

KATSELABORITE TEGEVUSE ÜLDKRITEERIUMID

**General criteria for the operation of testing
laboratories**

EESSÕNA

Käesolev Eesti standard sisaldab Euroopa standardi EN 45001:1989 "General criteria for the operation of testing laboratories" ingliskeelse teksti ja selle ekvivalentse eestikeelse tõlke.

Euroopa standardi tõlkisid ja valmistasid kinnitamiseks ette Standardiameti, RAS Metrosert, AS EhitusTEST ning Eesti Keele Instituudi spetsialistid - töögrupi juht Edi Kulderknup.

Standardi kavand on läbi arutatud ja heaks kiidetud Standardiameti standardikomisjoni poolt 21.04.1995.

Euroopa standard EN 45001:1989 on kasutusele võetud Eesti standardina Standardiameti käskkirjaga 29.05.1995 nr. 6.

Registrisse kantud 21.06.1995 nr. 940.

Standard on ette nähtud kasutamiseks katselaborite akrediteerimisel.

This standard consists of the English text of the European Standard EN 45001:1989 "General criteria for the operation of testing laboratories".

The standard also contains an Estonian translation of the English text. The European Standard EN 45001:1989 has the status of an Estonian national standard.

Kirjastamis- ja paljundusõigus kuulub Eesti Standardiametile

UDC 620.1.008.6

Key words: Testing laboratories; performance evaluation; organization; test equipment; quality assurance

English version

General criteria for the operation of testing laboratories

Criteres generaux concernant le
fonctionnement de laboratoires

Allgemeine Kriterien zum Betreiben
von Prüflaboratorien

This European Standard was accepted by CEN/CENELEC on 23 June 1989. 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 Central Secretariat or to any CEN/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/CENELEC member into its own language and notified to the Central Secretariat has the same status as the official versions.

CEN/CENELEC members are the national standards organizations and national electrotechnical committees, respectively, of Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxemburg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

CEN/CENELEC

The joint European Standards Institution
Organisation Commune Europeenne de Normalisation
Die gemeinsame Europäische Normeninstitution

Central Secretariat: rue Brederode 2, B-1000 Brussels

LÜHIAJALUGU

Käesoleva Euroopa standardi on ette valmistanud Euroopa Ühenduse Komisjoni ja Euroopa Vabakaubandusassotsiatsiooni volitusel CEN/CENELEC ühine sertifitseermistöögrupp.

Euroopa Ühenduse Komisjoni kahe töögrupi ettevalmistatud dokumendid Certif. 87/15 ja Certif. 87/16 ringlesid CEN/CENELEC küsitlusprotseduuri kohaselt novembris 1987.

Kommentaari arutelu toimus Brüsseli kohtumisel juunis 1988, kus otsustati esitada korrigeeritud ning 7 eri dokumendiks jagatud kavand ametlikule hääletusele.

Nende kavandite tekst kiideti heaks ja ratifitseeriti nii CENELEC kui ka CEN Tehnikanõukogu poolt 1989-06-23.

Vastavalt CEN/CENELEC ühistele reeglitele peavad käesoleva Euroopa standardi kasutusele võtma: Austria, Belgia, Taani, Soome, Prantsusmaa, Saksamaa, Kreeka, Island, Iirimaa, Itaalia, Luksemburg, Holland, Norra, Portugal, Hispaania, Rootsi, Šveits ja Ühendatud Kuningriigid.

EESSÕNA

Käesolev Euroopa standard on koostatud eesmärgiga soodustada sellele vastavate laborite usaldatavust. Selle tulemuseni jõudmiseks vaadati läbi mitu asjakohast Euroopa ja rahvusvahelist dokumenti.

