Medical laboratories — Requirements for safety

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National foreword

This British Standard is the UK implementation of ISO 15190:2020. It supersedes BS ISO 15190:2003, which is withdrawn.

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Medical laboratories — Requirements for safety

Laboratoires de biologie médicale — Exigences pour la sécurité

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Foreword

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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.

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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.

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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

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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)”.

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[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;

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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;

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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.

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4.3.3 Physical security

Management and control of physical security shall be based on a comprehensive risk assessment. Laboratory entrances shall have lockable doors. These door locks shall not prevent exit in an emergency. Laboratory access shall be restricted to authorized personnel. Additional security measures, such as lockable doors, locked freezers, limited access to specific personnel, etc., can be required when handling and storing highly hazardous samples, cultures, chemical reagents or supplies as indicated by the risk assessment. The threat of theft and tampering with biological agents, samples, drugs, chemicals and confidential information shall be assessed, and appropriate steps taken to prevent these acts from happening.

All personnel shall be readily identifiable to guard from unauthorized access. Workers shall be provided with ready access to telephones, panic buttons or other emergency alert devices.

4.3.4 Inventory

The laboratory shall maintain an inventory of hazardous materials being ordered and shipped to the site. The risk group is to be determined for biohazards in alignment with inventory requirements. Controlled substances shall be appropriately stored in a secure location.

The laboratory shall implement an access control system, review and revise inventories and dispose of surplus hazardous materials. It is presupposed that hazardous material inventory policies and procedures are in compliance with applicable statutory and regulatory requirements.

4.3.5 Information management and security

The risk level shall be determined and aligned with the level of information security required. Access to confidential information shall be controlled (e.g. access codes). It is presupposed that information management and security procedures are developed with an awareness of applicable statutory and regulatory requirements.

4.3.6 Incident and emergency response

Laboratory security considerations shall be incorporated into incident and emergency response plans, investigation of incidents and implementation of corrective actions. The protocol for reporting incidents or suspicious activities shall be established and disseminated.

5 Safety management program

5.1 General considerations

A comprehensive safety program shall encompass all aspects of daily laboratory operations, including:

a) hazard identification and risk assessment;

b) biosafety and biosecurity hazards, to include blood-borne pathogens, respiratory protection;

c) chemical hazards;

d) physical hazards;

e) emergency preparedness and response;

f) fire safety;

g) laboratory ergonomics;

h) equipment safety;

i) personnel work practices;

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j) personal protective equipment;

k) transport of samples and hazardous materials;

l) waste disposal;

m) housekeeping practices;

n) incidents, injury, accidents and, occupational illnesses;

o) safety education and training; and

p) record keeping.

5.2 Management requirements

The procedures for the laboratory shall include detailed instructions concerning hazard identification, signs/symptoms of exposure, risk assessment and exposure minimization procedures. Procedures shall be periodically reviewed and updated by the management representative responsible for the work place activity at a frequency that ensures that they remain fit for purpose. A written plan, including protocols for hazard communication, shall be developed. The plan shall include the following:

a) arrangements for visitors and 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 and contaminated materials;

g) methods for identifying training needs and documentation;

h) procedures for obtaining, maintaining and distributing safety data sheets (SDS) 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 such as chemical, radioactive and biological materials.

5.3 Management responsibilities

5.3.1 General

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

5.3.2 Scientific manager

Where applicable, an individual(s) with responsibility for medical laboratory management at the facility shall also be designated with specific biorisk management responsibilities.

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Functions shall include:

a) planning and coordinating work activities, and ensuring adequate staffing levels, time, space, and equipment are available;

b) ensuring (where necessary in consultation with the biorisk management advisor) that hazard identification and risk assessments have been performed, reviewed by affected workers, subjected to approvals required by the biorisk management system, and that the required control measures are in place;

c) ensuring required authorizations for work are in place;

d) ensuring that all at-risk workers have been informed of risk assessments and control measures, and/or provisions for any recommended precautionary medical practices;

e) ensuring that all work is conducted in accordance with established policies and guidelines described in this document;

f) supervising workers, including ensuring only competent and authorized workers have access and can work in areas under supervision; and

g) ensuring that processes are in place to routinely measure the effectiveness of the control measures, and to change the control measures as appropriate to improve biorisk management performance.

