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Medical laboratories — Requirements for safety

Laboratoires de médecine — Exigences pour la sécurité

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Foreword

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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*.

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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.

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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.

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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.

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Medical laboratories — Requirements for safety

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*

3 Terms and definitions

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

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3.1
aerosols
system of particles dispersed in a gas, smoke, or fog

3.2
antisepsis
method for avoiding infection in a wound or during a clinical procedure by the use of a chemical agent such as an antiseptic

[BS 6324-1]

3.3
antiseptic
chemical germicide formulated to be used on skin or tissue

3.4
biological agent
any microorganism, including those which have been genetically modified, cell cultures and human endoparasites, which may be able to provoke any infection, allergy or toxicity

NOTE For classification of biological agents into risk groups, see Clause 4.

3.5
cleaning
process to remove any type of contamination, visible or not

3.6
control of infection plan
set of procedures to be used to limit spread of infection in either a hospital or a laboratory

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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

[BS 6324-1]

3.9
disinfection
process to reduce the number of microorganisms, but not usually of bacterial spores, without necessarily killing or removing all organisms

3.10
ergonomics
study of the efficiency of persons in their working environment

NOTE This term includes biomechanics, work physiology, anthropomorphy and man-machine interfaces.

3.11
extraction hood
fume hood
cabinet or cover above a laboratory device for the extraction of air or fumes which prevents their general circulation

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3.12
hazard
potential source of harm

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[IEC 61010-1:2001]

3.13
hazardous waste
waste that is potentially flammable, combustible, ignitable, corrosive, toxic, reactive, or injurious to people or the environment

3.14
material safety data sheet
MSDS
technical bulletin providing detailed hazard and precautionary information

3.15
microbiological safety cabinet
MSC
biological safety cabinet
ventilated enclosure, intended to offer protection to the user and the environment from the aerosols arising from handling of potentially hazardous and hazardous microorganisms, with means for filtering air discharged to the atmosphere

NOTE Adapted from EN 12469:2000.

3.16
microorganism
microbiological entity, cellular or non-cellular, capable of replication or of transferring genetic material

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3.17
noise
unwanted sound in the form of acoustic energy which may adversely affect health

3.18
personal protective equipment
material, including clothing, used to prevent contamination of a person by chemical or biological matter

3.19
radionuclide
natural or synthetically produced unstable nucleus of an atom that emits ionizing radiation

3.20
risk
combination of the probability of occurrence of harm and the severity of that harm

3.21
safety hood
covering over a medical laboratory workplace or device intended to reduce risk to a laboratory worker

3.22
spill kit
set of equipment used for the removal of chemical or microbiological material from a laboratory surface or apparatus

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3.23
splash guard
device used to prevent personal contamination by a liquid

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3.24
sterilization
validated process used to render a product free from microorganisms

3.25
technical area
space in a medical laboratory allocated for the preparation or examination of samples

3.26
tissue
any coherent collection of animal or plant specialized cells

4 Risk group classification

Biological agents are classified into four risk groups:

a) Risk Group I (low individual and community risk)

This group includes those microorganisms, bacteria, fungi, viruses and parasites which are unlikely to cause disease in healthy workers or animals (e.g. non-pathogenic biological agents).

b) Risk Group II (moderate individual risk, limited community risk)

This group includes pathogens that can cause human or animal disease, but under normal circumstances are unlikely to be a serious hazard to healthy laboratory workers, the community, livestock or the environment (e.g. *Staphylococcus aureus*, *Listeria monocytogenes*). Laboratory exposures rarely cause infection leading to serious disease; effective treatment and preventive measures are available and the risk of spread is limited.

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c) Risk Group III (high individual risk, low community risk)

This group includes pathogens that usually cause serious human or animal disease, or which can result in serious economic consequences but do not ordinarily spread by casual contact from one individual to another, or that can be treated by antimicrobial or antiparasitic agents (e.g. *Salmonella typhi*, prion).

d) Risk Group IV (high individual risk, high community risk)

This group includes pathogens that usually produce very serious human or animal disease, often untreatable, and may be readily transmitted from one individual to another, or from animal to human or vice-versa, directly or indirectly, or by casual contact (e.g. smallpox virus).

