This document is a preview generated by EVS

# MEDITSIINILABORID
# Ohutusnõuded

Medical laboratories
Requirements for safety

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

## EESTI STANDARDI EESSÕNA

Käesolev Eesti standard EVS-ISO 15190:2007 “Meditsiinilaborid. Ohutusnõuded” sisaldab rahvusvahelise standardi ISO 15190:2003 “Medical laboratories - Requirements for safety” identset ingliskeelset teksti.

Standard EVS-ISO 15190:2007 on kinnitatud Eesti Standardikeskuse 19.06.2009 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.

Standard on kättesaadav Eesti Standardikeskusest.

## NATIONAL FOREWORD

This Estonian Standard EVS-ISO 15190:2007 consists of the identical English text of the International Standard ISO 15190:2003 “Medical laboratories - Requirements for safety”.

This standard is ratified with the order of Estonian Centre for Standardisation dated 19.06.2009 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.

The standard is available from Estonian Centre for Standardisation.

## Käsitlusala

Käesolev rahvusvaheline standard täpsustab ohutusnõudeid meditsiinilaboris.

## Scope

This International Standard specifies requirements for safe practices in the medical laboratory.

This document is a preview generated by EVS

**ICS 11.100** Laboratoorne meditsiin
**Võtmesõnad:** meditsiinilabor, ohutusnõuded

**Standardite reprodutseerimis- ja levitamisõigus kuulub Eesti Standardikeskusele**

Andmete paljundamine, taastekitamine, kopeerimine, salvestamine elektroonilisse süsteemi või edastamine ükskõik millises vormis või millisel teel on keelatud ilma Eesti Standardikeskuse poolt antud kirjaliku loata.

Kui Teil on küsimusi standardite autorikaitse kohta, palun võtke ühendust Eesti Standardikeskusega:
Aru 10 Tallinn 10317 Eesti; www.evs.ee; Telefon: 605 5050; E-post: info@evs.ee

**Right to reproduce and distribute belongs to the Estonian Centre for Standardisation**

No part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying, without permission in writing from Estonian Centre for Standardisation.

If you have any questions about standards copyright, please contact Estonian Centre for Standardisation:
Aru str 10 Tallinn 10317 Estonia; www.evs.ee; Phone: 605 5050; E-mail: info@evs.ee

This document is a preview generated by EVS

# Contents

Page



© ISO 2003 — All rights reserved

This document is a preview generated by EVS


© ISO 2003 — All rights reserved

This document is a preview generated by EVS

## 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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 15190 was prepared by Technical Committee ISO/TC 212, *Clinical laboratory testing and* in vitro *diagnostic test systems*.

© ISO 2003 — All rights reserved

## Introduction

This International Standard specifies requirements to establish and maintain a safe working environment in a medical laboratory. As with all such safety guidelines, there are requirements to ensure that there is a named person ultimately responsible and that all employees take personal responsibility for

— their own safety at work and,

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

Every task requires risk assessment, with the aim that hazards be eliminated wherever possible. Where this cannot be done, the risk from each hazard is reduced to as low a level as practicable, using the following order of priority:

a) by substitution;

b) by containment; or

c) by the use of personal protective measures and equipment.

Safety is the primary consideration; cost is of secondary importance.

While this International Standard is intended for use throughout the currently recognized disciplines of medical laboratory services, other services and disciplines may 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 International Standard 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 International Standard.

This document is a preview generated by EVS


© ISO 2003 — All rights reserved

# Medical laboratories — Requirements for safety

This document is a preview generated by EVS

## 1 Scope

This International Standard specifies requirements for safe practices in the medical laboratory.

## 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 15189:2003, *Medical laboratories — Particular requirements for quality and competence*

© ISO 2003 — All rights reserved