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Medical laboratories — Requirements for safety

Laboratoires de médecine — Exigences pour la sécurité



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Contents

Page

Foreword.....	v
Introduction	vi
1 Scope.....	1
2 Normative references	1
3 Terms and definitions.....	1
4 Risk group classification.....	3
5 Management requirements	4
5.1 Management responsibilities.....	4
5.2 Management of staff health.....	4
6 Designing for safety.....	4
6.1 Preliminary considerations	4
6.2 General design requirements	4
6.3 Physical conditions	5
7 Staffing, procedures, documentation, inspection and records	6
7.1 Laboratory Safety Officer	6
7.2 Procedures	6
7.3 Safety programme audits and inspection	7
7.4 Safety manual.....	8
7.5 Records	8
8 Identification of hazards.....	9
9 Reporting of incidents, injury, accidents and occupational illnesses	9
10 Training	9
11 Personnel responsibilities	10
11.1 Food, drink and like substances	10
11.2 Cosmetics, hair, beards and jewellery.....	10
11.3 Immunization status	10
11.4 Personal property	11
11.5 Festive decorations	11
12 Clothing and personal protective equipment (PPE), including gloves, eye, face, foot and respiratory protection.....	11
12.1 Protective clothing in the laboratory	11
12.2 Protective clothing outside the laboratory.....	11
12.3 Face and body protection	11
12.4 Gloves	11
12.5 Footwear	12
12.6 Respiratory protection.....	12
12.7 Handwashing.....	12
12.8 Training	13
12.9 Equipment.....	13
12.10 Eyewash stations	13
12.11 Emergency showers	13
13 Good housekeeping practices.....	14
14 Safe work practices	14
14.1 Safe work practices with all material of biological origin.....	14
14.2 Special requirements for working in microbiology laboratories	15

This is a preview of "ISO 15190:2003". [Click here to purchase the full version from the ANSI store.](#)

15	Aerosols	15
16	Microbiological safety cabinets, chemical safety hoods and cabinets	16
17	Chemical safety	16
17.1	Measures to avoid chemical contamination	16
17.2	Emergency measures applicable when chemical contamination has occurred	17
17.3	Discarded chemicals	17
18	Radiation safety	17
18.1	Radionuclides	17
18.2	Radiation protection advisors, officers, and supervisors	17
18.3	Workplace monitoring	18
18.4	UV and laser light sources (including light from high-intensity sources)	18
18.5	Microwave equipment	18
19	Fire precautions	19
19.1	Construction	19
19.2	Secondary exits	19
19.3	Alarm systems	19
19.4	Fire risk reduction strategies	19
19.5	Storage of flammable materials	19
19.6	Fire safety training programmes	20
19.7	Firefighting equipment	20
20	Emergency evacuations	20
21	Electrical equipment	20
22	Transport of samples	21
23	Waste disposal	21
	Annex A (informative) Action-plan outline for implementation of this International Standard	23
	Annex B (informative) Laboratory safety audit	25
	Annex C (informative) Decontamination, cleaning and disinfection following a spillage	35
	Bibliography	37

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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.

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*.

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.