
**Conformity assessment —
Requirements for accreditation
bodies accrediting conformity
assessment bodies**

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

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

This document was prepared by the ISO Committee on Conformity Assessment (CASCO) and circulated for voting to the national bodies of both ISO and IEC, and was approved by both organizations.

This second edition cancels and replaces the first edition (ISO/IEC 17011:2004), which has been technically revised.

The main changes compared to the previous edition are as follows:

- alignment with the CASCO common structure for standards and incorporation of CASCO common elements in clauses on impartiality, confidentiality, complaints and appeal and management system;
- recognition of proficiency testing as an accreditation activity;
- addition of new definitions for “accreditation scheme” (see 3.8), “flexible scope of accreditation” (see 3.7), “remote assessment” (see 3.26) and “assessment programme” (see 3.27);
- introduction of the concept of risk;
- incorporation of competence criteria in the document, including an informative annex on knowledge and skills.

Introduction

This document specifies the requirements for accreditation bodies accrediting conformity assessment bodies. In the context of this document, activities covered by accreditation include but are not limited to testing, calibration, inspection, certification of management systems, persons, products, processes and services, provision of proficiency testing, production of reference materials, validation and verification.

It is important for interested parties to know that conformity assessment bodies are competent to perform their tasks. For that reason, there is an increasing demand for impartial attestation of their competence. Such attestation is done by accreditation bodies that are impartial and independent in relation to the conformity assessment bodies and the conformity assessment bodies' clients. Accreditation bodies normally operate in a non-profit distributing manner and conduct regular assessments of conformity assessment bodies to ensure that conformity assessment bodies conform to relevant international standards and other normative documents.

A system to accredit conformity assessment bodies is intended to provide for a consistent application of conformity assessment to international consensus based standards and conformity assessment schemes, in order to benefit public health, safety, environment and welfare and support regulators and end users. It can facilitate national and cross-border trade, as pursued by trade authorities and organizations.

This document can be used to support peer evaluation mechanisms which have been created at regional and international levels and through which confidence is provided that accreditation bodies are operating in accordance with this document.

In this document, the following verbal forms are used:

- “shall” indicates a requirement;
- “should” indicates a recommendation;
- “may” indicates a permission;
- “can” indicates a possibility or a capability.

Further details can be found in the ISO/IEC Directives, Part 2.

For the purposes of research, users are encouraged to share their views on this document and their priorities for changes to future editions. Click on the link below to take part in the online survey:

[17011_ed2_usersurvey](#)

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Conformity assessment — Requirements for accreditation bodies accrediting conformity assessment bodies

1 Scope

This document specifies requirements for the competence, consistent operation and impartiality of accreditation bodies assessing and accrediting conformity assessment bodies.

NOTE In the context of this document, activities covered by accreditation include, but are not limited to, testing, calibration, inspection, certification of management systems, persons, products, processes and services, provision of proficiency testing, production of reference materials, validation and verification.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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/IEC 17000, *Conformity assessment — Vocabulary and general principles*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO/IEC 17000 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <http://www.electropedia.org/>

3.1

accreditation

third-party attestation related to a *conformity assessment body* (3.4) conveying formal demonstration of its competence to carry out specific conformity assessment tasks

[SOURCE: ISO/IEC 17000:2004, 5.6]

3.2

accreditation body

authoritative body that performs *accreditation* (3.1)

Note 1 to entry: The authority of an accreditation body is generally derived from government.

[SOURCE: ISO/IEC 17000:2004, 2.6]

3.3

accreditation body logo

logo used by an *accreditation body* (3.2) to identify itself

3.4

conformity assessment body

body that performs conformity assessment activities and that can be the object of *accreditation* (3.1)

Note 1 to entry: Whenever the term “conformity assessment body” is used in the text, it applies to both the applicant and accredited conformity assessment bodies, unless otherwise specified.

[SOURCE: ISO/IEC 17000:2004, 2.5, modified — The words “and that can be the object of accreditation” have been added to the definition and the Note to entry has been added.]

3.5

conformity assessment activity

activity conducted by a *conformity assessment body* (3.4) when assessing conformity

Note 1 to entry: In the context of this document, activities covered by *accreditation* (3.1) include, but are not limited to, testing, calibration, inspection, certification of management systems, persons, products, processes and services, provision of proficiency testing, production of reference materials, validation and verification. For simplicity, these are referred to as conformity assessment activities being performed by conformity assessment bodies.

3.6

scope of accreditation

specific conformity assessment activities for which *accreditation* (3.1) is sought or has been granted

3.7

flexible scope of accreditation

scope of accreditation (3.6) expressed to allow conformity assessment bodies to make changes in methodology and other parameters which fall within the competence of the *conformity assessment body* (3.4) as confirmed by the *accreditation body* (3.2)

3.8

accreditation scheme

rules and processes relating to the *accreditation* (3.1) of conformity assessment bodies to which the same requirements apply

Note 1 to entry: Accreditation scheme requirements include, but are not limited to, ISO/IEC 17020, ISO/IEC 17021, ISO/IEC 17025, ISO/IEC 17024, ISO 17034, ISO/IEC 17043, ISO/IEC 17065, ISO 15189 and ISO 14065.

3.9

accreditation activity

individual operational tasks of the *accreditation process* (3.11)

Note 1 to entry: See [Clause 7](#).

3.10

impartiality

presence of objectivity

Note 1 to entry: Objectivity means that conflicts of interest do not exist, or are resolved so as not to adversely influence subsequent activities of the *accreditation body* (3.2).

Note 2 to entry: Other terms that are useful in conveying the element of impartiality include “independence”, “freedom from conflict of interests”, “freedom from bias”, “lack of prejudice”, “neutrality”, “fairness”, “open-mindedness”, “even-handedness”, “detachment”, “balance”.

[SOURCE: ISO/IEC 17021-1:2015, 3.2, modified — The words “certification body” have been replaced by “accreditation body” in Note 1 to entry.]