Käesolev standard baseerub suures osas ISO/IEC juhenditel, eriti:

ISO/IEC Guide 2, "General terms and their definitions concerning standardization and related activities",

ISO/IEC Guide 25, "General requirements for the technical competence of testing laboratories",

ISO/IEC Guide 38, "General requirements for the acceptance of testing laboratories",

ISO/IEC Guide 43, "Development and operation of laboratory proficiency testing",

ISO/IEC Guide 45, "Guidelines for the presentation of test results",

ISO/IEC Guide 49, "Guidelines for development of a quality manual for testing laboratory"

ja ILAC (International Laboratory Accreditation Conference) töö.

Mõnel juhul vajasid need tekstid muudatusi või selgitusi Euroopa eesmärke arvestades. Sellised muudatused või selgitused on pigem erandiks kui reeglilik.

Käesolevas standardis püstitatud kriteeriumid on need, millele peaksid laborid vastama ja mida peaksid kasutama akrediteerimisorganid laborite akrediteerimisel ning õiguspädevad organid laborite määramisel õigusaktidest tulenevate ülesannete täitmiseks ja kõik teised laboreid hindavad organisatsioonid.

Kriteeriumid on eelkõige mõeldud käsitlemiseks üldkriteeriumidena, mis hõlmavad kõiki katsetusalasid, kalibreerimine kaasa arvatud. Sellest tulenevalt võib ilmned vajadus nende täiendamiseks, kui teatud tööstusharu või muud valdkonnad (nt tervishoid ja tööohutus) seda vajavad.

BRIEF HISTORY

This European Standard has been prepared under mandate of the Commission of the European Communities and the European Free Trade Association, by a joint CEN/CENELEC Working Group on Certification.

The documents Certif. 87/15 and Certif. 87/16, prepared by two Working Groups of the Commission of the European Communities, were circulated under the common CEN/CENELEC enquiry procedure in November 1987.

The comments were discussed during the Brussels meeting in June 1988 where it was decided to submit an updated draft split in 7 separate documents to the formal voting.

The text of these drafts was approved and ratified by the CENELEC Technical Board on 1989-06-23 and by the CEN Technical Board on 1989-06-23.

According to the Common CEN/CENELEC Rules, the following countries are bound to implement this European Standard : Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxemburg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, United Kingdom.

FOREWORD

This European standard has been drawn up with the objective of promoting confidence in those laboratories which conform to it. In order to arrive at this result, the various relevant European and international documents have been examined.

This standard is based very much on ISO/IEC guides in particular:

- ISO/IEC guide 2, "General terms and their definitions concerning standardization and related activities",
- ISO/IEC guide 25, "General requirements for the technical competence of testing laboratories",
- ISO/IEC guide 38, "General requirements for the acceptance of testing laboratories",
- ISO/IEC guide 43, "Development and operation of laboratory proficiency testing",
- ISO/IEC guide 45, "Guidelines for the presentation of test results" and
- ISO/IEC guide 49, "Guidelines for development of a quality manual for testing laboratory"

and on the work of ILAC (International Laboratory Accreditation Conference). In some instances these texts required modification or clarification for European purposes. Such modifications or clarifications are the exception rather than the rule.

The criteria set out in this standard are those to which laboratories should conform and which should be used by accreditation bodies in accrediting laboratories, by public authorities when designating laboratories for regulatory purposes and by any other organizations assessing laboratories.

The criteria are, above all, written to be considered as general criteria covering all fields of testing including calibration. This implies that the set of criteria may have to be supplemented when certain industrial or other sectors (e.g. health and safety) make use of it.

Käesolev standard moodustab osa järgmiste katsetust, sertifitseerimist ja akrediteerimist käsitlevate standardite sarjast:

EN 45001 General criteria for the operation of testing laboratories

EN 45002 General criteria for the assessment of testing laboratories

EN 45003 General criteria for laboratory accreditation bodies

EN 45011 General criteria for certification bodies operating product certification

EN 45012 General criteria for certification bodies operating Quality System certification

EN 45013 General criteria for certification bodies operating certification of personnel

EN 45014 General criteria for suppliers' declaration of conformity

Käesolev eessõna ei moodusta standardi lahutamatu osa.

