

SLOVENSKI STANDARD

SIST EN ISO/IEC 17011:2004

01-december-2004

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SIST EN 45003:1999
SIST EN 45010:1998

Ugotavljanje skladnosti – Splošne zahteve za akreditacijske organe, ki akreditirajo organe za ugotavljanje skladnosti (ISO/IEC 17011:2004)

Conformity assessment - General requirements for accreditation bodies accrediting conformity assessment bodies (ISO/IEC 17011:2004)

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Konformitätsbewertung - Allgemeine Anforderungen an Akkreditierungsstellen, die Konformitätsbewertungsstellen akkreditieren (ISO/IEC 17011:2004)

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Évaluation de la conformité - Exigences générales pour les organismes d'accréditation procédant à l'accréditation d'organismes d'évaluation de la conformité (ISO/IEC 17011:2004)

Ta slovenski standard je istoveten z: EN ISO/IEC 17011:2004

ICS:

03.120.20	Certificiranje proizvodov in podjetij. Ugotavljanje skladnosti	Product and company certification. Conformity assessment
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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO/IEC 17011

September 2004

ICS 03.120.20

Supersedes EN 45003:1995, EN 45010:1998

English version

**Conformity assessment - General requirements for accreditation
bodies accrediting conformity assessment bodies (ISO/IEC
17011:2004)**

Évaluation de la conformité - Exigences générales pour les
organes d'accréditation procédant à l'accréditation des
organes d'évaluation de la conformité (ISO/IEC
17011:2004)

Konformitätsbewertung - Allgemeine Anforderungen an
Akkreditierungsstellen, die Konformitätsbewertungsstellen
akkreditieren (ISO/IEC 17011:2004)

This European Standard was approved by CEN and CENELEC on 1 July 2004.

CEN and CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN Management Centre or to any CEN or CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN or CENELEC member into its own language and notified to the CEN Management Centre has the same status as the official versions.

CEN and CENELEC members are the national standards bodies and national electrotechnical committees, respectively, of Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.



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EN ISO/IEC 17011:2004 (E)**Foreword**

This document (EN ISO/IEC 17011:2004) has been prepared by CASCO "Committee on Conformity Assessment" in collaboration with Technical Committee CEN/CLC/TC 1 "Criteria for conformity assessment bodies", the secretariat of which is held by SN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by March 2005, and conflicting national standards shall be withdrawn at the latest by March 2005.

This document supersedes EN 45003:1995 and EN 45010:1998.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

Endorsement notice

The text of ISO/IEC 17011:2004 has been approved by CEN and CENELEC as EN ISO/IEC 17011:2004 without any modifications.

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INTERNATIONAL STANDARD

**ISO/IEC
17011**

First edition
2004-09-01

Corrected version
2005-02-15

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).

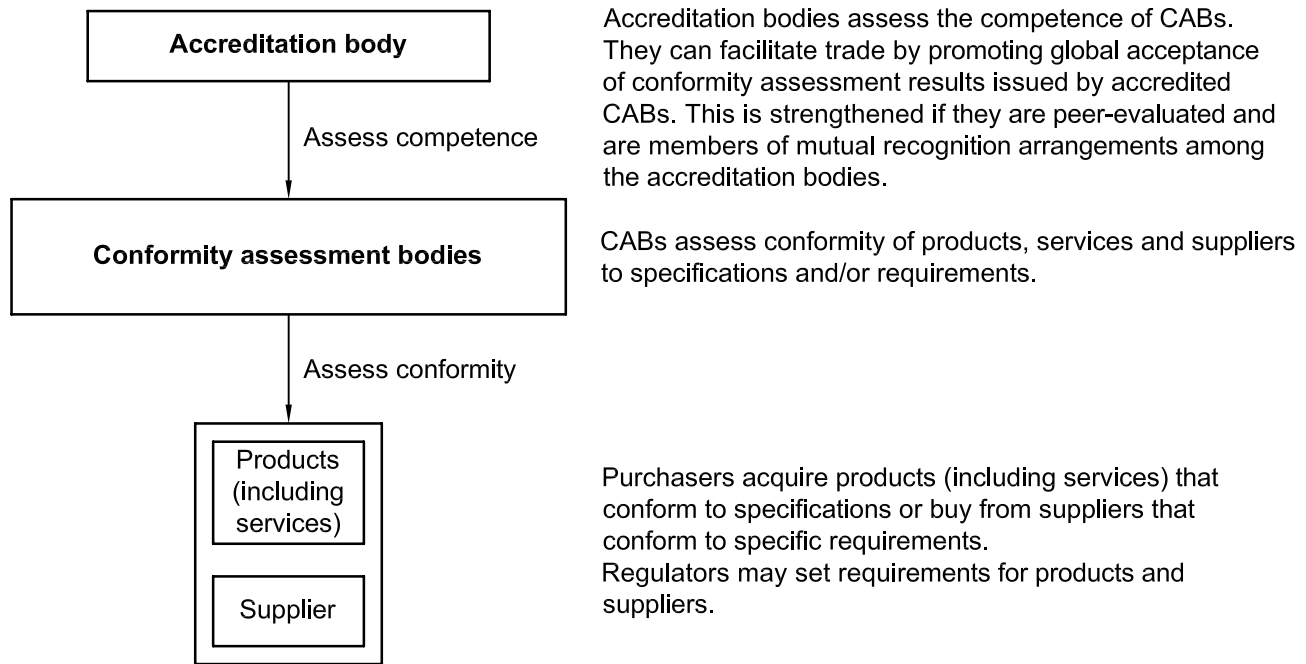
A system to accredit CAB conformity assessment services should provide confidence to the purchaser and regulator. Such a system should facilitate cross-border trade, as pursued by trade authorities and organizations. The ultimate goal is to achieve one-stop accreditation and one-stop conformity assessment.

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.

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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.

ISO/IEC 17011:2004(E)**3.3****accreditation body logo**

logo used by an accreditation body to identify itself

3.4**accreditation certificate**

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

3.5**accreditation symbol**

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

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

3.6**appeal**

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

NOTE Adverse decisions include

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

3.7**assessment**

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

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

3.8**assessor**

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

3.9**complaint**

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

3.10**conformity assessment body****CAB**

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

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