3.11

accreditation process

activities from application through to granting and maintenance of *accreditation* (3.1) as defined by the *accreditation scheme* (3.8)

3.12

accreditation symbol

symbol issued by an *accreditation body* (3.2) to be used by accredited conformity assessment bodies to indicate they are accredited

3.13**accreditation decision**

decision on *granting* (3.14), *maintaining* (3.15), *extending* (3.16), *reducing* (3.17), *suspending* (3.18) and *withdrawing* (3.19) *accreditation* (3.1)

3.14**granting accreditation**

awarding *accreditation* (3.1) for a defined *scope of accreditation* (3.6)

3.15**maintaining accreditation**

confirming the continuance of *accreditation* (3.1) for a defined *scope*

3.16**extending accreditation**

adding conformity assessment activities to the *scope of accreditation* (3.6)

3.17**reducing accreditation**

cancelling part of the *scope of accreditation* (3.6)

3.18**suspending accreditation**

putting temporary restrictions in place for all or part of the *scope of accreditation* (3.6)

3.19**withdrawing accreditation**

cancelling *accreditation* (3.1) for the full *scope*

3.20**complaint**

expression of dissatisfaction, other than *appeal* (3.21), by any person or organization, to an *accreditation body* (3.2), relating to the activities of that accreditation body or of an accredited *conformity assessment body* (3.4), where a response is expected

[SOURCE: ISO/IEC 17000:2004, 6.5, modified — The words “to a conformity assessment body or accreditation body, relating to the activities of that body” have been replaced by “to an accreditation body, relating to the activities of that accreditation body or of an accredited conformity assessment body”.]

3.21**appeal**

request by a *conformity assessment body* (3.4) for reconsideration of any adverse *accreditation decision* (3.13) related to its desired *accreditation* (3.1) status

3.22**assessment**

process undertaken by an *accreditation body* (3.2) to determine the competence of a *conformity assessment body* (3.4), based on standard(s) and/or other normative documents and for a defined *scope of accreditation* (3.6)

3.23**reassessment**

assessment (3.22) performed to renew the *accreditation* (3.1) cycle

3.24**assessment technique**

method used by an *accreditation body* (3.2) to perform an *assessment* (3.22)

Note 1 to entry: Assessment techniques, can include, but are not limited to:

— on-site assessment;

- *remote assessment* (3.26);
- *witnessing* (3.25);
- document review;
- file review;
- measurement audits;
- review of performance in proficiency testing and other interlaboratory comparisons;
- validation audits;
- unannounced visits;
- interviewing.

3.25

witnessing

observation by the *accreditation body* (3.2) of a *conformity assessment body* (3.4) carrying out conformity assessment activities within its *scope of accreditation* (3.6)

3.26

remote assessment

assessment (3.22) of the physical location or virtual site of a *conformity assessment body* (3.4), using electronic means

Note 1 to entry: A virtual site is an online environment allowing persons to execute processes, e.g. in a cloud environment.

3.27

assessment programme

set of *assessments* (3.22) consistent with a specific *accreditation scheme* (3.8) that the *accreditation body* (3.2) performs on a specific *conformity assessment body* (3.4) during an *accreditation* (3.1) cycle

3.28

assessment plan

description of the activities and arrangements for an *assessment* (3.22)

[SOURCE: ISO 19011:2011, 3.15, modified — The word “audit” has been replaced by “assessment”.]

3.29

accreditation body personnel

internal or external individuals carrying out activities on behalf of the *accreditation body* (3.2)

3.30

assessor

person assigned by an *accreditation body* (3.2) to perform, alone or as part of an assessment team, an *assessment* (3.22) of a *conformity assessment body* (3.4)

3.31

team leader

assessor (3.30) who is given the overall responsibility for the management of an *assessment* (3.22)

3.32

technical expert

person assigned by an *accreditation body* (3.2), working under the responsibility of an *assessor* (3.30), who provides specific knowledge or expertise with respect to the *scope of accreditation* (3.6) to be assessed and does not assess independently

Note 1 to entry: A technical expert is not expected to have assessor qualifications and training.

3.33**interested party**

person or organization with a direct or indirect interest in *accreditation* (3.1)

Note 1 to entry: 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 bodies.

Note 2 to entry: Interested parties can include the *accreditation body* (3.2), conformity assessment bodies, their associations and their clients, industry services, trade associations, scheme owners, governmental regulatory bodies or other governmental services, or non-governmental organizations, including consumer organizations.

3.34**consultancy**

participation in any of the activities of a *conformity assessment body* (3.4) subject to *accreditation* (3.1)

EXAMPLE 1 Preparing or producing manuals or procedures for a conformity assessment body.

EXAMPLE 2 Participating in the operation or management of a conformity assessment body.

EXAMPLE 3 Giving specific advice or specific training towards the development and implementation of the management system, operational procedures and/or competence of a conformity assessment body.

4 General requirements**4.1 Legal entity**

The accreditation body shall be a legal entity, or a defined part of a legal entity such that it is legally responsible for its accreditation activities.

NOTE 1 Governmental accreditation bodies are deemed to be legal entities on the basis of their status within their government.

NOTE 2 An accreditation body that is part of a larger body can operate under a different name.