5.4 Management of staff health

5.4.1 General

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

5.4.2 Immunization

The organization shall:

a) establish and implement vaccination policy as part of the worker health programme;

b) base the immunization programme for a given laboratory upon:

— a documented laboratory infection-risk assessment;

— advice from local public health officials; applicable national, regional or local regulations and guidelines;

c) encourage personnel to have immunizations to prevent infections associated with organisms to which the person is likely to be exposed;

d) offer hepatitis B vaccine to personnel working with or handling human blood, sera, body fluids or human tissue; and

e) maintain immunization records as advised by national, regional and local requirements.

NOTE Many laboratory-acquired infectious diseases can be effectively prevented through an active immunization programme. The selection of vaccines for use can vary, based upon the potential hazards of the institution or setting (see Annex I).

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5.4.3 Psychological hazards

5.4.3.1 General

Laboratory management shall take responsibility and actions to reduce organizational, environmental and personal factors that contribute to excessive stress.

NOTE 1 The psychosocial environment of the laboratory can affect the way a worker responds to physical or psychological stress. Excessive stress can impair a person's coping abilities and result in physical, behavioural, emotional or mental symptoms.

NOTE 2 Factors that contribute to excessive stress include organizational factors (e.g. conflict, working alone, critical incident stress, fatigue and hours of work, technological change, bullying/harassment), environmental factors (i.e. noise, air quality), and personal factors (e.g. substance abuse, mental illness, age-related factors, work-life conflict).

5.4.3.2 Organizational factors

Laboratory management shall take responsibility and actions to reduce these factors.

This includes:

a) actions, such as effective communication strategies, that reduce workplace organizational factors;

b) facilitation of peer support systems;

c) workload assessment and redistribution;

d) task and schedule re-design;

e) implementation of revised training programs; and

f) establishment of employee health services and assistance programs.

Laboratory management shall be aware of any statutory and regulatory requirements pertaining to violence, harassment or other forms of abuse in the workplace. Where the laboratory is part of a hospital or other organization, there can be shared responsibility with other facility representatives.

5.4.3.3 Environmental Stressors

Approaches to manage environmental stressors should include:

a) proactive communication protocols; and

b) procedures to address complaints and purchasing controls.

Actions to address personal stress management can include:

a) self-renewal activities (e.g. vacations);

b) improved health practices;

c) counselling;

d) communication opportunities; and

e) physician prescribed treatment.

5.4.4 Employee impairment

Employees can show a decrease in their level of competence for several reasons and over different time frames. Acute deterioration, especially if over a few days or weeks, requires more immediate

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intervention to prevent potential harm to patients or safety risks to the employee or co-workers. The organization shall ensure that:

a) the decrease is assessed against the prior documented competence of that employee;

NOTE An employee who in the past has performed at a high level can deteriorate significantly and still appear to meet the minimum level of competence. That individual nonetheless is at increased risk for committing errors.

b) supervisory personnel undertake an assessment of possible impairment based on objective evidence as per documented policy (see Annex D);

c) the employee is removed from further activity until evaluated for an underlying cause (see Annex D);

d) work that the employee has performed while possibly impaired is evaluated for correctness; and

e) the employee does not return to the prior responsibilities until either the underlying cause of the impairment has resolved, the employee is demonstrated to be competent for work at the current level of performance, or alternate responsibilities are assigned where the impairment will not affect performance. The underlying cause can be sufficient for termination if appropriately documented.

