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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

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.