Laborimeditsiin. Nõuded võrdlusmõõtmisi teostavatele laboritele

Laboratory medicine - Requirements for reference measurement laboratories

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 15195:2004 sisaldab Euroopa standardi EN ISO 15195:2003 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 15195:2004 consists of the English text of the European standard EN ISO 15195:2003.
Standard on kinnitatud Eesti Standardikeskuse 23.11.2004 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.	This standard is ratified with the order of Estonian Centre for Standardisation dated 23.11.2004 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.
Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 01.10.2003.	Date of Availability of the European standard text 01.10.2003.
Standard on kättesaadav Eesti standardiorganisatsioonist.	The standard is available from Estonian standardisation organisation.

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EUROPEAN STANDARD
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EN ISO 15195

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English version

Laboratory medicine

Requirements for reference measurement laboratories
(ISO 15195 : 2003)

Médecine de laboratoires – Exigences pur les laboratoires réalisant des mesurages de référence (ISO 15195 : 2003)

Laboratoriumsmedizin – Anforderungen an die Referenzmesslaboratorien (ISO 15195 : 2003)

This European Standard was approved by CEN on 2003-07-24.

CEN 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 Management Centre or to any CEN member.

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

CEN members are the national standards bodies of Austria, Belgium, the Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Luxembourg, Malta, the Netherlands, Norway, Portugal, Slovakia, Spain, Sweden, Switzerland, and the United Kingdom.

CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

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

Ref. No. EN ISO 15195 : 2003 E

Foreword

International Standard

ISO 15195 : 2003 Laboratory medicine – Requirements for reference measurement laboratories,

which was prepared by ISO/TC 212 'Clinical laboratory testing and in vitro diagnostic test systems' of the International Organization for Standardization, has been adopted by Technical Committee CEN/TC 140 'In vitro diagnostic medical devices', the Secretariat of which is held by DIN, as a European Standard.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, and conflicting national standards withdrawn, by April 2004 at the latest.

In accordance with the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard:

Austria, Belgium, the Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Luxembourg, Malta, the Netherlands, Norway, Portugal, Slovakia, Spain, Sweden, Switzerland, and the United Kingdom.

Endorsement notice

The text of the International Standard ISO 15195 : 2003 was approved by CEN as a European Standard without any modification.

NOTE: Normative references to international publications are listed in Annex ZA (normative).

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Introduction

The general requirements for the competence of calibration laboratories are laid down in ISO/IEC 17025 for testing and calibration laboratories. This International Standard refers to the specific aspects of calibration laboratories in the field of laboratory medicine where such “calibration laboratories” are usually denoted as “reference measurement laboratories.”

The results produced by medical laboratories should be traceable to reference materials and/or reference measurement procedures of higher order, whenever these are available. This is necessary in order to allow transferability of measurement results in patient samples irrespective of the place and time of measurement.

In order to achieve this goal, the first and essential step is to define the quantity to be measured. Once the quantity has been defined, a reference measurement system should be established, consisting of

- reference materials,
- reference measurement procedures, and
- reference measurement laboratories.

The reference measurement laboratories should be embedded in international (global) networks organized under the auspices of, for example, International Federation of Clinical Chemistry and Laboratory Medecine (IFCC) and International Committee of weights and Measures (CIPM).

Reference measurement laboratories must operate with a traceability to the highest metrological level available and with a lower uncertainty than routine laboratories. The metrological level of the results provided by reference measurement laboratories should be appropriate to enable routine laboratories to fulfil medical requirements. The specific requirements of medical laboratories carrying out routine measurements are addressed in ISO 15189.

The presentation of reference measurement procedures and the description of reference materials are the subject of ISO standards (ISO 15193 and ISO 15194, respectively). This International Standard describes the performance characteristics required for reference measurement laboratories in laboratory medicine. These are highly specialized laboratories often attached to or subcontracted by entities such as national metrology institutes, quality assessment/proficiency testing organizations, academic centres, or *in vitro* diagnostic medical device manufacturers.

Reference measurement laboratories should implement reference measurement procedures and produce results of measurement that are accurate and traceable to national or international primary reference materials when such are available. Whenever possible, traceability should be established to a reference material which forms an embodiment of the SI unit (ISO 17511).

