of this International Standard. The management shall ensure effective communication of the needs of interested parties. The management shall also ensure that the policies are understood, implemented and maintained at all levels of the accreditation body. The objectives should be measurable and shall be consistent with the accreditation body's policies.

NOTE Those accreditation bodies that are signatories to a mutual recognition arrangement may refer to the obligations of the mutual recognition arrangement in their policies.

5.2.2 The accreditation body shall operate a management system appropriate to the type, range and volume of work performed. All applicable requirements of this International Standard shall be addressed either in a manual or in associated documents. The accreditation body shall ensure that the manual and relevant associated documents are accessible to its personnel and shall ensure effective implementation of the system's procedures.

5.2.3 The accreditation body's top management shall appoint a member of management who, irrespective of other responsibilities, shall have responsibility and authority that includes

- a) ensuring that procedures needed for the management system are established, and
- b) reporting to top management on the performance of the management system and any need for improvement.

5.3 Document control

The accreditation body shall establish procedures to control all documents (internal and external) that relate to its accreditation activities. The procedures shall define the controls needed

- a) to approve documents for adequacy prior to issue,
- b) to review and update as necessary and re-approve documents,
- c) to ensure that changes and the current revision status of documents are identified,
- d) to ensure that relevant versions of applicable documents are available to personnel, subcontractors, assessors and experts of the accreditation body and CABs at points of use,
- e) to ensure that documents remain legible and readily identifiable,
- f) to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose, and
- g) to safeguard, where relevant, the confidentiality of documents.

5.4 Records

5.4.1 The accreditation body shall establish procedures for identification, collection, indexing, accessing, filing, storage, maintenance and disposal of its records.

5.4.2 The accreditation body shall establish procedures for retaining records for a period consistent with its contractual and legal obligations. Access to these records shall be consistent with the confidentiality arrangements.

5.5 Nonconformities and corrective actions

The accreditation body shall establish procedures for the identification and management of nonconformities in its own operations. The accreditation body shall also, where necessary, take actions to eliminate the causes of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the impact of the problems encountered. The procedures shall cover the following:

- a) identifying nonconformities (e.g. from complaints and internal audits);
- b) determining the causes of nonconformity;
- c) correcting nonconformities;
- d) evaluating the need for actions to ensure that nonconformities do not recur;
- e) determining the actions needed and implementing them in a timely manner;
- f) recording the results of actions taken;
- g) reviewing the effectiveness of corrective actions.

5.6 Preventive actions

The accreditation body shall establish procedures to identify opportunities for improvement and to take preventive actions to eliminate the causes of potential nonconformities. The preventive actions taken shall be appropriate to the impact of the potential problems. The procedures for preventive actions shall define requirements for

- a) identifying potential nonconformities and their causes,
- b) determining and implementing the preventive actions needed,
- c) recording results of actions taken, and
- d) reviewing the effectiveness of the preventive actions taken.

5.7 Internal audits

5.7.1 The accreditation body shall establish procedures for internal audits to verify that they conform to the requirements of this International Standard and that the management system is implemented and maintained.

NOTE As an indication, ISO 19011 provides guidelines for conducting internal audits.

5.7.2 Internal audits shall be performed normally at least once a year. The frequency of internal audits may be reduced if the accreditation body can demonstrate that its management system has been effectively implemented according to this International Standard and has proven stability. An audit programme shall be planned, taking into consideration the importance of the processes and areas to be audited, as well as the results of previous audits.

5.7.3 The accreditation body shall ensure that

- a) internal audits are conducted by qualified personnel knowledgeable in accreditation, auditing and the requirements of this International Standard,
- b) internal audits are conducted by personnel different from those who perform the activity to be audited,
- c) personnel responsible for the area audited are informed of the outcome of the audit,
- d) actions are taken in a timely and appropriate manner, and
- e) any opportunities for improvement are identified.

5.8 Management reviews

5.8.1 The accreditation body's top management shall establish procedures to review its management system at planned intervals to ensure its continuing adequacy and effectiveness in satisfying the relevant requirements, including this International Standard and the stated policies and objectives. These reviews should be conducted normally at least once a year.

