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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.