5.5 Laboratory safety officer

An appropriately qualified and experienced laboratory safety officer shall be designated to assist the laboratory management with safety issues and directly report to the laboratory management. This person shall ensure the development, maintenance and monitoring of an effective laboratory safety programme that addresses all safety aspects of the laboratory's activities, including biological, chemical, physical, occupational, and radiological safety as applicable. An effective laboratory safety programme shall include risk assessment and mitigation, education, orientation and training, audit and evaluation, and programmes to promote safe laboratory practice.

Responsibilities of the laboratory safety officer shall include but are not limited to:

a) provide advice and guidance on the establishment and implementation of the laboratory safety policy and an up-to-date safety manual;

b) provide and maintain a current safety manual;

c) ensure applicable safety-related requirements, guidelines and practices are communicated to all staff involved in the laboratory work flow and operations and provide clarifications as needed;

d) advise on risk management issues within the organization (e.g. laboratory management, biorisk management committee, occupational health department, security) and ensure that relevant and up-to-date information on risk management is made available to laboratory staff and management;

e) identify, assess, prioritize and document safety risks and hazards that exist as well as those that could arise within the laboratory or result from its activities and regularly review this documentation and make updates as needed;

f) develop risk reduction strategies and specify practices and procedures that will reduce safety risks and hazards to an acceptable level (or eliminate them) and verify, in conjunction with stakeholders, that all relevant safety risk considerations are addressed;

g) assist laboratory staff in developing standard operating procedures (SOPs) that incorporate safe practices;

h) ensure documentation of all safety related materials (e.g. SDS) and authorizations needed for specific work activities;

i) provide guidance on the selection and provision of appropriate personal protective equipment based on the risk assessment for each activity within the laboratory;

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j) monitor the implementation of the laboratory safety requirements, practices, procedures, and programs, including conducting regular safety audits and inspections, and evaluating risk management performance;

k) advise and assist laboratory management in ensuring that all activities are performed in conformance with applicable safety standards;

l) conduct regular review of laboratory facilities, engineering controls, operation and maintenance practices (including housekeeping) to identify changes in practices, procedures and technology that can present new risks;

m) respond to safety risk alerts and work with the laboratory management to stop activities that are unsafe or pose immediate health risks to laboratory and/or non-laboratory personnel;

n) advise or participate in the reporting, investigation, follow-up, and documentation of accidents, incidents, near-misses;

o) ensure review of all incident reports, including remedial actions, by the laboratory director and other responsible personnel;

p) assist in responding to any regulatory actions or investigations;

q) oversee routine decontamination procedures and decontamination procedures after an accident and provide guidance on when work can resume after decontamination;

r) ensure the establishment of a waste management plan which considers applicable requirements and guidelines;

s) contribute to the development and delivery of laboratory safety training/education activities and evaluate their effectiveness and identify needs for new and refresher trainings;

t) participate or assist in the assessment of ergonomic needs for laboratory staff and communicate them to the laboratory management;

u) actively participate in organizational safety improvement activities such as laboratory safety or biosafety committee(s);

v) serve as, at least, an ex officio memberif not its chair-holder, on the laboratory's safety committee;

w) collaborate or serve as liaison with other personnel with safety-related responsibilities, such as radiation safety officer, biorisk management advisor, and emergency response services; and

x) ensure awareness of applicable statutory and regulatory requirements for a laboratory safety program.

5.6 Safety manual

The safety manual shall be readily available in work areas as required reading for all employees. The manual shall be in accordance with the facility safety policy and be specific for the laboratory's needs including, but not limited to, the following major categories as applicable:

a) safety policy;

b) fire prevention;

c) electrical safety;

d) chemical safety;

e) radiation;

f) biological hazards; and

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g) hazardous waste disposal.

The safety manual shall include detailed instructions for workplace evacuation and the protocol for dealing with an incident (see Annex A for more information on action plans). The safety manual shall be reviewed and updated at least annually by laboratory management.

Other information sources available in the laboratory shall include, but shall not be limited to, SDS on all chemicals and agents handled in the laboratory and other reference materials including texts and authoritative journal articles.