4.2 Accreditation agreement

The accreditation body shall establish a legally enforceable arrangement with each conformity assessment body that requires the conformity assessment body to conform to at least the following:

- a) to commit to fulfil continually the requirements for accreditation for the scope for which accreditation is sought or granted and to commit to provide evidence of fulfilment. This includes agreement to adapt to changes in the requirements for accreditation;
- b) to cooperate as is necessary to enable the accreditation body to verify fulfilment of requirements for accreditation;
- c) to provide access to conformity assessment body personnel, locations, equipment, information, documents and records as necessary to verify fulfilment of requirements for accreditation;
- d) to arrange the witnessing of conformity assessment activities when requested by the accreditation body;
- e) to have, where applicable, legally enforceable arrangements with their clients that commit the clients to provide, on request, access to accreditation body assessment teams to assess the conformity assessment body's performance when carrying out conformity assessment activities at the client's site;
- f) to claim accreditation only with respect to the scope for which it has been granted;
- g) to commit to follow the accreditation body's policy for the use of the accreditation symbol;
- h) not to use its accreditation in such a manner as to bring the accreditation body into disrepute;

- i) to inform the accreditation body without delay of significant changes relevant to its accreditation;

NOTE Such changes can concern:

- its legal, commercial, ownership or organizational status;
- the organization, top management and key personnel;
- resources and location(s);
- scope of accreditation;
- other matters that can affect the ability of the conformity assessment body to fulfil requirements for accreditation.

- j) to pay fees as determined by the accreditation body;
- k) to assist in the investigation and resolution of any accreditation-related complaints about the conformity assessment body referred to it by the accreditation body.

4.3 Use of accreditation symbols and other claims of accreditation

4.3.1 The accreditation body shall take measures to ensure that the accredited conformity assessment body:

- a) fully conforms to the requirements of the accreditation body for claiming accreditation status, when making reference to its accreditation in communication media;
- b) does not make any misleading or unauthorized statement regarding its accreditation;
- c) upon withdrawal of its accreditation, discontinues its use of any reference to that accreditation;
- d) does not refer to its accreditation in a way so as to imply that a product, process, service, management system or person is approved by the accreditation body;
- e) informs its affected clients of the suspension, reduction or withdrawal of its accreditation and the associated consequences without undue delay.

4.3.2 When an accreditation body has an accreditation symbol, the accreditation body shall have the legal right to use it and the accreditation symbol shall be legally protected.

4.3.3 The accreditation body shall have a documented policy governing the use of the accreditation symbol and claims of accreditation status. This policy shall specify as a minimum:

- a) requirements for the use and monitoring of the accreditation symbol in combination with any conformity assessment body mark;
- b) that the accreditation symbol is not affixed on its own or used to imply that a product, process or service (or any part of it) has been certified or approved by the accreditation body;
- c) requirements for reproduction of the accreditation symbol;
- d) requirements for any reference to accreditation;
- e) requirements for the use of the accreditation symbol and claims of accreditation status in communication media;
- f) that the conformity assessment body only uses the accreditation symbol and claims of accreditation status for the specific activities covered by the scope of accreditation.

4.3.4 The accreditation symbol shall have, or be accompanied with, a clear indication as to which conformity assessment activity the accreditation is related.

4.3.5 The accreditation body shall take suitable action to deal with incorrect or unauthorized claims of accreditation status, or misleading or unauthorized use of accreditation symbols and the accreditation body logo.

NOTE Suitable actions can include requests for corrective action, suspension, withdrawal of accreditation, publication of the transgression and, if necessary, legal action.

4.4 Impartiality requirements

4.4.1 Accreditation shall be undertaken impartially.

4.4.2 The accreditation body shall be responsible for the impartiality of its accreditation activities and shall not allow commercial, financial or other pressures to compromise impartiality. Where an accreditation body, including a governmental accreditation body, is part of a larger entity, the accreditation body shall be organized so that accreditation is provided impartially.

4.4.3 The accreditation body shall have top management commitment to impartiality. It shall document and make public an impartiality policy which includes the importance of impartiality in carrying out its accreditation activities, managing conflict of interest and ensuring objectivity of its accreditation activities.

4.4.4 All accreditation body personnel and committees who could influence the accreditation process shall act objectively and shall be free from any undue commercial, financial and other pressures that could compromise impartiality. The accreditation body shall require all personnel and committee members to disclose any potential conflict of interest whenever it may arise.

4.4.5 The accreditation body shall document and implement a process to provide opportunity for effective involvement by interested parties for safeguarding impartiality. The accreditation body shall ensure a balanced representation of interested parties with no single party predominating.

4.4.6 The accreditation body shall have a process to identify, analyse, evaluate, treat, monitor and document on an ongoing basis the risks to impartiality arising from its activities including any conflicts arising from its relationships or from the relationships of its personnel. The process shall include identification of and consultation with appropriate interested parties as described in [4.4.5](#) to advise on matters affecting impartiality including openness and public perception.

NOTE 1 Sources of risks to impartiality of the accreditation body can be based on ownership, governance, management, personnel, shared resources, finances, contracts, outsourcing, training, marketing and payment of a sales commission or other inducement for the referral of new clients, etc.

NOTE 2 One way of fulfilling the consultation with the interested parties is by the use of a committee.

4.4.7 Where any risks to impartiality are identified, the accreditation body shall document and demonstrate how it eliminates or minimizes such risks and document any residual risk. The demonstration shall cover all potential risks that are identified, whether they arise from within the accreditation body or from the activities of other persons, bodies or organizations.

4.4.8 Top management shall review any residual risk to determine if it is within the level of acceptable risk.

4.4.9 When an unacceptable risk to impartiality is identified and which cannot be mitigated to an acceptable level, then accreditation shall not be provided.

4.4.10 The accreditation body's policies, processes and procedures shall be non-discriminatory and shall be applied in a non-discriminatory way. The accreditation body shall make its services accessible to all applicants whose application for accreditation falls within the scope of its accreditation activities as defined within its policies and rules. Access shall not be conditional upon the size of the applicant conformity assessment body or membership of any association or group, nor shall accreditation be conditional upon the number of conformity assessment bodies already accredited.

NOTE It is not considered discriminatory when an accreditation body refuses services to a conformity assessment body because of proven evidence of fraudulent behaviour, falsification of information or deliberate violation of accreditation requirements.

4.4.11 The accreditation body and any part of the same legal entity shall not offer or provide any service that affects its impartiality, such as:

- a) conformity assessment activities covered by accreditation which include but are not limited to testing, calibration, inspection, certification of management systems, persons, products, processes and services, provision of proficiency testing, production of reference materials, validation and verification;
- b) consultancy.

