

**Vastavushindamine. Üldnõuded
vastavushindamisasutusi akrediteerivatele
akrediteerimisasutustele**

Conformity assessment - General requirements for
accreditation bodies accrediting conformity assessment
bodies

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO/IEC 17011:2004 sisaldab Euroopa standardi EN ISO/IEC 17011:2004 ingliskeelset teksti.

Standard on kinnitatud Eesti Standardikeskuse 26.10.2004 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.

Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 01.09.2004.

Standard on kättesaadav Eesti standardiorganisatsioonist.

This Estonian standard EVS-EN ISO/IEC 17011:2004 consists of the English text of the European standard EN ISO/IEC 17011:2004.

This standard is ratified with the order of Estonian Centre for Standardisation dated 26.10.2004 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.

Date of Availability of the European standard text 01.09.2004.

The standard is available from Estonian standardisation organisation.

ICS 03.120.20

Võtmesõnad:

Standardite reprodutseerimis- ja levitamiseõigus kuulub Eesti Standardikeskusele

Andmete paljundamine, taastekitamine, kopeerimine, salvestamine elektroonilisse süsteemi või edastamine ükskõik millises vormis või millisel teel on keelatud ilma Eesti Standardikeskuse poolt antud kirjaliku loata.

Kui Teil on küsimusi standardite autorikaitse kohta, palun võtke ühendust Eesti Standardikeskusega:
Aru 10 Tallinn 10317 Eesti; www.evs.ee; Telefon: 605 5050; E-post: info@evs.ee

Deutsche und Englische Fassung
German and English version

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

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)

Diese Europäische Norm wurde von CENELEC am 1. Juli 2004
angenommen.

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

Die CEN- und CENELEC-Mitglieder sind gehalten, die
CEN/CENELEC-Geschäftsordnung zu erfüllen, in der die
Bedingungen festgelegt sind, unter denen dieser Europäischen
Norm ohne jede Änderung der Status einer nationalen Norm zu
geben ist. Auf dem letzten Stand befindliche Listen dieser
nationalen Normen mit ihren bibliographischen Angaben sind beim
Management-Zentrum des CEN oder bei jedem CEN- oder
CENELEC-Mitglied auf Anfrage erhältlich.

CEN and CENELEC members are bound to comply with the
CEN/CENELEC Internal Regulations which stipulate the conditions
for inclusion of this amendment into the relevant 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.

Diese Europäische Norm wurde vom CEN und CENELEC in drei
offiziellen Fassungen (Deutsch, Englisch, Französisch). Eine
Fassung in einer anderen Sprache, die von einem CEN- oder
CENELEC-Mitglied in eigener Verantwortung durch Übersetzung in
seine Landessprache gemacht und dem Management-Zentrum des
CEN mitgeteilt worden ist, hat den gleichen Status wie die
offiziellen Fassungen.

This amendment 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-Mitglieder sind die nationalen Normungsinstitute von Belgien,
Dänemark, Deutschland, Estland, Finnland, Frankreich,
Griechenland, Irland, Island, Italien, Lettland, Litauen, Luxemburg,
Malta, den Niederlanden, Norwegen, Österreich, Polen, Portugal,
Schweden, der Schweiz, der Slowakei, Slowenien, Spanien, der
Tschechischen Republik, Ungarn, dem Vereinigten Königreich und
Zypern.

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 the
United Kingdom.



Management-Zentrum des CEN:
rue de Stassart, 36 B-1050 Brüssel

Management Zentrum des CENELEC:
rue de Stassart, 35 B-1050 Brüssel

CEN Management Centre:
rue de Stassart, 36 B-1050 Brussels

CENELEC Management Centre:
rue de Stassart, 35 B-1050 Brussels

Foreword

This document EN ISO/IEC 17011:2004 has been prepared by Technical Committee ISO/CASCO "Committee on Conformity Assessment" in collaboration with Technical Committee CEN/CENELEC/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 the 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.

Contents

	Page
Foreword.....	3
Introduction	7
1 Scope	11
2 Normative references	11
3 Terms and definitions.....	11
4 Accreditation body	17
4.1 Legal responsibility	17
4.2 Structure	17
4.3 Impartiality.....	19
4.4 Confidentiality.....	21
4.5 Liability and financing	21
4.6 Accreditation activity.....	21
5 Management.....	23
5.1 General.....	23
5.2 Management system.....	23
5.3 Document control	25
5.4 Records.....	25
5.5 Nonconformities and corrective actions.....	25
5.6 Preventive actions	27
5.7 Internal audits	27
5.8 Management reviews.....	27
5.9 Complaints	29
6 Human resources.....	31
6.1 Personnel associated with the accreditation body	31
6.2 Personnel involved in the accreditation process	31
6.3 Monitoring	33
6.4 Personnel records	33
7 Accreditation process	33
7.1 Accreditation criteria and information.....	33
7.2 Application for accreditation	35
7.3 Resource review	35
7.4 Subcontracting the assessment	37
7.5 Preparation for assessment	37
7.6 Document and record review	39
7.7 On-site assessment.....	41
7.8 Analysis of findings and assessment report	41
7.9 Decision-making and granting accreditation.....	43
7.10 Appeals	45
7.11 Reassessment and surveillance	47
7.12 Extending accreditation	49
7.13 Suspending, withdrawing or reducing accreditation.....	49
7.14 Records on CABs	49
7.15 Proficiency testing and other comparisons for laboratories	49
8 Responsibilities of the accreditation body and the CAB.....	51
8.1 Obligations of the CAB.....	51
8.2 Obligations of the accreditation body	53
8.3 Reference to accreditation and use of symbols	53
Bibliography	57

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.

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