5.8.2 Inputs to management reviews shall include, where available, current performance and improvement opportunities related to the following:

- a) results of audits;
- b) results of peer evaluation where relevant;
- c) participation in international activities, where relevant;
- d) feedback from interested parties;
- e) new areas of accreditation;
- f) trends in nonconformities;
- g) status of preventive and corrective actions;
- h) follow-up actions from earlier management reviews;
- i) fulfilment of objectives;
- j) changes that could affect the management system;
- k) appeals;
- l) analysis of complaints.

5.8.3 The outputs from the management review shall include actions related to

- a) improvement of the management system and its processes,
- b) improvement of services and accreditation process in conformity with the relevant standards and expectations of interested parties,
- c) need for resources, and
- d) defining or redefining of policies, goals and objectives.

5.9 Complaints

The accreditation body shall establish procedures for dealing with complaints. The accreditation body

- a) shall decide on the validity of the complaint,
- b) shall, where appropriate, ensure that a complaint concerning an accredited CAB is first addressed by the CAB,
- c) shall take appropriate actions and assess their effectiveness,
- d) shall record all complaints and actions taken, and
- e) shall respond to the complainant.

6 Human resources

6.1 Personnel associated with the accreditation body

6.1.1 The accreditation body shall have a sufficient number of competent personnel (internal, external, temporary, or permanent, full time or part time) having the education, training, technical knowledge, skills and experience necessary for handling the type, range and volume of work performed.

6.1.2 The accreditation body shall have access to a sufficient number of assessors, including lead assessors, and experts to cover all of its activities.

6.1.3 The accreditation body shall make clear to each person concerned the extent and the limits of their duties, responsibilities and authorities.

6.1.4 The accreditation body shall require all personnel to commit themselves formally by a signature or equivalent to comply with the rules defined by the accreditation body. The commitment shall consider aspects relating to confidentiality and to independence from commercial and other interests, and any existing or prior association with CABs to be assessed.

6.2 Personnel involved in the accreditation process

6.2.1 The accreditation body shall describe for each activity involved in the accreditation process

- a) the qualifications, experience and competence required, and
- b) initial and ongoing training required.

6.2.2 The accreditation body shall establish procedures for selecting, training and formally approving assessors and experts used in the assessment process.

6.2.3 The accreditation body shall identify the specific scopes in which each assessor and expert has demonstrated competence to assess.

6.2.4 The accreditation body shall ensure that assessors and, where relevant, experts

- a) are familiar with accreditation procedures, accreditation criteria and other relevant requirements,
- b) have undergone a relevant accreditation assessor training,
- c) have a thorough knowledge of the relevant assessment methods,
- d) are able to communicate effectively, both in writing and orally, in the required languages, and
- e) have appropriate personal attributes.

NOTE Guidance on personal attributes may be found in publications such as ISO 19011.

6.3 Monitoring

6.3.1 The accreditation body shall ensure the satisfactory performance of the assessment and the accreditation decision-making process by establishing procedures for monitoring the performance and competence of the personnel involved. In particular, the accreditation body shall review the performance and competence of its personnel in order to identify training needs.

6.3.2 The accreditation body shall conduct monitoring (e.g. by on-site observations, or by using other techniques such as review of assessment reports, feedback from CABs and peer monitoring of assessors) to evaluate an assessor's performance and to recommend appropriate follow-up actions to improve performance. Each assessor shall be observed on-site regularly, normally every three years, unless there is sufficient supporting evidence that the assessor is continuing to perform competently.

6.4 Personnel records

6.4.1 The accreditation body shall maintain records of relevant qualifications, training, experience and competence of each person involved in the accreditation process. Records of training, experience and monitoring shall be kept up to date.

6.4.2 The accreditation body shall maintain up-to-date records on assessors and experts consisting of at least the following:

- a) name and address;
- b) position held and for external assessors and experts, the position held in their own organization;
- c) educational qualifications and professional status;
- d) work experience;
- e) training in management systems, assessment and conformity assessment activities;
- f) competence for specific assessment tasks;
- g) experience in assessment and results of their regular monitoring.

7 Accreditation process

7.1 Accreditation criteria and information

7.1.1 The general criteria for accreditation of CABs shall be those set out in the relevant normative documents such as International Standards and Guides for the operation of CABs.