5.7 Safety program audits and inspection

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 and prophylaxis;

h) first aid services and equipment;

i) investigation of accidents and illnesses;

j) health and safety committee review;

k) records and statistics; and

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

NOTE 1 Checklists, tailored to the area to be surveyed, are effective aids to auditing (see Annex B on conducting a laboratory safety audit).

Laboratory management shall be responsible for ensuring that safety inspections are undertaken.

Work sites shall be surveyed/inspected at least annually.

This is to ensure:

a) the proper state of readiness and function of fire emergency apparatus, alarms and evacuation procedures;

b) the status of procedures and materials for hazardous spillage containment, including emergency showers and eyewash facilities;

c) the proper containment and control for the storage of flammable and combustible, infective, radioactive, toxic materials; and

d) the status of decontamination and disposal procedures.

NOTE 2 Records of safety audits and examination of trends of incients can provide information for taking appropriate remedial actions.

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5.8 Records

5.8.1 General

Records shall be kept in accordance with ISO 15189. It shall be noted that international, national or regional regulations or guidelines may apply.

5.8.2 Occupational health and safety, injury and adverse incident records

There shall be a mechanism for recording and reporting occupational illness, injury, adverse incidents, and consequential actions, while at the same time respecting the confidentiality of individuals.

NOTE Refer to ISO 45001.

5.8.3 Hazardous waste records

Hazardous waste disposal records shall be an integral part of the safety programme. Records of hazardous waste disposal, risk assessments, safety surveys and consequential actions shall be retained in an accessible file. It is presupposed that they are maintained with an awareness of applicable statutory and regulatory requirements.

5.9 Safety Training and orientation

5.9.1 Scope of personnel safety training

The laboratory safety officer (see 5.5) shall ensure that specific and appropriate safety training programmes are implemented for all laboratory-associated personnel, including:

a) technical and administrative;

b) transport;

c) maintenance;

d) housekeeping/cleaning;

e) students;

f) contract staff; and

g) volunteers.

In addition to safety training, laboratory management shall ensure that all new employees are oriented/trained in the laboratory's general and role specific safety requirements, regardless of how much experience they can have from their previous employment.

5.9.2 Safety Training programme

A comprehensive safety training programme shall:

a) include an introduction for new employees;

b) require periodic retraining for experienced employees;

c) be job or task specific and tailored according to the employee's job description;

d) include appropriate considerations for conditions such as pregnancy, immunodeficiency and physical disability;

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e) address at a minimum, fire prevention and preparedness, chemical and radiation safety, biological hazards, infection prevention, occupational health and safety (e.g. vaccines) first aid and environmental protection;

f) be routinely updated; and

g) undergo ongoing monitoring/assessment of risks to assess the training/re-training needs.

Personnel training records shall be retained in an accessible file for a period of time and include dates of safety orientation and annual updates of safety training for each employee.

Employees shall be required to read the appropriate safety manual before beginning to work in an area. Confirmation in writing shall be obtained from the staff member that they have received appropriate training and that safety manuals have been read and understood, including the dates when these were carried out. The laboratory's accident/incident reports should also be considered as a source for determining the areas in which additional training is required.

5.9.3 Fire prevention and control training

Instruction and training shall be given to all laboratory workers and personnel who share the building. This shall include:

a) recognition and evaluation of fire hazards;

b) planning to reduce the risk of fire; and

c) all actions to take when fires occur.

5.9.4 First aid training

The laboratory shall ensure that:

a) there are designated personnel trained in first aid;

b) materials and procedures are provided to mitigate adverse effects and incidents occurring to people within the laboratory involving chemical, toxic or potentially infectious materials; and

c) laboratory personnel have ready access to first aid materials/kits at all times.

There shall also be guidelines for the treatment and, where required, immediate emergency medical attention consistent with the hazards likely to be experienced within the laboratory. All staff shall be familiar with the procedures to be taken following needlestick injuries or exposure to infectious agents via other mechanisms.