4.4.12 In case the accreditation body is linked to a body offering consultancy or undertaking those conformity assessment activities mentioned in [4.4.11](#) bullet a), the accreditation body shall have:

- a) different top management (see [5.7](#));
- b) different personnel performing the accreditation decision-making processes (see [Clause 5](#));
- c) distinctly different name, logos and symbols;
- d) effective mechanisms to prevent any influence on the outcome of any accreditation activity.

4.4.13 The accreditation body's activities shall not be presented as linked with consultancy or other services that pose an unacceptable risk to impartiality. 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.

NOTE Accreditation bodies can carry out, for example, the following duties that are not considered a risk to impartiality:

- arranging and participating as a lecturer in training, orientation or educational courses, provided that these courses confine themselves to the provision of generic information that is freely available in the public domain, i.e. they cannot provide specific solutions to a conformity assessment body in relation to the activities of that organization;
- adding value during assessments, e.g. by identifying opportunities for improvement as they become evident during the assessment without recommending specific solutions;
- advising other accreditation bodies on development of accreditation process;
- advising scheme owners on accreditation requirements, including requirements within relevant conformity assessment standards.

4.5 Financing and liability

4.5.1 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 the source(s) of its income.

4.5.2 The accreditation body shall evaluate the risks arising from its activities and have arrangements to cover liabilities arising from its activities.

4.6 Establishing accreditation schemes

4.6.1 The accreditation body shall develop or adopt accreditation schemes. The accreditation body shall document the rules and processes for its accreditation schemes referring to the relevant International Standards and/or other normative documents.

4.6.2 The accreditation body shall ensure that any guidance, application or normative documents it uses have been developed by committees or persons possessing the necessary competence and with participation of appropriate interested parties. These documents shall not contradict or exclude any of the requirements included in the relevant international standards and/or other normative documents.

NOTE 1 Where international application or guidance documents are available, these can be used.

NOTE 2 The accreditation body can adopt and/or develop application or guidance documents, normative documents and/or participate in their development.

4.6.3 The accreditation body shall have a policy and documented procedures to determine the suitability of the conformity assessment schemes and standards for accreditation purposes.

4.6.4 The accreditation body shall establish, document, implement and maintain a process for developing and extending its accreditation schemes. The following shall be considered:

- a) feasibility of launching or extending an accreditation scheme;
- b) analysis of its present competence and resources;
- c) accessing and employing expertise;
- d) the need for application or guidance documents;
- e) training of accreditation body personnel;
- f) implementation or transition arrangements;
- g) views of interested parties.

4.6.5 Before an accreditation body discontinues an accreditation scheme in part or in full, at least the following shall be considered:

- a) views of interested parties;
- b) contractual duties;
- c) transition arrangements;
- d) external communication regarding the discontinuation;
- e) information published by the accreditation body.

5 Structural requirements

5.1 The accreditation body shall be structured and managed so as to safeguard impartiality.

5.2 The accreditation body shall document its entire organizational structure, including lines of authority and responsibility.

5.3 If the accreditation body is part of a larger entity, the accreditation body shall be identified.

5.4 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.

5.5 The accreditation body shall have authority and be responsible for its accreditation decisions which shall not be subject to approval by any other organization or person.

5.6 The accreditation body shall document the duties, responsibilities and authorities of top management and other personnel associated with the accreditation body who are involved in the accreditation process.

5.7 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, processes and procedures;
- c) supervision of the finances of the accreditation body;
- d) development or adoption of activities for the schemes for which it provides accreditation;
- e) decisions on accreditation;
- f) performance of assessments and accreditation processes;
- g) responding to complaints and appeals in a timely manner;
- h) contractual arrangements;
- i) provision of adequate resources;
- j) delegation of authority to committees or individuals, as required, to undertake defined activities on behalf of top management;
- k) safeguarding of impartiality.

5.8 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 interested parties participating.

6 Resource requirements

6.1 Competence of personnel

6.1.1 General

The accreditation body shall have processes to ensure its personnel have appropriate knowledge and skills relevant to the accreditation schemes and geographic areas in which it operates.

6.1.2 Determination of competence criteria

6.1.2.1 The accreditation body shall have a documented process for determining and documenting the competence criteria for personnel involved in the management and performance of assessments and other accreditation activities. Competence criteria shall be determined with regard to the requirements

of each accreditation scheme and shall include the required knowledge and skills for performing accreditation activities.

6.1.2.2 The accreditation body shall ensure the assessment team, and the accreditation body personnel who review documents, review assessment reports and make accreditation decisions, demonstrate knowledge of the following:

- assessment principles, practices and techniques;
- general management system principles and tools.

6.1.2.3 The accreditation body shall ensure the assessment team, and the accreditation body personnel who review applications, select assessment team members, review documents, review assessment reports, make accreditation decisions and manage accreditation schemes, demonstrate knowledge of the following:

- accreditation body's rules and processes;
- accreditation and accreditation scheme requirements and relevant guidance and application documents;
- conformity assessment scheme requirements, other procedures and methods used by the conformity assessment body.

6.1.2.4 The accreditation body shall ensure the assessment team, and the accreditation body personnel who review assessment reports, make accreditation decisions and manage accreditation schemes, demonstrate knowledge of risk based assessment principles.

6.1.2.5 The accreditation body shall ensure the assessment team, and the accreditation body personnel who review documents, review assessment reports, make accreditation decisions and manage accreditation schemes, demonstrate knowledge of general regulatory requirements related to the conformity assessment activities.

6.1.2.6 The accreditation body shall ensure the assessment team demonstrates the following knowledge and skills:

- knowledge of practices and processes of the conformity assessment body business environment;
- communication skills appropriate to interact with all levels within the conformity assessment body;
- note-taking and report-writing skills;
- opening and closing meeting skills;
- interviewing skills;
- assessment-management skills.

