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

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

Draft International Standards are circulated to the national bodies for voting. Publication as an International Standard requires approval by at least 75 % of the national 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).

It was circulated for voting to the national bodies of both ISO and IEC, and was approved by both organizations.

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.

This corrected version of ISO/IEC 17011:2004 incorporates the following corrections:

- the French title has been amended;
- the Foreword has been corrected to include reference to voting by IEC national bodies;
- the copyright has been corrected to ISO only.

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.

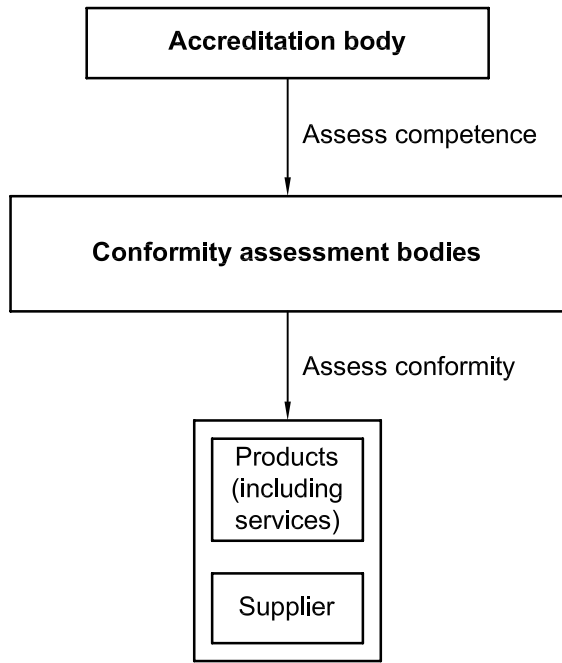
It is important for the purchaser, regulator and the public to know that these CABs are competent to perform their tasks. For that reason there is an increasing demand for impartial verification of their competence. Such verification is done by authoritative accreditation bodies that are impartial in 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.



Accreditation bodies assess the competence of CABs. They can facilitate trade by promoting global acceptance of conformity assessment results issued by accredited CABs. This is strengthened if they are peer-evaluated and are members of mutual recognition arrangements among the accreditation bodies.

CABs assess conformity of products, services and suppliers to specifications and/or requirements.

Purchasers acquire products (including services) that conform to specifications or buy from suppliers that conform to specific requirements. Regulators may set requirements for products and suppliers.

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

Figure 1 – Flowchart
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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.

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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.