7.1.2 The accreditation body shall make publicly available, and update at adequate intervals, the following:

- a) detailed information about its assessment and accreditation processes, including arrangements for granting, maintaining, extending, reducing, suspending and withdrawing accreditation;
- b) a document or reference documents containing the requirements for accreditation, including technical requirements specific to each field of accreditation, where applicable;
- c) general information about the fees relating to the accreditation;
- d) a description of the rights and obligations of CABs;
- e) information on the accredited CABs as described in 8.2.1;
- f) information on procedures for lodging and handling complaints and appeals;
- g) information about the authority under which the accreditation programme operates;
- h) a description of its rights and duties;
- i) general information about the means by which it obtains financial support;
- j) information about its activities and stated limitations under which it operates;
- k) information about the related bodies as described in 4.3.7, if applicable.

7.2 Application for accreditation

7.2.1 The accreditation body shall require a duly authorized representative of the applicant CAB to make a formal application that includes the following:

- a) general features of the CAB, including corporate entity, name, addresses, legal status and human and technical resources;
- b) general information concerning the CAB such as its activities, its relationship in a larger corporate entity if any, and addresses of all its physical location(s) to be covered by the scope of accreditation;
- c) a clearly defined, requested, scope of accreditation;
- d) an agreement to fulfil the requirements for accreditation and the other obligations of the CAB, as described in 8.1.

7.2.2 The accreditation body shall require the applicant CAB to provide at least the following information relevant to the accreditation prior to commencement of the assessment:

- a) a description of the conformity assessment services that the CAB undertakes, and a list of standards, methods or procedures for which the CAB seeks accreditation, including limits of capability where applicable;
- b) a copy (on paper or in electronic form) of the quality manual of the CAB, and relevant associated documents and records, such as information on participation in proficiency testing as described in 7.15, where applicable.

7.2.3 The accreditation body shall review for adequacy the information supplied by the CAB.

7.3 Resource review

7.3.1 The accreditation body shall review its ability to carry out the assessment of the applicant CAB, in terms of its own policy, its competence and the availability of suitable assessors and experts.

7.3.2 The review shall also include the ability of the accreditation body to carry out the initial assessment in a timely manner.

7.4 Subcontracting the assessment

7.4.1 The accreditation body shall normally undertake the assessment on which accreditation is based. The accreditation body shall not subcontract the decision-making. If the accreditation body subcontracts assessments, it shall have a policy describing the conditions under which subcontracting may take place. A properly documented agreement covering the arrangements, including confidentiality and conflict of interest, shall be drawn up.

NOTE Contracting of external individual assessors and experts is not to be considered as subcontracting.

7.4.2 The accreditation body

- a) shall take full responsibility for all subcontracted assessments and shall itself have competence in the decision-making,
- b) shall maintain its responsibility for granting, maintaining, extending, reducing, suspending or withdrawing accreditation,
- c) shall ensure that the body and its personnel involved in the assessment process, to which assessment has been subcontracted, are competent and comply with the applicable requirements of this International Standard and any provisions and guidelines given by the subcontracting accreditation body, and
- d) shall obtain the written consent of the CAB to use a particular subcontractor.

7.4.3 The accreditation body shall list the subcontractors it uses for assessments and shall have means for assessing and monitoring their competence and for recording the results.

7.5 Preparation for assessment

7.5.1 Before the initial assessment, a preliminary visit may be conducted with the agreement of the CAB. This visit may result in identification of deficiencies in the system of the applicant CAB or its competencies. The accreditation body shall have clear rules and shall exercise due care to avoid consultancy during such activities.

7.5.2 The accreditation body shall formally appoint an assessment team consisting of a lead assessor and, where required, a suitable number of assessors and/or experts for each specific scope. When selecting the assessment team, the accreditation body shall ensure that the expertise brought to each assignment is appropriate. In particular, the team as a whole

- a) shall have appropriate knowledge of the specific scope for which accreditation is sought, and
- b) shall have understanding sufficient to make a reliable assessment of the competence of the CAB to operate within its scope of accreditation.

7.5.3 The accreditation body shall ensure that team members act in an impartial and non-discriminatory manner. In particular,

- a) assessment team members shall not have provided consultancy to the CAB which might compromise the accreditation process and decision, and
- b) in accordance with the provisions of 6.1.4, the assessment team members shall inform the accreditation body, prior to the assessment, about any existing, former or envisaged link or competitive position between themselves or their organization and the CAB to be assessed.

7.5.4 The accreditation body shall inform the CAB of the names of the members of the assessment team and the organization they belong to, sufficiently in advance to allow the CAB to object to the appointment of any particular assessor or expert. The accreditation body shall have a policy for dealing with such objections.