6.1.2.7 The accreditation body shall ensure the accreditation body personnel who review documents demonstrate note-taking and report-writing skills.

6.1.2.8 The group or individual that takes the accreditation decisions shall understand the applicable accreditation scheme requirements and shall have competence to evaluate the outcomes of the assessment, including where appropriate related recommendations of the assessment team.

NOTE [Annex A](#) summarizes [6.1.2.2](#) to [6.1.2.8](#).

6.1.2.9 Where additional specific competence criteria have been established for a specific accreditation scheme, these shall be applied.

6.1.3 Competence management

6.1.3.1 The accreditation body shall:

- a) establish and implement a documented process for the initial evaluation and on-going monitoring of all personnel involved in accreditation processes;
- b) ensure that its evaluation methods are effective to demonstrate competence of accreditation body personnel;
- c) prior to undertaking accreditation activities, authorize personnel to perform those activities of the accreditation process.

6.1.3.2 The accreditation body shall have documented processes for selecting, training and formally authorizing assessors. The accreditation body shall have documented processes for selecting and authorizing technical experts and familiarizing them with relevant requirements and procedures used in the accreditation process. The initial competence evaluation of an assessor shall include determining the ability to apply required knowledge and skills during assessments.

NOTE One method of evaluating an assessor is to have competent individuals observing the assessor conducting an assessment.

6.1.3.3 The accreditation body shall identify training needs and shall provide access to specific training to ensure all personnel involved in accreditation processes are competent for the accreditation activities they perform.

6.1.3.4 There shall be a documented process for monitoring competence and performance of all personnel involved in the assessment activities based on the frequency of their involvement and the level of risk linked to the accreditation activities they perform. In particular, the accreditation body shall review and record the competence of its personnel taking into account their performance in order to take any necessary corrective action.

6.1.3.5 The accreditation body shall monitor each assessor considering each accreditation scheme for which the assessor is authorized. The documented monitoring process of assessors shall include a combination of on-site evaluation, review of assessment reports and feedback from personnel, conformity assessment bodies or from other interested parties.

6.1.3.6 Each assessor shall be observed during an assessment at regular intervals. This shall be at least every three years, unless there is sufficient supporting evidence that the assessor is continuing to perform competently. If the interval is extended, justification shall be made.

6.2 Personnel involved in the accreditation process

6.2.1 The accreditation body shall have access to a sufficient number of competent personnel to manage and support all its accreditation activities for all accreditation schemes.

6.2.2 The accreditation body shall have enforceable arrangements requiring all personnel to conform to applicable policies and implement processes as defined by the accreditation body. The arrangements shall address aspects relating to confidentiality and impartiality and shall require all personnel to notify the accreditation body of any existing, prior or foreseeable relationships which may compromise impartiality.

6.2.3 The accreditation body shall give assessors and technical experts access to an up-to-date set of documented procedures giving assessment instructions and all relevant information on the accreditation processes.

6.3 Personnel records

The accreditation body shall maintain records, including qualifications, training, competence, results of monitoring, experience, professional status and professional affiliations for personnel managing or performing accreditation activities.

6.4 Outsourcing

6.4.1 The accreditation body shall itself normally undertake the accreditation activities.

6.4.2 Accreditation decisions shall not be outsourced. The person(s) assigned by the accreditation body to make an accreditation decision shall be employed by, or shall be under enforceable arrangements with the accreditation body.

6.4.3 The accreditation body shall describe the conditions under which outsourcing may take place and when applicable shall have a documented procedure for outsourcing.

6.4.4 The accreditation body shall have an enforceable arrangement covering the outsourcing arrangements, including confidentiality and conflicts of interests, with each body that provides outsourced services.

6.4.5 The accreditation body shall:

- a) take responsibility for all activities outsourced to another body;
- b) ensure that the body that provides outsourced services, and the individuals that it uses, conform to requirements of the accreditation body and also to the applicable provisions of this document, including competence, impartiality and confidentiality;
- c) obtain the consent of the conformity assessment body to use a particular provider of any outsourced parts of the assessment.

6.4.6 The accreditation body shall have a documented process for the approval and monitoring of all bodies that provide outsourced services used for accreditation processes, and shall ensure that records of the competence of all personnel involved in accreditation processes are maintained.

NOTE 1 Where the accreditation body engages individuals or employees of other organizations to provide additional resources or expertise, the use of these individuals does not constitute outsourcing provided they are individually contracted to operate under the accreditation body's management system (see [6.2.2](#)).

NOTE 2 Mutual recognition arrangements based on this document can fulfil some of the requirements in [6.4.4](#), [6.4.5](#) and [6.4.6](#).

7 Process requirements

7.1 Accreditation requirements

The general requirements for accreditation of conformity assessment bodies shall be those set out in the relevant International Standards and/or other normative documents for the operation of conformity assessment bodies.

7.2 Application for accreditation

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

- a) general features of the conformity assessment body, including legal entity, name, address(es), legal status and human and technical resources;
- b) general information concerning the conformity assessment body such as its relationship in a larger entity if any, addresses of all its physical location(s) and, information on activities conducted at all locations including virtual site(s);
- c) a clearly defined scope of accreditation as defined in [7.8.3](#) for which the conformity assessment body seeks accreditation, including limits of capability where applicable;
- d) a commitment to continually fulfil the requirements for accreditation and the other obligations of the conformity assessment body.

7.2.2 The accreditation body shall require the applicant conformity assessment body to provide information demonstrating that the accreditation requirements are addressed prior to commencement of the assessment.

7.2.3 The accreditation body shall review the information supplied by the conformity assessment body to determine the suitability of the application for accreditation to initiate an assessment.

7.2.4 At any point in the application or initial assessment process, if there is evidence of fraudulent behaviour, if the conformity assessment body intentionally provides false information or if the conformity assessment body conceals information, the accreditation body shall reject the application or terminate the assessment process.

