Medical laboratories - Particular requirements for quality and competence

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EESTI STANDARDIKESKUS
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NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 15189:2008 sisaldab Euroopa standardi EN ISO 15189:2007 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 15189:2008 consists of the English text of the European standard EN ISO 15189:2007.
Standard on kinnitatud Eesti Standardikeskuse 19.05.2008 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.	This standard is ratified with the order of Estonian Centre for Standardisation dated 19.05.2008 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 .	Date of Availability of the European standard text .
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Medizinische Laboratorien - Besondere Anforderungen an die Qualität und Kompetenz (ISO 15189:2007)

This European Standard was approved by CEN on 9 April 2007.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
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EUROPÄISCHES KOMITEE FÜR NORMUNG

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Foreword

This document (EN ISO 15189:2007) 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of an identical text or by endorsement, at the latest by October 2007, and conflicting national standards shall be withdrawn at the latest by October 2007.

This document supersedes EN ISO 15189:2003.

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, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

Endorsement notice

The text of ISO 15189:2007 has been approved by CEN as EN ISO 15189:2007 without any modifications.

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Introduction

This International Standard, based upon ISO/IEC 17025 and ISO 9001, provides requirements for competence and quality that are particular to medical laboratories[1)]. It is acknowledged that a country could have its own specific regulations or requirements applicable to some or all its professional personnel and their activities and responsibilities in this domain.

Medical laboratory services are essential to patient care and therefore have to be available to meet the needs of all patients and the clinical personnel responsible for the care of those patients. Such services include arrangements for requisition, patient preparation, patient identification, collection of samples, transportation, storage, processing and examination of clinical samples, together with subsequent validation, interpretation, reporting and advice, in addition to the considerations of safety and ethics in medical laboratory work.

Whenever allowed by national regulations, it is desirable that medical laboratory services include the examination of patients in consultation cases, and that those services actively participate in the prevention of disease in addition to diagnosis and patient management. Each laboratory ought also to provide suitable educational and scientific opportunities for professional staff working with it.

While this International Standard is intended for use throughout the currently recognised disciplines of medical laboratory services, those working in other services and disciplines could also find it useful and appropriate. In addition, bodies engaged in the recognition of the competence of medical laboratories will be able to use this International Standard as the basis for their activities. If a laboratory seeks accreditation, it should select an accrediting body which operates to appropriate international standards and which takes into account the particular requirements of medical laboratories.

Demonstrated conformity to this International Standard does not imply conformity of the quality management system within which the laboratory operates to all the requirements of ISO 9001. This International Standard is not intended to be used for the purposes of certification.

The correlation between the clauses and subclauses of this second edition of ISO 15189 and those of ISO 9001:2000 and of ISO/IEC 17025:2005 is detailed in Annex A of this International Standard.

1) In other languages, these laboratories can be designated by the equivalent of the English term “clinical laboratories.”

Medical laboratories — Particular requirements for quality and competence

1 Scope

1.1 This International Standard specifies requirements for quality and competence particular to medical laboratories.

1.2 This International Standard is for use by medical laboratories in developing their quality management systems and assessing their own competence, and for use by accreditation bodies in confirming or recognising the competence of medical laboratories.

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 31 (all parts), *Quantities and units*

ISO 9000:2005, *Quality management systems — Fundamentals and vocabulary*

ISO 9001:2000, *Quality management systems — Requirements*

ISO/IEC Guide 43-1, *Proficiency testing by interlaboratory comparisons — Part 1: Development and operation of proficiency testing schemes*

ISO/IEC 17025:2005, *General requirements for the competence of testing and calibration laboratories*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
accreditation
procedure by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks

3.2
accuracy of measurement
closeness of the agreement between the result of a measurement and a true value of the measurand

[VIM:1993, definition 3.5]