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Medical laboratories — Requirements for safety

Laboratoires de biologie médicale — Exigences pour la sécurité

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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).

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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]

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)".

[SOURCE: ISO 14971:2007, 2.22, modified — "Note 1 to entry" has been added.]

3.25
safety data sheet
SDS
technical bulletin providing detailed *hazard* (3.13) and precautionary information

3.26
spill kit
set of equipment used for the removal of chemical or microbiological material from a laboratory surface or apparatus

3.27
splash guard
device used to prevent personal contamination by a liquid

3.28
sterilization
validated process used to render a product free from *microorganisms* (3.15)

3.29
technical area
space in a medical laboratory allocated for the preparation or examination of samples

3.30
tissue
any coherent collection of animal or plant specialized cells

4 Designing for safety

4.1 Preliminary considerations

When new construction is being considered, or where a laboratory is already established and structural changes are proposed, appropriate building codes containing specific architectural safety standards for the laboratory shall be followed. It is presupposed that national and local building regulations are taken into consideration. No structural or engineering work shall be undertaken without the appropriate authorization by the laboratory director or designate.

The design process shall include the identification and consultation of the individuals involved in the planning, construction and operation of the facilities, including:

a) scientific staff and other users;

b) biological risk management adviser, biological risk management committee;

c) bioscience and/or safety personnel;

d) designers;

e) builders;

f) maintenance managers;

g) suppliers of materials and equipment;

h) start-up entities;

i) certification entities;

j) regulatory bodies;

k) public emergency services; and

l) other relevant parties identified in the risk assessment.

4.2 General design requirements

When designing the laboratory, the organization shall:

a) ensure that containment of microbiological, chemical, radiological and physical hazards is appropriate to the level of assessed risks in technical work areas;

b) provide a safe environment in associated non-technical areas and adjoining public space to limit risk to the surrounding community;

c) account for the safety for all laboratory stakeholders, including staff, patients, visitors, vendors, maintenance staff, cleaning staff, etc.;

d) ensure the design process includes the identification and review of local regulations and standards considered relevant, including building regulations, as well as those related to biosecurity and biosafety in the laboratory;

e) include the identification and consultation of the people involved in the planning, construction and operation of the facilities, including:

— scientific staff and other users;

— biological risk management adviser and/or biological risk management committee;

— safety personnel;

— designers and builders;

— maintenance managers;

— suppliers of materials and equipment;

— start-up and certification entities;

— regulatory bodies;

— public emergency services;

— other relevant parties identified in the risk assessment.

f) ensure effective separation between laboratory sections in which there are incompatible activities;

g) ensure the design facilitates the prevention of cross-contamination where examination procedures pose a hazard or where work could be affected or influenced by not being separated;

h) ensure that the air-circulating system for the medical laboratory, ensures effective separation between contaminated areas (each area should have an individual air-circulating system);

i) ensure that there be complete separation (from floor to ceiling, including doors) of clean and contaminated work-spaces;

NOTE Physical separation level corresponds according to the nature of the microorganisms handled and whose risk of contamination could be mitigated by hygiene measures such as hand washing or disinfection of inert surfaces especially in areas where clinical samples are handled.

j) ensure each area has environmental controls and facilities, furnishings, work surfaces and floor finishes appropriate to the activity being performed there;

k) ensure that selected surfaces (bench tops, chairs, flooring) are chemical resistant, impermeable, durable and readily cleanable;

l) ensure that materials that have the potential to retain biohazardous materials (e.g. carpet) are avoided to minimize the risk to staff, patients or visitors;

m) ensure corridors and passages to the exits are clear of obstructions;

n) ensure there is sufficient unobstructed space for safe working, including adequate space around large pieces of equipment for maintenance personnel;

o) ensure the provision of a quiet and uninterrupted work environment where it is needed;

p) ensure dedicated handwashing sinks are fixed within all areas where biological materials are handled and are placed near exits, and hand-operated sink handles should be replaced with motion, elbow, knee or foot operated equipment wherever possible;

q) ensure sinks installed for hand washing in areas where biological materials are handled have unimpeded drainage;

r) ensure the laboratory is illuminated naturally or artificially to a level that is optimal for safe working, minimizing glare and distracting reflections;

s) ensure that the facility design encorporates drench showers where the nature of the chemical hazard is such that there can be a risk of gross body contamination;

t) ensure safety design is also considered when bringing on new examinations, especially when high risk tests or technology are introduced; the laboratory shall have a risk based approach to assessing safety considerations and procedures needed;

u) ensure special consideration is given to geographical conditions in areas such as those susceptible to earthquakes, tsunamis, hurricanes, etc., for design, construction and safety programs; and

v) ensure that the privacy of individual patients is protected.

4.3 Laboratory security

4.3.1 General

Laboratory security refers to the practices and controls that reduce the risk of unintentional exposure or release of materials and security, to practices and controls that reduce the risk of loss, theft, misuse, diversion of, or intentional unauthorized release of materials.

4.3.2 Risk assessment and security program

The laboratory shall conduct a risk assessment as a critical first step in developing a laboratory security plan/program. The risk assessment is dependent on the nature of the hazards, inventory complexity and physical infrastructure. The security element cannot be separable from overall safety.

The assessment needs to:

a) identify and prioritize assets (e.g. material, equipment, physical resource inventory; chemical, biological and radiological hazards);

b) identify and define threats and vulnerabilities;

c) determine risk levels, mitigation strategies; and

d) assign and document potential events to risk levels.

The laboratory shall design and implement a security program using the risk assessment as the foundation.