7.2.5 Where the accreditation body conducts a preliminary visit before the initial assessment, it shall be conducted with the agreement of the conformity assessment body. The accreditation body shall have clear rules for the conduct of preliminary visits and shall exercise due care to avoid consultancy.

7.3 Resource review

7.3.1 The accreditation body shall review its ability to carry out the assessment of the applicant conformity assessment body, in terms of its own policy and procedures, its competence and the availability of personnel suitable for the assessment activities and decision making.

7.3.2 The review shall also include the ability of the accreditation body to carry out the initial assessment in a timely manner. Where the initial assessment cannot be conducted in a timely manner, this shall be communicated to the conformity assessment body.

7.4 Preparation for assessment

7.4.1 The accreditation body shall appoint an assessment team consisting of a team leader and, where required, a suitable number of assessors and/or technical experts for the scope to be assessed. 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 of accreditation;
- b) shall have understanding sufficient to make a reliable assessment of the competence of the conformity assessment body to operate within its scope of accreditation.

7.4.2 The accreditation body shall inform the conformity assessment body of the names of the members of the assessment team and any observers, and the organization(s) they belong to, sufficiently in advance to provide the conformity assessment body the opportunity to lodge an objection to the appointment of any particular team members or observers with supporting justification. The accreditation body shall have a policy for dealing with such objections.

7.4.3 The accreditation body shall clearly define the assignment given to the assessment team.

7.4.4 The accreditation body shall establish documented procedures to assess the competence of a conformity assessment body to perform all activities in its scope of accreditation irrespective of where these activities are performed. These procedures shall describe the manner in which the scope of an applicant or an accredited conformity assessment body is covered through the use of a combination of on-site assessments and other assessment techniques sufficient to provide confidence in the conformity with the relevant accreditation criteria.

7.4.5 The procedures shall ensure that the assessment team assesses the performance of a sample of the conformity assessment activities representative of the scope of accreditation. The assessment shall cover a sample of locations and personnel to determine the competence of the conformity assessment body to perform the activities covered by its scope of accreditation.

7.4.6 In selecting the activities to be assessed the accreditation body shall consider the risk associated with the activities, locations and personnel covered by the scope of accreditation.

7.4.7 The accreditation body shall develop an assessment plan to cover the activities to be assessed, the locations at which activities will be assessed, the personnel to be assessed where applicable and the assessment techniques to be utilized including witnessing where appropriate or applicable. The accreditation body shall justify where witnessing is not appropriate or applicable.

7.4.8 The accreditation body shall confirm with the conformity assessment body the date(s) and plan for the assessment.

7.4.9 The accreditation body shall ensure that the assessment team is provided with the appropriate requirements documents, previous assessment records, if applicable, and the relevant documents and records of the conformity assessment body.

7.5 Review of documented information

7.5.1 The assessment team shall review all relevant documented information supplied by the conformity assessment body to evaluate its system for conformity with the relevant standard(s) and other requirements for accreditation.

7.5.2 The accreditation body can decide not to proceed with further assessment based on the review of the documented information. In such cases, the results with their justification shall be reported in writing to the conformity assessment body.

7.6 Assessment

7.6.1 The accreditation body shall have documented procedures for describing the assessment techniques used, the circumstances in which they are to be used and the rules for determining assessment durations. The procedures shall include how the accreditation body will report the assessment findings to the conformity assessment body.

7.6.2 For an assessment whether performed on-site or remotely, the assessment team shall commence the assessment with an opening meeting at which the purpose of the assessment and accreditation

requirements are clearly defined, and the assessment plan as well as the scope for the assessment are confirmed.

7.6.3 The assessment team shall conduct the assessment based on the assessment plan.

7.6.4 The assessment team shall analyse all relevant information and objective evidence gathered prior to and during the assessment to determine the competence of the conformity assessment body as determined through its conformity with the requirements for accreditation.

7.6.5 Where the assessment team cannot reach a conclusion on a finding, the team shall refer back to the accreditation body for clarification.

7.6.6 The accreditation body's documented reporting procedures shall require the following.

- a) For an assessment, whether performed on-site or remotely, a meeting shall take place between the assessment team and the conformity assessment body at the end of the assessment. At this meeting, the assessment team shall report on the findings identified during the assessment and detail in writing any nonconformities. An opportunity shall be provided for the conformity assessment body to seek clarification on the findings including the nonconformities, if any, and their basis.
- b) A written report on the outcome of the assessment shall be provided to the conformity assessment body without undue delay and within a defined timeframe. This assessment report shall contain comments on competence as determined through conformity, the scope assessed and shall identify nonconformities, if any, to be resolved in order to conform to all of the requirements for accreditation. Comments on competence as determined through conformity included in the assessment report shall be adequate to support the conclusions arising from the assessment. The team's observations on areas for possible improvement may also be presented to the conformity assessment body but shall not recommend specific solutions.
- c) If the report on the outcome of the assessment [see bullet b) above] differs from the outcome delivered at the close of the assessment [see bullet a) above], the accreditation body shall provide an explanation to the assessed conformity assessment body, in writing.

7.6.7 The accreditation body shall be responsible for the content of all of its assessment reports.

7.6.8 When nonconformities are identified, the accreditation body shall define time limits for correction and/or corrective actions to be implemented. The accreditation body shall require the conformity assessment body to provide an analysis of the extent and cause (e.g. root cause analysis) of the nonconformities and to describe within a defined time the specific actions taken or planned to be taken to resolve the nonconformities.

7.6.9 The accreditation body shall ensure that the responses of the conformity assessment body to resolve nonconformities are reviewed to determine if the actions are considered to be sufficient and appropriate. Where the conformity assessment body's 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.

7.7 Accreditation decision-making

7.7.1 The accreditation body shall describe its process for all types of accreditation decisions.

7.7.2 The accreditation body shall ensure that each decision on granting, maintaining, extending, reducing, suspending and withdrawing accreditation is taken by competent person(s) or committee(s) different from those who carried out the assessment. However, where maintaining is not related to a reassessment (see [7.9.4](#)) and there is no modification to the scope, or where the reduction, suspension or

withdrawal is requested by the conformity assessment body, then the accreditation body can implement a process which does not require an independent decision.

