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LABORIMEDITSIIN. NÕUDED VÕRDLUSMÕÕTMISI TEOSTAVATE KALIBREERIMISLABORITE PÄDEVUSELE

Laboratory medicine - Requirements for the competence of calibration laboratories using reference measurement procedures (ISO 15195:2018)

EESTI STANDARDIKESKUS
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NATIONAL FOREWORD

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See Eesti standard EVS-EN ISO 15195:2019 sisaldab Euroopa standardi EN ISO 15195:2019 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 15195:2019 consists of the English text of the European standard EN ISO 15195:2019.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 06.02.2019.	Date of Availability of the European standard is 06.02.2019.
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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 15195

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Supersedes EN ISO 15195:2003

English Version

Laboratory medicine - Requirements for the competence of calibration laboratories using reference measurement procedures (ISO 15195:2018)

Biologie médicale - Exigences relatives à la compétence des laboratoires d'étalonnage utilisant des procédures de mesure de référence (ISO 15195:2018)

Laboratoriumsmedizin - Anforderungen an die Kompetenz von Kalibrierlaboratorien mit Referenzmessverfahren (ISO 15195:2018)

This European Standard was approved by CEN on 7 December 2018.

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Ref. No. EN ISO 15195:2019 E

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European foreword

This document (EN ISO 15195:2019) has been prepared by Technical Committee ISO/TC 212 "Clinical laboratory testing and in vitro diagnostic test systems" in collaboration with Technical Committee CEN/TC 140 “In vitro diagnostic medical devices” the secretariat of which is held by DIN.

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of an identical text or by endorsement, at the latest by August 2019, and conflicting national standards shall be withdrawn at the latest by February 2022.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 15195:2003.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association.

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

Endorsement notice

The text of ISO 15195:2018 has been approved by CEN as EN ISO 15195:2019 without any modification.

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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).

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For an explanation of 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 www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 212, *Clinical laboratory testing and in vitro diagnostic test systems*.

This second edition cancels and replaces the first edition (ISO 15195:2003), which has been technically revised.

The main changes compared to the previous edition are as follows:

— inclusion of ISO/IEC 17025:2017 as a normative reference;

— removal of clauses that duplicate requirements in ISO/IEC 17025:2017;

— reorganization of this document so that it follows the structure of ISO/IEC 17025:2017.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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Introduction

The general requirements for the competence of calibration laboratories are specified in ISO/IEC 17025:2017 for testing and calibration laboratories. This document refers to the additional aspects for the competence 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 to allow transferability of measurement results in patient samples irrespective of the place and time of measurement.

The metrological level of the results provided by calibration laboratories should be appropriate to support medical laboratories to fulfil medical requirements. The specific requirements of medical laboratories are addressed in ISO 15189.

Calibration 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).

The calibration laboratory should provide traceable values on reference materials supplied by customers to the highest available level of reference measurement procedures or reference materials.

In many instances, properties of biological materials cannot be expressed in SI units because the molecular structure of their analytes is not exactly known and can be different in a reference material from that in a native sample of human origin (e.g. state of glycosylation of a protein).

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, thermometry, potentiometry) should have values that are traceable to the respective SI unit.

The traceability concept, including its applicability and limitations are described in detail in ISO 17511.

The requirements described in this document and in ISO/IEC 17025:2017 are prerequisites for calibration laboratories to perform their tasks adequately.

This document may form a basis for the accreditation of a calibration laboratory that applies for recognition of the performance of a reference measurement procedure.

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Laboratory medicine — Requirements for the competence of calibration laboratories using reference measurement procedures

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1 Scope

This document specifies the requirements for competence to carry out reference measurement procedures in laboratory medicine, using the requirements of ISO/IEC 17025:2017 as a normative reference and listing additional requirements for calibration laboratories to perform their tasks adequately.

The relationship between clauses in this document and ISO/IEC 17025:2017 are summarized in Annex A.

Examinations of properties with results reported on a nominal or ordinal scale are not included.

This document is not applicable to medical laboratories.

NOTE Requirements for medical laboratories are specified in ISO 15189[1].

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 Guide 98-3, *Uncertainty of measurement — Part 3: Guide to the expression of uncertainty in measurement (GUM:1995)*

ISO/IEC Guide 99, *International vocabulary of metrology — Basic and general concepts and associated terms (VIM)*

ISO 15193, *In vitro diagnostic medical devices — Measurement of quantities in samples of biological origin — Requirements for content and presentation of reference measurement procedures*

ISO 15194, *In vitro diagnostic medical devices — Measurement of quantities in samples of biological origin — Requirements for certified reference materials and the content of supporting documentation*

ISO/IEC 17025:2017, *General requirements for the competence of testing and calibration laboratories*

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 values for catalytic concentration of enzymes assigned calibrators and control materials*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO/IEC Guide 99 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

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