MEDITSIINILABORID
Ohutusnõuded

Medical laboratories
Requirements for safety
(ISO 15190:2020, identical)

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-ISO 15190:2020 „Meditsiinilaborid. Ohutusnõuded“ sisaldab rahvusvahelise standardi ISO 15190:2020 Medical laboratories. Requirements for safety“ identset ingliskeelset teksti.	This Estonian Standard EVS-ISO 15190:2020 consists of the identical English text of the International Standard ISO 15190:2020 „Medical laboratories. Requirements for safety“.
Ettepaneku rahvusvahelise standardi mbertrüki meetodil ülevõtuks on esitanud EVS/TK 11, standardi avaldamist on korraldanud Eesti Standardikeskus.	Proposal to adopt the International Standard by reprint method has been presented by EVS/TK 11, the Estonian Standard has been published by the Estonian Centre for Standardisation.
Standard EVS-ISO 15190:2020 on jõustunud sellekohase teate avaldamisega EVS Teatajas.	Standard EVS-ISO 15190:2020 has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

Käsitlusala

See dokument määratleb ohutu töötamise praktikate nõuded meditsiinilaboris (edaspidi: labor).

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

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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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on 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 the following URL: 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 15190:2003), which has been technically revised. The main changes compared to the previous edition are as follows:

— updates of existing sections and the addition of sections including but not limited to, risk assessment, ergonomics, employee impairment, emergency preparedness and a comprehensive safety management program.

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.

Introduction

This document specifies requirements to establish and maintain a safe working environment in a medical laboratory. As with all such safety guidelines, requirements are set forth to specify the role and responsibilities of the laboratory safety officer in ensuring that all employees take personal responsibility for

— their own safety at work, and

— the safety of others who can be affected by it.

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 examination requests;

— patient preparation, patient identification;

— collection of samples;

— transportation;

— storage;

— processing;

— and examination of clinical samples;

— subsequent interpretation;

— and reporting and advice.

Whenever advised by national, regional or local regulations and requirements, 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, enhancing the welfare of healthcare stakeholders in addition to diagnosis and patient management. Each laboratory should also provide suitable educational and scientific opportunities for professional staff.

While this document is intended for use throughout the currently recognized disciplines of medical laboratory services, other services and disciplines can find it useful and appropriate. However, medical laboratories handling human pathogens requiring containment levels 3 and 4 will need to meet additional requirements to ensure safety.

While this document is not intended to provide guidance on accreditation, it may be used for such purposes by a government, professional, or other authoritative body.

International, national or regional regulations or guidelines may apply to specific topics covered in this document.

Medical laboratories — Requirements for Safety

1 Scope

This document specifies requirements for safe practices in the medical laboratory (herein after referred to as "the laboratory").

2 Normative references

The following document is referred to in the text in such a way that some or all of its 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 15189, *Medical laboratories — Requirements for quality and competence*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 15189 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

— IEC Electropedia: available at http://www.electropedia.org/

3.1
adverse incident
adverse event
any event that is not consistent with the desired, normal, or usual operation of the organization

3.2
aerosols
colloidal suspensions of liquid or solid particles dispersed in a gas (usually air), smoke or fog

3.3
antiseptic
chemical germicide formulated to be used on skin or *tissue* (3.30)

3.4
biological agent
any *microorganism* (3.15), including those which have been genetically modified, cell cultures and human endo-parasites, which can provoke any infection, allergy or toxicity

3.5
biological safety cabinet
BSC
ventilated enclosure, intended to offer protection to the user and the environment from the *aerosols* (3.2) arising from handling of potentially hazardous *microorganisms* (3.15), with means for filtering air discharged to the atmosphere

[SOURCE: EN 12469:2000, 3.3 modified]