This standard forms part of the following series of standards covering testing, certification and accreditation:

- EN 45001 General criteria for the operation of testing laboratories
- EN 45002 General criteria for the assessment of testing laboratories
- EN 45003 General criteria for laboratory accreditation bodies
- EN 45011 General criteria for certification bodies operating product certification
- EN 45012 General criteria for certification bodies operating Quality System certification
- EN 45013 General criteria for certification bodies operating certification of personnel
- EN 45014 General criteria for suppliers' declaration of conformity

This foreword does not form an integral part of the standard.

SISUKORD

1	EESMÄRK JA KASUTUSALA	8
2	MÄÄRATLUSED	8
2.1	Katse	8
2.2	Katsemeetod	8
2.3	Katseprotokoll	8
2.4	Katselabor	8
2.5	Laboritevaheline võrdluskatse	8
2.6	(Labori) tasemekatse	8
2.7	(Labori) akrediteerimine	8
2.8	(Laborite) akrediteerimissüsteem	8
2.9	(Laborite) akrediteerimisorgan	8
2.10	Akrediteeritud labor	8
2.11	(Labori) akrediteerimiskriteeriumid	10
2.12	Labori hindamine	10
2.13	Labori assessor	10
3	JURIIDILINE IDENTSUS	10
4	ERAPOOLETUS, SÖLTUMATUS JA AUSUS	10
5	TEHNILINE KOMPETENTSUS	10
5.1	Juhtimine ja organisatsioon	10
5.2	Personal	12
5.3	Ruumid ja seadmed	12
5.3.1	Kasutusvalmidus	12
5.3.2	Ruumid ja töökeskkond	12
5.3.3	Seadmed	12
5.4	Tööprotseduurid	14
5.4.1	Katsemeetodid ja -protseduurid	14
5.4.2	Kvaliteedisüsteem	16
5.4.3	Katseprotokoll	16
5.4.4	Andmestik	18
5.4.5	Katseobjektide käsitlemine	20
5.4.6	Konfidentsiaalsus ja kaitetus	20
5.4.7	Alltöövõtt	20
6	KOOSTÖÖ	20
6.1	Koostöö klientidega	20
6.2	Koostöö akrediteerimisorganiga	22
6.3	Koostöö teiste laboritega ning standardeid ja eeskirju koostavate organitega	22
7	AKREDITEERITUSEST TULENEVAD KOHUSTUSED	22

CONTENTS

	Page
1 Object and field of application	9
2 Definitions	9
2.1 test	9
2.2 test method	9
2.3 test report	9
2.4 testing laboratory	9
2.5 interlaboratory test comparisons	9
2.6 (laboratory) proficiency testing	9
2.7 (laboratory) accreditation	9
2.8 (laboratory) accreditation system	9
2.9 (laboratory) accreditation body	9
2.10 accredited laboratory	9
2.11 (laboratory) accreditation criteria	11
2.12 laboratory assessment	11
2.13 laboratory assessor	11
3 Legal identity	11
4 Impartiality, independence and integrity	11
5 Technical competence	11
5.1 Management and organization	11
5.2 Personnel	13
5.3 Premises and equipment	13
5.3.1 Availability	13
5.3.2 Premises and environment	13
5.3.3 Equipment.....	13
5.4 Working procedures	15
5.4.1 Test methods and procedures	15
5.4.2 Quality System	17
5.4.3 Test reports	17
5.4.4 Records	19
5.4.5 Handling of test samples or items	21
5.4.6 Confidentiality and security	21
5.4.7 Subcontracting	21
6 Cooperation	21
6.1 Cooperation with clients	21
6.2 Cooperation with bodies granting accreditation	23
6.3 Cooperation with other laboratories and with bodies producing standards and regulations	23
7 Duties resulting from the use of accreditation	23

KATSELABORITE TEGEVUSE ÜLDKRITERIUMID

General criteria for the operation of testing laboratories

Käesolev standard on identne EN 45001:1989 ja lubatud CENi poolt Eesti standardina välja anda