7.5.5 The accreditation body shall clearly define the assignment given to the assessment team. The task of the assessment team is to review the documents collected from the CAB and to conduct the on-site assessment.

7.5.6 The accreditation body shall establish procedures for sampling (if applicable) where the scope of the CAB covers a variety of specific conformity assessment services. The procedures shall ensure that the assessment team witness a representative number of examples to ensure proper evaluation of the competence of the CAB.

7.5.7 For initial assessments, in addition to visiting the main or head office, visits shall be made to all other premises of the CAB from which one or more key activities are performed and which are covered by the scope of accreditation.

NOTE Key activities include: policy formulation, process and/or procedure development and, as appropriate, contract review, planning conformity assessments, review, approval and decision on the results of conformity assessments.

7.5.8 For surveillance and reassessment, where the CAB works from various premises, the accreditation body shall establish procedures for sampling to ensure proper assessment. All premises from which one or more key activities are performed should be assessed within a defined timeframe.

7.5.9 The accreditation body shall agree, together with the CAB and the assigned assessment team, to the date and schedule for the assessment. However, it remains the responsibility of the accreditation body to pursue a date that is in accordance with the surveillance and reassessment plan.

7.5.10 The accreditation body shall ensure that the assessment team is provided with the appropriate criteria documents, previous assessment records, and the relevant documents and records of the CAB.

7.6 Document and record review

7.6.1 The assessment team shall review all relevant documents and records supplied by the CAB (as described in 7.2.1 and 7.2.2) to evaluate its system, as documented, for conformity with the relevant standard(s) and other requirements for accreditation.

7.6.2 The accreditation body may decide not to proceed with an on-site assessment based on the nonconformities found during document and record review. In such cases, the nonconformities shall be reported in writing to the CAB.

7.7 On-site assessment

7.7.1 The assessment team shall commence the on-site assessment with an opening meeting at which the purpose of the assessment and accreditation criteria are clearly defined, and the assessment schedule as well as the scope for the assessment are confirmed.

7.7.2 The assessment team shall conduct the assessment of the conformity assessment services of the CAB at the premises of the CAB from which one or more key activities are performed and, where relevant, shall perform witnessing at other selected locations where the CAB operates, to gather objective evidence that the applicable scope the CAB is competent and conforms to the relevant standard(s) and other requirements for accreditation.

7.7.3 The assessment team shall witness the performance of a representative number of staff of the CAB to provide assurance of the competence of the CAB across the scope of accreditation.

7.8 Analysis of findings and assessment report

7.8.1 The assessment team shall analyse all relevant information and evidence gathered during the document and record review and the on-site assessment. This analysis shall be sufficient to allow the team to determine the extent of competence and conformity of the CAB with the requirements for accreditation. The team's observations on areas for possible improvement may also be presented to the CAB. However, consultancy shall not be provided.

7.8.2 Where the assessment team cannot reach a conclusion about a finding, the team should refer back to the accreditation body for clarification.

7.8.3 The accreditation body's reporting procedures shall ensure that the following requirements are fulfilled.

- a) A meeting shall take place between the assessment team and the CAB prior to leaving the site. At this meeting, the assessment team shall provide a written and/or oral report on its findings obtained from the analysis (see 7.8.1). An opportunity shall be provided for the CAB to ask questions about the findings, including nonconformities, if any, and their basis.
- b) A written report on the outcome of the assessment shall be promptly brought to the attention of the CAB. This assessment report shall contain comments on competence and conformity, and shall identify nonconformities, if any, to be resolved in order to conform with all of the requirements for accreditation.
- c) The CAB shall be invited to respond to the assessment report and to describe the specific actions taken or planned to be taken, within a defined time, to resolve any identified nonconformities.

7.8.4 The accreditation body shall remain responsible for the content of the assessment report, including nonconformities, even if the lead assessor is not a permanent staff member of the accreditation body.

7.8.5 The accreditation body shall ensure that the responses of the CAB to resolve nonconformities are reviewed to see if the actions appear to be sufficient and effective. If the CAB responses are found not to be sufficient, further information shall be requested. Additionally, evidence of effective implementation of actions

taken may be requested, or a follow-up assessment may be carried out to verify effective implementation of corrective actions.