Medical laboratories dealing with Risk Groups III and IV infectious agents will need to meet additional requirements to ensure safety.

NOTE In Europe, “Risk Groups I, II, III and IV” are termed “Hazard Groups 1, 2, 3 and 4”. For the purposes of this International Standard, the terms may be considered interchangeable and local usage will determine the actual terminology required. Risk Groups II, III and IV may also be termed “pathogens” or “infectious agents”.

5 Management requirements

5.1 Management responsibilities

Laboratory management shall have responsibility for the safety of all employees and visitors to the laboratory. The ultimate responsibility shall rest with the laboratory director or a named person of equivalent standing.

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5.2 Management of staff health

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All personnel shall have documented evidence of training related to potential risks associated with working with any medical (clinical) laboratory facility.

All personnel should be advised to inform their family doctor/personal physician that they work in a medical laboratory. All personnel should be strongly encouraged to have immunizations to prevent infections associated with organisms to which the person is likely to be exposed. For example, all personnel working with or handling human blood, sera, body fluids or human tissue should be offered hepatitis B vaccine. Records of immunizations should be kept in accordance with ISO 15189.

6 Designing for safety

6.1 Preliminary considerations

When new construction is being considered, or where a laboratory is already established and structural changes are proposed, appropriate national and local building regulations and building codes containing specific architectural safety standards for laboratories shall be followed. No structural or engineering work shall be undertaken without the appropriate permission being given by the laboratory director or his/her nominated representative.

NOTE International and national standards bodies are sources of helpful information.

6.2 General design requirements

Laboratories shall be designed to ensure that containment of microbiological, chemical, radiological and physical hazards is appropriate to the level of assessed risks in technical work areas, and provides a safe working environment in associated office areas and adjoining public space to limit risk to the surrounding community. Corridors and passages to the exits shall be clear of obstructions.

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The laboratory should be designed to ensure a clear separation of phlebotomy facilities where they are included in the laboratory area, sample reception, administrative and analytical areas. Each area should have environmental controls and facilities, furnishings, work surfaces and floor finishes appropriate to the activity being performed there. There should be sufficient unobstructed space for safe working, including adequate space around large pieces of equipment for maintenance personnel. There should be suitable and adequate designated spaces, proximal to, but safely separated from, laboratory working space for the safe and secure storage of samples, chemicals, records, and for rubbish or designated laboratory waste prior to disposal.

Dedicated handwashing sinks should be fixed within all areas where biological materials are handled. Wherever possible, hand-operated sink handles should be replaced with motion-, elbow-, knee- or foot-operated equipment. Sinks installed for hand washing in areas where biological materials are handled should have unimpeded drainage (i.e. no stoppers in the basin) and the temperature of the hot water supplied should be such that hands can be held comfortably in the water flow.

A water temperature of 45 °C is recommended.

NOTE If taps (faucets) are hand-operated, it is good practice to turn them on using a paper towel or similar material to avoid hand contamination.

In designing the air-circulating system for the medical laboratory, effective separation between contaminated areas should be considered. Each area should have an individual air-circulating system.

6.3 Physical conditions

6.3.1 Lighting

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Laboratories shall be illuminated naturally or artificially to a level that is optimal for safe working. Glare and distracting reflections should be minimized.

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6.3.2 Temperature

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Any equipment generating excessive heat or chill shall be isolated from the general workspace. Personal protective equipment, including thermal protective gloves and appropriate clothing, shall be provided to allow for personnel safety and comfort.

Ambient temperature in laboratories should be controlled as far as possible to a level compatible with laboratory worker comfort.

6.3.3 Ventilation

Any equipment with the potential to generate exhaust fumes or emit excessive heat, steam, odour or toxicity shall be isolated from the general workspace and placed under a suitable extraction hood. If such arrangements are not possible, special arrangements for worker comfort shall be provided.

Local natural or mechanical ventilation is advised where unpleasant or nauseous odours could arise from certain manual processes.

Ambient humidity and changes of air in laboratories should be made compatible with laboratory worker comfort and safety.

Air flowrates should be monitored regularly to ensure adequate ventilation and should be engineered to avoid dispersion of potentially infectious agents and toxic fumes.