7.7.3 The information provided to the accreditation decision-maker(s) for review shall include the following:

- a) unique identification of the conformity assessment body;
- b) date(s) and type(s) of assessment(s) (e.g. initial, reassessment);
- c) name(s) of the assessor(s) and, if applicable, technical expert(s) involved in the assessment;
- d) unique identification of all locations assessed;
- e) scope of accreditation that was assessed;
- f) the assessment report(s);
- g) a statement on the adequacy of the organization and procedures adopted by the conformity assessment body to give confidence in its competence, as determined through its fulfilment of the requirements for accreditation;
- h) sufficient information to demonstrate the satisfactory response to all nonconformities;
- i) where relevant, any further information that may assist in determining the competence of the conformity assessment body as determined through conformity with requirements;
- j) where appropriate, a recommendation as to the accreditation decision for the proposed scope.

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

7.7.5 The accreditation body shall, without undue delay, make the accreditation decision on the basis of an evaluation of all information received and any other relevant information. Without undue delay, the conformity assessment body shall be notified in writing of the decision including justification where relevant.

7.7.6 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 document.

7.8 Accreditation information

7.8.1 The accreditation body shall provide information on the accreditation to the accredited conformity assessment body that shall identify the following:

- a) the identity and, where relevant, the accreditation body logo;
- b) the name of the accredited conformity assessment body and the name of the legal entity, if different;
- c) scope of accreditation;
- d) locations of the accredited conformity assessment body and, as applicable, the conformity assessment activities performed at each location and covered by the scope of accreditation;
- e) the unique accreditation identification of the accredited conformity assessment body;
- f) the effective date of accreditation and, if applicable, its expiry or renewal date;

- g) a statement of conformity and a reference to the international standard(s) and/or other normative document(s), including issue or revision used for assessment of the conformity assessment body.

NOTE The information can be provided in an accreditation certificate or other suitable means (e.g. electronic media).

7.8.2 The effective date of accreditation shall be the date of or a date after the accreditation decision.

7.8.3 The scope of accreditation shall, at least, identify the following.

a) For certification bodies:

- the type of certification (e.g. management systems, products, processes, services or persons);
- certification scheme(s);
- the standards, normative documents and/or regulatory requirements to which management systems, products, processes and services, or persons are certified, as applicable;
- industry sectors, where relevant;
- product, processes, service and persons categories where relevant.

b) For inspection bodies:

- the type of inspection body (as defined in ISO/IEC 17020);
- inspection schemes, where relevant;
- the field and range of inspection for which accreditation has been granted;
- the regulations, inspection methods, standards and/or specifications containing the requirements against which the inspection is to be performed, as applicable.

c) For calibration laboratories:

- the calibration and measurement capability (CMC) expressed in terms of:
 - measurand or reference material;
 - calibration or measurement method or procedure and type of instrument or material to be calibrated or measured;
 - measurement range and additional parameters where applicable, e.g. frequency of applied voltage;
 - measurement uncertainty.

d) For testing laboratories (including medical laboratories):

- materials or products tested;
- component, parameter or characteristic tested;
- tests or types of tests performed and, where appropriate, the techniques, methods and/or equipment used.

e) For proficiency testing providers:

- schemes that the proficiency testing provider is competent to provide;
- type of proficiency testing items;

- the measurand(s) or characteristic(s) or where appropriate the type of measurand(s) or characteristic(s) that are to be identified, measured or tested.
- f) For reference material producers:
- types of reference materials (certified reference material, reference material or both);
 - the reference material matrix or artefact;
 - the property/properties characterized;
 - the approach used to assign property values.
- g) For validation and verification bodies:
- identification of the activity (validation or verification or both);
 - the standards, normative documents and/or regulatory requirements to which validation or verification or both is to be performed, as applicable;
 - validation and/or verification scheme, where relevant;
 - industry sector, where relevant.
- h) For other conformity assessment bodies:
- the specific conformity assessment activities the conformity assessment body is accredited for;
 - the standards, normative documents and/or regulatory requirements containing the requirements against which the conformity assessment activity is to be performed, as applicable;
 - conformity assessment scheme, where relevant;
 - industry sector, where relevant.

7.8.4 When the accreditation body uses a flexible scope of accreditation, it shall have documented procedures on how it addresses and manages flexible scopes. The procedure shall include how the accreditation body addresses 7.8.3 bullets a) to h), including specifying how the information required for bullets a) to h) shall be maintained and made available on request.

7.9 Accreditation cycle

7.9.1 An accreditation cycle shall begin at or after the date of the decision for granting the initial accreditation or decision after reassessment (see 7.9.4) and shall not be longer than five years.

7.9.2 The accreditation body shall apply an assessment programme for assessing the conformity assessment body activities during the accreditation cycle to ensure that the conformity assessment activities representative of the scope of accreditation at the relevant locations are assessed during the accreditation cycle (see 7.4.4). Factors such as knowledge obtained by the accreditation body about the conformity assessment body's management system and activities and the performance of the conformity assessment body shall be considered by the accreditation body when establishing the assessment programme.

7.9.3 The assessment programme shall ensure that the requirements of the international standards and other normative documents containing requirements for conformity assessment bodies and the scope of accreditation shall be assessed taking risk into consideration. A sample of the scope of accreditation shall be assessed at least every two years. The time between consecutive on-site assessments shall not exceed two years. However, if the accreditation body determines that an on-site assessment is not applicable, it shall use another assessment technique to achieve the same objective as the on-site assessment being replaced and justify the use of such techniques (e.g. remote assessment).

7.9.4 Before the end of the accreditation cycle, a reassessment shall be planned and performed taking into consideration the information gathered from assessments performed over the accreditation cycle. The reassessment shall confirm the competence of the conformity assessment body and cover all the requirements of the standard(s) for which the conformity assessment body is accredited. An accreditation decision shall be made after the reassessment.