7.8.6 The information provided to the accreditation decision-maker(s) shall include the following, as a minimum:

- a) unique identification of the CAB;
- b) date(s) of the on-site assessment;
- c) name(s) of the assessor(s) and/or experts involved in the assessment;
- d) unique identification of all premises assessed;
- e) proposed scope of accreditation that was assessed;
- f) the assessment report;
- g) a statement on the adequacy of the internal organization and procedures adopted by the CAB to give confidence in its competence, as determined through its fulfilment of the requirements for accreditation;
- h) information on the resolution of all nonconformities;
- i) any further information that may assist in determining fulfilment of requirements and the competence of the CAB;
- j) where applicable, a summary of the results of proficiency testing or other comparisons conducted by the CAB and any actions taken as a consequence of the results;
- k) where appropriate, a recommendation as to granting, reducing or extending accreditation for the proposed scope.

7.9 Decision-making and granting accreditation

7.9.1 The accreditation body shall, prior to making a decision, be satisfied that the information (see 7.8.6) is adequate to decide that the requirements for accreditation have been fulfilled.

7.9.2 The accreditation body shall, without undue delay, make the decision on whether to grant or extend accreditation on the basis of an evaluation of all information received (see 7.8.6) and any other relevant information.

7.9.3 Where the accreditation body uses the results of an assessment already performed by another accreditation body, it shall have assurance that the other accreditation body was operating in accordance with the requirements of this International Standard.

7.9.4 The accreditation body shall provide an accreditation certificate to the accredited CAB. This accreditation certificate shall identify (on the front page, if possible) the following:

- a) the identity and logo of the accreditation body;
- b) the unique identity of the accredited CAB;
- c) all premises from which one or more key activities are performed and which are covered by the accreditation;
- d) the unique accreditation number of the accredited CAB;
- e) the effective date of granting of accreditation and, as applicable, the expiry date;

- f) a brief indication of, or reference to, the scope of accreditation;
- g) a statement of conformity and a reference to the standard(s) or other normative document(s), including issue or revision used for assessment of the CAB.

7.9.5 The accreditation certificate shall also identify the following:

- a) for certification bodies:
 - 1) the type of certification,
 - 2) the standards or normative documents, or regulatory requirements or types thereof, to which products, personnel, services or management systems are certified, as applicable,
 - 3) industry sectors, where relevant,
 - 4) product categories, where relevant, and
 - 5) personnel categories, where relevant;
- b) for inspection bodies:
 - 1) the type of inspection body (e.g. as defined in ISO/IEC 17020),
 - 2) the field and range of inspection for which accreditation has been granted, and
 - 3) the regulations, standards or specifications or types thereof containing the requirements against which the inspection is to be performed, as applicable;
- c) for calibration laboratories:
 - 1) the calibrations, including the types of measurements performed, the measurement ranges and the best measurement capability (BMC) or equivalent¹⁾;
- d) for testing laboratories:
 - 1) the tests or types of tests performed and materials or products tested and, where appropriate, the methods used.

7.10 Appeals

7.10.1 The accreditation body shall establish procedures to address appeals by CABs.

7.10.2 The accreditation body

- a) shall appoint a person, or group of persons, to investigate the appeal who are competent and independent of the subject of the appeal,
- b) shall decide on the validity of the appeal,
- c) shall advise the CAB of the final decision(s) of the accreditation body,
- d) shall take follow-up action where required, and
- e) shall keep records of all appeals, of final decisions, and of follow-up actions taken.

1) The concept of best measurement capability is currently under review for inclusion in the VIM.

7.11 Reassessment and surveillance

7.11.1 Reassessment is similar to an initial assessment as described in 7.5 to 7.9, except that experience gained during previous assessments shall be taken into account. Surveillance on-site assessments are less comprehensive than reassessments.

7.11.2 The accreditation body shall establish procedures and plans for carrying out periodic surveillance on-site assessments, other surveillance activities and reassessments at sufficiently close intervals to monitor the continued fulfilment by the accredited CAB of the requirements for accreditation.

7.11.3 The accreditation body shall design its plan for reassessment and surveillance of each accredited CAB so that representative samples of the scope of accreditation are assessed on a regular basis.

The interval between on-site assessments, whether reassessment or surveillance, depends on the proven stability that the services of the CAB have reached.