This standard is identical with EN 45001:1989 and is published with permission of CEN

Tõlgendamise erimeelsuste korral on kehtiv ingliskeelne tekst	In case of interpretation disputes the English text applies
---	---

1 EESMÄRK JA KASUTUSALA

Käesolev Euroopa standard määratleb katselaborite, kaasa arvatud kalibreerimis-laborid, tehnilise kompetentsuse üldkriteeriumid, sõltumata tegevusvaldkonnast. Standard on mõeldud kasutamiseks katselaboritele ja neid akrediteerivatele organitele ning teiste laborite tehnilist kompetentsust tunnustavatele organitele. Konkreetse tegevusvaldkonna jaoks võib siin esitatud kriteeriumide kogumit täiendada.

2 MÄÄRATLUSED

Käesoleva Euroopa standardi jaoks on rakendatud järgmisi ISO/IEC Guide 2, 1986, "General terms and their definitions concerning standardization and related activities" määratlusi:

- 2.1 **katse** - tehniline operatsioon toote, protsessi või teenuse ühe või mitme iseloomustava tunnuse määramiseks täpselt määratletud protseduuri kohaselt;
- 2.2 **katsemeetod** - katse sooritamise täpselt määratletud tehniline protseduur;
- 2.3 **katseprotokoll** - katsetulemusi ja muud asjakohast informatsiooni sisaldav dokument;
- 2.4 **katselabor** - katseid teostav labor;
- 2.5 **laboritevaheline võrdluskatse** - samade või samalaadsete objektide või materjalide katsetuste korraldamine, teostamine ja hindamine kahe või enama labori osalemisel vastavalt ettemääratud tingimustele;
- 2.6 **(labori) tasemekatse** - labori katsetustaseme määramine laboritevahelise võrdluskatse abil;
- 2.7 **(labori) akrediteerimine** - katselabori kompetentsuse ametlik tunnustamine teatud katsete või katsetusliikide sooritamiseks;
- 2.8 **(laborite) akrediteerimissüsteem** - oma protseduuri- ja juhtimisreeglitega süsteem laborite akrediteerimiseks;
- 2.9 **(laborite) akrediteerimisorgan** - organ, kes juhib ja haldab laborite akrediteerimissüsteemi ning annab akrediteerituse;
- 2.10 **akrediteeritud labor** - katselabor, mis on saanud akrediteerituse;

1 Object and field of application

This European Standard specifies general criteria for the technical competence of testing laboratories including calibration laboratories, irrespective of the sector involved.

It is intended for the use of testing laboratories and their accreditation bodies as well as other bodies concerned with recognizing the competence of testing laboratories.

This set of criteria may have to be supplemented when applied to a particular sector.

2 Definitions

For the purpose of this European Standard the following definitions contained in ISO/IEC Guide 2, edition 1986, "General terms and their definitions concerning standardization and related activities" are applicable:

- 2.1 **test:** Technical operation that consists of the determination of one or more characteristics of a given product, processor service according to a specified procedure.
- 2.2 **test method:** Specified technical procedure for performing a test.
- 2.3 **test report:** Document that presents test results and other information relevant to a test.
- 2.4 **testing laboratory:** Laboratory that performs tests.
- 2.5 **interlaboratory test comparisons:** Organization, performance and evaluation of tests on the same or similar items or materials by two or more laboratories in accordance with predetermined conditions.
- 2.6 **(laboratory) proficiency testing:** Determination of laboratory testing performance by means of interlaboratory test comparisons.
- 2.7 **(laboratory) accreditation:** Formal recognition that a testing laboratory is competent to carry out specific tests or specific types of tests.
- 2.8 **(laboratory) accreditation system:** System that has its own rules of procedure and management for carrying out laboratory accreditation.
- 2.9 **(laboratory) accreditation body:** Body that conducts and administers a laboratory accreditation system and grants accreditation.
- 2.10 **accredited laboratory:** Testing laboratory to which accreditation has been granted.