In many instances, properties of biological materials cannot be expressed in SI units as the molecular structure of their analytes is not exactly known and may be different in a reference material from that in a native sample of human origin (e.g. state of glycosylation of a protein); then the traceability chain ends at a lower level, e.g., at an arbitrary international unit (int. unit). However, the reference measurement laboratory should provide traceable values on reference materials supplied by customers to the highest available level of reference measurement procedures or reference materials.

Even if the value for a property of a biological material is not traceable to an SI unit, each step of a reference measurement procedure (e.g. gravimetry, volumetry, temperature measurement) should have values that are traceable to the respective SI unit.

The traceability concept, its applicability and limitations are described in detail in the standard “Metrological traceability of values assigned to calibrators and control materials” (ISO 17511).

Further tasks of reference measurement laboratories may include upon request:

— assisting in investigation of new or existing measurement procedures with regard to their trueness,

— providing accurate (true and precise) assigned values with stated uncertainty to materials for calibration, internal quality control, and external quality assessment,

— acting as consultants to government, industry, and organizations conducting external quality assessment schemes as well as to specialized individual laboratories.

The requirements described in this document and in ISO/IEC 17025 are prerequisites for reference measurement laboratories to perform their tasks adequately. When the reference measurement laboratory is integrated into a routine laboratory, the management system, personnel and equipment requirements of the reference laboratory should comply with this International Standard and be independent of the routine laboratory.

This International Standard should aid in establishing confidence in reference measurement laboratories that are able to demonstrate their competence in accordance with the requirements laid down here.

This International Standard may form a basis for the accreditation of a reference measurement laboratory that applies for official recognition of the performance of a reference measurement procedure. Reference measurement laboratories are usually accredited by the national metrology institutes or national accrediting bodies.

NOTE The requirements for recognition and operation are set out in ISO/IEC Guide 58. The International Laboratory Accreditation Cooperation (ILAC) coordinates and supervises the regional organizations of national accrediting bodies, such as the European Cooperation for Accreditation (EA), which ensures that member bodies recognize each other's accreditation certificates.

This International Standard may furthermore facilitate collaboration between reference measurement laboratories performing interlaboratory comparisons and encourage the highly desirable formation of international networks of reference measurement laboratories.

It is understood that reference measurement procedures should be of high metrological order and the analytical principle of measurement applied should allow an adequately low uncertainty. The results of reference measurements should be traceable to reference materials or to a reference procedure of higher order when available.

1 Scope

This International Standard gives the specific requirements for reference measurement laboratories in laboratory medicine. Examinations of properties with results reported on a nominal or ordinal scale are not included.

This International Standard is not applicable to routine medical laboratories.

NOTE 1 It is the laboratory's responsibility to comply with the relevant legal health and safety requirements.

NOTE 2 Requirements for routine medical laboratories are specified in ISO 15189.

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 15193, *In vitro diagnostic medical devices — Measurement of quantities in samples of biological origin — Presentation of reference measurement procedures*

ISO 15194:2002, *In vitro diagnostic medical devices — Measurement of quantities in samples of biological origin — Description of reference materials*

ISO 17511, *In vitro diagnostic medical devices — Measurement of quantities in biological samples — Metrological traceability of values assigned to calibrators and control materials*

ISO 18153, *In vitro diagnostic medical devices — Measurement of quantities in biological samples — Metrological traceability of assigned values for catalytic concentration of enzymes in calibrators and control materials*

International vocabulary of basic and general terms in metrology (VIM). BIPM, IEC, IFCC, ISO, IUPAC, IUPAP and OIML, 1993[1)]

Guide to the expression of uncertainty in measurement (GUM). BIPM, IEC, IFCC, ISO, IUPAC, IUPAP and OIML,1993[1)]

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1) This vocabulary has been prepared simultaneously in English and French by a joint working group consisting of experts appointed by:

BIPM International Bureau of Weights and Measures
IEC International Electrotechnical Commission
IFCC International Federation of Clinical Chemistry and Laboratory Medicine
ISO International Organization for Standardization
IUPAC International Union of Pure and Applied Chemistry
IUPAP International Union of Pure and Applied Physics
OIML International Organization of Legal Metrology