Accreditation bodies shall rely on either reassessment alone or a combination of reassessment and surveillance, as follows:

- a) if based on reassessment alone, then the reassessment shall take place at intervals not exceeding 2 years; or
- b) if the combination of reassessment and surveillance is relied upon, then the accreditation body shall undertake a reassessment at least every 5 years. However, the interval between the surveillance on-site assessments should not exceed 2 years.

It is, however, recommended that the first surveillance on-site assessment be carried out no later than 12 months from the date of initial accreditation.

7.11.4 Surveillance on-site assessments shall be planned taking into account other surveillance activities.

7.11.5 When, during surveillance or reassessments, nonconformities are identified, the accreditation body shall define strict time limits for corrective actions to be implemented.

7.11.6 The accreditation body shall confirm the continuation of accreditation, or decide on the renewal of accreditation, based on the results of surveillance and reassessments described above.

7.11.7 The accreditation body may conduct extraordinary assessments as a result of complaints or changes (see 8.1.2), etc. The accreditation body shall advise CABs of this possibility.

7.12 Extending accreditation

The accreditation body shall, in response to an application for an extension of scope of an accreditation already granted, undertake the necessary activities to determine whether or not the extension may be granted. Where appropriate, assessment and granting procedures shall be as in defined in 7.5 to 7.9.

7.13 Suspending, withdrawing or reducing accreditation

7.13.1 The accreditation body shall establish procedures for the suspension, withdrawal or reduction of the scope of accreditation.

NOTE Depending on the type of conformity assessment, the rules set by the accreditation body may differ.

7.13.2 The accreditation body shall make decisions to suspend and/or withdraw accreditation when an accredited CAB has persistently failed to meet the requirements of accreditation or to abide by the rules for accreditation.

NOTE The CAB may ask for suspension or withdrawal of accreditation.

7.13.3 The accreditation body shall make decisions to reduce the scope of accreditation of the CAB to exclude those parts where the CAB has persistently failed to meet the requirements for accreditation, including competence.

NOTE The CAB may ask for reduction of its scope of accreditation.

7.14 Records on CABs

7.14.1 The accreditation body shall maintain records on CABs to demonstrate that requirements for accreditation, including competence, have been effectively fulfilled.

7.14.2 The accreditation body shall keep the records on CABs secure to ensure confidentiality. The records on CABs shall be managed appropriately in a manner as described in 5.4.

7.14.3 Records on CABs shall include

- a) relevant correspondence,
- b) assessment records and reports,
- c) records of committee deliberations, if applicable, and accreditation decisions, and
- d) copies of accreditation certificates.

7.15 Proficiency testing and other comparisons for laboratories

7.15.1 The accreditation body shall establish procedures to take into account, during the assessment and the decision-making process, the laboratory's participation and performance in proficiency testing.

7.15.2 The accreditation body may organize proficiency testing or other comparisons itself, or may involve another body judged to be competent. The accreditation body shall maintain a list of appropriate proficiency testing and other comparison programmes.

NOTE Guidelines on operation and selection of proficiency testing and related definitions exist in ISO/IEC Guide 43-1 and ISO/IEC Guide 43-2.

7.15.3 The accreditation body shall ensure that its accredited laboratories participate in proficiency testing or other comparison programmes, where available and appropriate, and that corrective actions are carried out when necessary. The minimum amount of proficiency testing and the frequency of participation shall be specified in cooperation with interested parties and shall be appropriate in relation to other surveillance activities.

NOTE 1 It is recognized that there are particular areas where proficiency testing is impractical.

NOTE 2 Proficiency testing may also be used in many types of inspection. Clause 7.15 should be read in this sense.

8 Responsibilities of the accreditation body and the CAB

8.1 Obligations of the CAB

8.1.1 The accreditation body shall require the CAB to conform to the following.

- a) The CAB shall commit to fulfil continually the requirements for accreditation set by the accreditation body for the areas where accreditation is sought or granted. This includes agreement to adapt to changes in the requirements for accreditation, as set out in 8.2.4.
- b) When requested, the CAB shall afford such accommodation and cooperation as is necessary to enable the accreditation body to verify fulfilment of requirements for accreditation. This applies to all premises where the conformity assessment services take place.

- c) The CAB shall provide access to information, documents and records as necessary for the assessment and maintenance of the accreditation.
- d) The CAB shall provide access to those documents that provide insight into the level of independence and impartiality of the CAB from its related bodies, where applicable.
- e) The CAB shall arrange the witnessing of CAB services when requested by the accreditation body.
- f) The CAB shall claim accreditation only with respect to the scope for which it has been granted accreditation.
- g) The CAB shall not use its accreditation in such a manner as to bring the accreditation body into disrepute.
- h) The CAB shall pay fees as shall be determined by the accreditation body.