7.9.5 The accreditation body may conduct extraordinary assessments as a result of complaints or changes, or other matters that may affect the ability of the conformity assessment body to fulfil requirements for accreditation. The accreditation body shall advise conformity assessment bodies of this possibility.

7.10 Extending accreditation

7.10.1 The accreditation body shall have a documented procedure for extending the scope of accreditation. Based on the risk associated with the activities or locations to be covered in the scope extension, the accreditation body shall define the appropriate assessment technique(s) to apply and consider the corresponding requirements defined in 7.3 to 7.9.

7.10.2 The accreditation body shall take into account extensions granted when reviewing the assessment programme and planning the subsequent assessment.

7.11 Suspending, withdrawing or reducing accreditation

7.11.1 The accreditation body shall have documented procedure(s) and criteria to decide in which circumstances the accreditation shall be suspended, withdrawn or reduced when an accredited conformity assessment body has failed to meet the requirements of accreditation or to abide by the rules for accreditation or has voluntarily requested a suspension, withdrawal or reduction.

7.11.2 Where there is evidence of fraudulent behaviour, or the conformity assessment body intentionally provides false information or conceals information, the accreditation body shall initiate its process for withdrawal of accreditation.

7.11.3 The accreditation body shall have a documented procedure and criteria for lifting suspension of accreditation.

7.12 Complaints

7.12.1 The accreditation body shall have a documented process to receive, evaluate and make decisions on complaints. The accreditation body shall, where appropriate, ensure that a complaint concerning an accredited conformity assessment body is first addressed by the conformity assessment body.

7.12.2 A description of the handling process for complaints shall be available to any interested party.

7.12.3 Upon receipt of a complaint, the accreditation body shall confirm whether the complaint relates to accreditation activities that it is responsible for and, if so, shall deal with it.

7.12.4 The handling process for complaints shall include at least the following elements and methods:

- a) a description of the process for receiving, validating, investigating the complaint, and deciding what actions are to be taken in response to it;
- b) tracking and recording complaints, including actions undertaken to resolve them;
- c) ensuring that any appropriate action is taken in a timely manner.

7.12.5 The accreditation body shall acknowledge receipt of the complaint and provide the complainant with progress reports and the outcome.

7.12.6 The accreditation body shall be responsible for gathering and verifying all necessary information to validate the complaint.

7.12.7 The accreditation body shall be responsible for all decisions at all levels of the handling process for complaints.

7.12.8 The decision to be communicated to the complainant shall be made by, or reviewed and approved by, individual(s) not involved in the activities in question.

7.12.9 The accreditation body shall give formal notice of the end of the complaint handling process to the complainant.

7.12.10 Investigation and decision on complaints shall not result in any discriminatory actions against the complainant.

7.13 Appeals

7.13.1 The accreditation body shall have a documented process to receive, evaluate and make decisions on appeals.

7.13.2 A description of the handling process for appeals shall be available to any interested party.

7.13.3 The accreditation body shall be responsible for all decisions at all levels of the handling process for appeals.

7.13.4 Investigation and decision on appeals shall not result in any discriminatory actions.

7.13.5 The handling process for appeals shall include at least the following elements and methods:

- a) a description of the process for receiving, validating, investigating the appeal and deciding what actions are to be taken in response to it;
- b) tracking and recording appeals, including actions undertaken to resolve them;
- c) ensuring that any appropriate action is taken in a timely manner.

7.13.6 The accreditation body receiving the appeal shall be responsible for gathering and verifying all necessary information to validate the appeal.

7.13.7 The accreditation body shall acknowledge receipt of the appeal and provide the appellant with progress reports and the outcome.

7.13.8 The decision to be communicated to the appellant shall be made by, or reviewed and approved by, individual(s) not involved in the activities in question.

7.13.9 The accreditation body shall give formal notice of the end of the appeals handling process to the appellant.

7.14 Records on conformity assessment bodies

7.14.1 The accreditation body shall maintain records on conformity assessment bodies to demonstrate that requirements for accreditation have been effectively fulfilled.

7.14.2 The accreditation body shall have a documented policy and documented procedures on the retention of records. Records of conformity assessment body shall be retained at least for the duration of the current cycle plus the previous full accreditation cycle.

8 Information requirements

8.1 Confidential information

8.1.1 The accreditation body shall be responsible through legally enforceable agreements for the management of all information obtained or created during the accreditation process. The accreditation body shall inform the conformity assessment body, in advance, of the information it intends to place in the public domain. Except for information that the conformity assessment body makes publicly available, or when agreed between the accreditation body and the conformity assessment body (e.g. for the purpose of responding to complaints), all other information obtained during accreditation process is considered proprietary information and shall be regarded as confidential.

8.1.2 When the accreditation body is required by law or authorized by contractual arrangements to release confidential information, the conformity assessment body shall, unless prohibited by law, be notified of the information provided.

8.1.3 Information about the conformity assessment body obtained from sources other than the conformity assessment body (e.g. complainant, regulators) shall be confidential between the conformity assessment body and the accreditation body. The provider (source) of this information shall be confidential to the accreditation body and shall not be shared with the conformity assessment body, unless agreed by the source.

8.1.4 Personnel, including any committee members, contractors, personnel of external bodies, or individuals acting on the accreditation body's behalf, shall keep confidential all information obtained or created during the performance of the accreditation body's activities, except as required by law.

8.2 Publicly available information

8.2.1 The accreditation body shall make publicly available through publications, electronic media or other means, without request, and update at adequate intervals, the following:

- a) information about the accreditation body:
 - 1) information about the authority under which the accreditation body operates;
 - 2) a description of the accreditation body's rights and duties;
 - 3) general information about the means by which the accreditation body obtains financial support;
 - 4) information about the accreditation body's activities, other than accreditation;