Ventilation ducts should be isolated from the general workspace in order to avoid dispersion or airborne infectious agents or smells in the rest of the workplace.

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6.3.4 Noise

Excessive noise levels shall be avoided within the laboratory workspace. Selection and location of equipment shall take account of individual pieces of equipment and their contribution to the cumulative noise levels in the work place. Steps shall be taken to minimize or attenuate noise generation.

6.3.5 Ergonomic factors

Laboratory activity, workspace and equipment (e.g. chairs, laboratory workstations, computer keyboards and displays), as well as vibration-producing and ultrasonic equipment, etc., shall be designed or positioned to reduce the risks of ergonomic distress disorders and accidents.

6.3.6 Design for working with viable pathogens

All laboratories working with viable biological agents shall have design characteristics appropriate to the containment of microorganisms of moderate to high risk to the individual. Laboratories designed to work with organisms of Risk Group III or above shall include design characteristics for greater containment.

6.3.7 Door signs

Laboratories shall be identified at each entrance and exit point, with emergency exits marked so as to distinguish them from normal exits. Signs at each site shall include the internationally accepted hazard indicators (e.g. biohazard, fire, radioactivity) and other relevant statutory signs.

6.3.8 Laboratory security

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Laboratory entrances shall have lockable doors. These door locks shall not prevent exit in an emergency. Laboratory access shall be restricted to authorized personnel. Locks may be required for internal doors, to restrict entry while high-risk samples are being examined. Additional security measures, such as lockable doors, locked freezers, limited access to specific personnel, etc., may be required when storing high-risk samples, cultures, chemical reagents or supplies. The threat of theft and tampering with biological agents, samples, drugs, chemicals and confidential information should be assessed, and appropriate steps taken to prevent these acts from happening.

7 Staffing, procedures, documentation, inspection and records

7.1 Laboratory Safety Officer

An appropriately qualified and experienced Laboratory Safety Officer shall be designated to assist the managers with safety issues. This person shall develop, maintain and monitor an effective laboratory safety programme.

An effective laboratory safety programme should include education, orientation and training, audit and evaluation, and programmes to promote safe laboratory practice.

The Laboratory Safety Officer shall be authorized to stop activities that are unsafe. If there is a Safety Committee, the Laboratory Safety Officer shall be at least an *ex officio* member of this Committee, if not its chairholder.

7.2 Procedures

The standard operating procedures for the laboratory shall include detailed instructions concerning any hazards involved and how to carry out the procedure with minimum risk. Procedures shall be reviewed and updated at least annually by the management representative responsible for the work place activity. A written plan, including protocols for hazard communication, shall be developed. The plan shall include the following:

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a) arrangements for visitors/contractors;

b) staff health surveillance;

c) arrangements for risk assessments to be carried out, findings recorded, and action to be taken;

d) procedures for monitoring inventory for identification of chemical and other hazardous materials, including appropriate labelling requirements, and safe storage and disposal;

e) procedures for safe practices in handling hazardous materials;

f) procedures to prevent theft of high risk/contaminated materials;

g) methods for identifying training needs and documentation;

h) procedures for obtaining, maintaining and distributing Material Safety Data Sheets (MSDS) for all materials used (to ensure that employees have 24-h access to this information);

i) procedures for the safe decontamination and maintenance of equipment;

j) emergency procedures including spillage protocols (see Annex A on action plans and Annex C on decontamination of spills);

k) incident recording/reporting and investigation; and

l) disposal of clinical waste.

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7.3 Safety programme audits and inspection

7.3.1 Safety programme audits

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The safety programme shall be audited and reviewed at least annually (by appropriately trained personnel) including, but not limited to, the following elements:

a) safety and health policy;

b) written work procedures that include safe work practices;

c) education and training of laboratory-associated staff;

d) supervision of workers;

e) regular inspections;

f) hazardous materials and substances;

g) health surveillance;

h) first aid services and equipment;

i) investigation of accidents and illnesses;

j) health and safety committee review;

k) records and statistics;

l) review of safety programme with requirement for follow-up to ensure that all required actions arising from the audit are completed.

NOTE Checklists, tailored to the area to be surveyed, are effective aids to auditing (see Annex B on conducting a laboratory safety audit).

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