

# INTERNATIONAL STANDARD

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**15190**

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## **Medical laboratories — Requirements for safety**

*Laboratoires de biologie médicale — Exigences pour la sécurité*



Reference number  
ISO 15190:2020(E)

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## ISO 15190:2020(E)



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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](http://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](http://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](http://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](http://www.iso.org/members.html).

## ISO 15190:2020(E)

### 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]

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### 3.6 cleaning

process to remove any type of contamination, visible or not

[SOURCE: ISO/TS 20658:2017, 3.5]

### 3.7 decontamination

procedure that eliminates or reduces microbial or toxic agents to a safe level with respect to the transmission of infection or other adverse effects

### 3.8 disinfectant

agent capable of causing *disinfection* (3.9)

### 3.9 disinfection

process to reduce the number of *microorganisms* (3.15), but not usually of bacterial spores, without necessarily killing or removing all organisms

### 3.10 droplets

very small drop of liquid

Note 1 to entry: A small drop, such as a particle of moisture discharged from the mouth during coughing, sneezing, or speaking.

Note 2 to entry: These can transmit pathogens and cause infection by dispersion into the air.

### 3.11 ergonomics

study of the efficiency and safety of persons in their working environment

Note 1 to entry: This term includes biomechanics, work physiology, anthropomorphy and man-machine interfaces.

### 3.12 extraction hood fume hood

laboratory device used for the extraction of air or fumes which prevents their general circulation

EXAMPLE Fume/ventilation hood, cabinet or cover.

Note 1 to entry: These can recirculate if filtered air/made safe.

### 3.13 hazard

potential source of *harm* (3.13)

[SOURCE: ISO Guide 73:2009, 3.5.1.4]

### 3.14 hazardous waste

waste that is potentially flammable, combustible, ignitable, corrosive, toxic, reactive, infectious or injurious to people or the environment

### 3.15 microorganism

microbiological entity, cellular or non-cellular, capable of replication or of transferring genetic material

**3.16**

**noise**

unwanted sound in the form of acoustic energy which can adversely affect health

**3.17**

**personal protective equipment**

variety of barriers including clothing and respirators used alone or in combination to protect mucous membranes, airways, skin, and clothing from contacts with infectious or hazardous agents

**3.18**

**physical hazard**

agent, factor or circumstance that can cause harm with or without contact

Note 1 to entry: Physical hazards can be classified as occupational or environmental.

Note 2 to entry: Physical hazards include but are not limited to radiation hazards, electrical hazards, ventilation hazards, heat, noise and pressure hazards.

**3.19**

**radionuclide**

natural or synthetically produced unstable nucleus of an atom that emits ionizing radiation

**3.20**

**record**

document stating results achieved or providing evidence of activities performed

Note 1 to entry: Records can be used, for example, to formalize traceability and to provide evidence of verification, preventive action and corrective action.

Note 2 to entry: Generally records need not be under revision control.

[SOURCE: ISO 9000:2015, 3.8.10]

**3.21**

**risk**

combination of the probability of occurrence of harm and the severity of that harm

Note 1 to entry: The probability of occurrence includes the exposure to a hazardous situation, the occurrence of a hazardous event and the possibility to avoid or limit the harm.

[SOURCE: ISO/IEC Guide 51:2014, 3.9]

**3.22**

**risk assessment**

overall process comprising a *risk* (3.21) analysis and a *risk evaluation* (3.23)

[SOURCE: ISO/IEC Guide 51:2014, 3.11]

**3.23**

**risk evaluation**

procedure based on the *risk* (3.21) analysis to determine whether tolerable *risk* (3.21) has been exceeded

[SOURCE: ISO/IEC Guide 51:2014, 3.12]

**3.24**

**risk management**

systematic application of management policies, procedures and practices to the tasks of analyzing, evaluating, controlling and monitoring *risk* (3.21)

Note 1 to entry: In ISO Guide 73:2009, 2.1, risk management is defined as “coordinated activities to direct and control an organization with regard to *risk* (3.21)”.