8.1.2 The accreditation body shall require that it is informed by the accredited CAB, without delay, of significant changes relevant to its accreditation, in any aspect of its status or operation relating to

- a) its legal, commercial, ownership or organizational status,
- b) the organization, top management and key personnel,
- c) main policies,
- d) resources and premises,
- e) scope of accreditation, and
- f) other such matters that may affect the ability of the CAB to fulfil requirements for accreditation.

8.2 Obligations of the accreditation body

8.2.1 The accreditation body shall make publicly available information about the current status of the accreditations that it has granted to CABs. This information shall be updated regularly. The information shall include the following:

- a) name and address of each accredited CAB;
- b) dates of granting accreditation and expiry dates, as applicable;
- c) scopes of accreditation, condensed and/or in full. If only condensed scopes are provided, information shall be given on how to obtain full scopes.

8.2.2 The accreditation body shall provide the CAB with information about suitable ways to obtain traceability of measurement results in relation to the scope for which accreditation is provided.

8.2.3 The accreditation body shall, where applicable, provide information about international arrangements in which it is involved.

8.2.4 The accreditation body shall give due notice of any changes to its requirements for accreditation. It shall take account of views expressed by interested parties before deciding on the precise form and effective date of the changes. Following a decision on, and publication of, the changed requirements, it shall verify that each accredited body carries out any necessary adjustments.

8.3 Reference to accreditation and use of symbols

8.3.1 An accreditation body, as proprietor of the accreditation symbol that is intended for use by its accredited CABs, shall have a policy governing its protection and use. The accreditation symbol shall have, or be accompanied with, a clear indication as to which activity (as indicated in Clause 1) the accreditation is

related. An accredited CAB is allowed to use this symbol on its reports or certificates issued within the scope of its accreditation.

8.3.2 The accreditation body shall take effective measures to ensure that the accredited CAB

- a) fully conforms with the requirements of the accreditation body for claiming accreditation status, when making reference to its accreditation in communication media such as the Internet, documents, brochures, or advertising,
- b) only uses the accreditation symbols for premises of the CAB that are specifically included in the accreditation,
- c) does not make any statement regarding its accreditation that the accreditation body may consider misleading or unauthorized,
- d) takes due care that no report or certificate nor any part thereof is used in a misleading manner,
- e) upon suspension or withdrawal of its accreditation (however determined), discontinues its use of all advertising matter that contains any reference to an accredited status, and
- f) does not allow the fact of its accreditation to be used to imply that a product, process, system or person is approved by the accreditation body.

8.3.3 The accreditation body shall take suitable action to deal with incorrect references to accreditation status, or misleading use of accreditation symbols found in advertisements, catalogues, etc.

NOTE Suitable actions include request for corrective action, withdrawal of accreditation, publication of the transgression and, if necessary, other legal action.

Bibliography

- [1] ISO 9001:2000, *Quality management systems — Requirements*
- [2] ISO 14024:1999, *Environmental labels and declarations — Type I environmental labelling — Principles and procedures*
- [3] ISO 19011:2002, *Guidelines for quality and/or environmental management systems auditing*
- [4] ISO/IEC 17020:1998, *General criteria for the operation of various types of bodies performing inspection*
- [5] ISO/IEC 17024:2003, *Conformity assessment — General requirements for bodies operating certification of persons*
- [6] ISO/IEC 17025:1999, *General requirements for the competence of testing and calibration laboratories*
- [7] ISO/IEC Guide 43-1:1997, *Proficiency testing by interlaboratory comparisons — Part 1: Development and operation of proficiency testing schemes*
- [8] ISO/IEC Guide 43-2:1997, *Proficiency testing by interlaboratory comparisons — Part 2: Selection and use of proficiency testing schemes by laboratory accreditation bodies*
- [9] ISO/IEC Guide 62:1996, *General requirements for bodies operating assessment and certification/registration of quality systems*
- [10] ISO/IEC Guide 65:1996, *General requirements for bodies operating product certification systems*
- [11] ISO/IEC Guide 66:1999, *General requirements for bodies operating assessment and certification/registration of environmental management systems (EMS)*