6 Hazard identification and Risk Assessment

6.1 Hazard identification

Working with the senior laboratory personnel, the laboratory safety officer shall identify and document the hazards and/or threats that exist or could arise within the laboratory or result from its activities (see 5.5) including:

a) inclusion of issues that are not those of direct laboratory origin, for example linked to the building structure or the external environment;

b) the systematic and clear identification of hazardous areas appropriate to the hazard concerned:

c) appropriate identification of the hazardous area using both signs (e.g. biohazard, fire, radioactivity) and physical barriers where applicable;

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d) clear identification of specific hazardous materials to be used within the laboratory or laboratory units;

e) marking of all entrances and exits to work areas as to the hazards present within;

f) provision of special attention to fire hazards and flammable materials, and to toxic, radioactive, harmful or biologically hazardous materials; and

g) making maintenance personnel who are not part of the laboratory staff, contractors and subcontractors aware of any hazards they can encounter.

Employees shall be trained, familiar with, and have specific written instructions concerning emergency procedures.

Identification and review of the potential hazards to the health of pregnant women shall be undertaken. A risk assessment shall be carried out and recorded.

NOTE See Clause 7, Clause 8 and Clause 9.

6.2 Job hazard assessment

To enable an effective risk management process and safety management programme, all hazards involved in laboratory processes shall be identified.

Job hazard assessments shall be performed that include:

a) identification and listing of the critical (major) steps of the job;

b) identification of all equipment to be used and procedures to be performed;

c) identification of potential hazards at each step that includes all types of hazards;

d) a review of available control measures, preferentially using in order of priority, engineering, administrative and personal protective equipment controls; and

e) verification of the effectiveness of controls and where not adequate, identification of more appropriate controls.

Employees should be the key participants in the identification, risk assessment and control process as they are performing the tasks and are typically best able to identify the process steps and potential risks. This activity shall be managed and led by the safety officer working together with the laboratory management.

6.3 Risk assessment

The organization shall ensure:

a) that there is a formalized system of risk assessment;

b) that suitable methodologies for assessing and prioritizing risks are identified, implemented, maintained and documented;

c) that risk assessments encompass a base-line safety assessment and take into account activity- or protocol-specific information, and should be based on the unique context of those activities and protocols;

d) that risk assessment identifies all potential scenarios of a particular activity that could produce a negative outcome;

e) that risks are prioritized based on an evaluation of the likelihood and consequences of each of the risks;

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f) that the risk assessment determines the most appropriate control measures and how the system will measure the effectiveness of those control measures; and

g) that approaches to risk assessment are defined with respect to scope, natures, and timing in order to be proactive rather than reactive.

NOTE 1 In addition to any formal workplace risk assessments that can be required, a safety checklist can be a satisfactory way to record and document the review programme.

Risk assessments shall be required for every examination procedure or service, or group of related examinations or services, with the aim that exposures to hazards be eliminated wherever possible. Risk assessment requires evaluation of both task-specific and environmental hazards.

Risk assessment at the highest level of the organization's legal entity shall include the following risk factors:

a) probability that exposure to the hazard will occur (i.e. likelihood that the hazard will result in injury) or frequency that workers are exposed to the hazard (i.e. how often the exposure occurs); and

b) severity of the outcome of the exposure to the hazard (i.e. the degree of harm or injury).

The numeric value for each level of the two risk factors shall be calculated to determine the combination of degree and frequency of danger presented by a hazard (i.e. low, medium and high). Records shall be made of the perceived level of risk, who could be affected, with what consequences, and to what degree of severity.

Risk prioritization shall be made according to those requiring immediate, intermediate, or long-term risk reduction strategies. This shall be based on the potential for harm, not on economic grounds, although this component cannot be ignored.

NOTE 2 There will be some occasions when a difficult decision has to be made to cease a particular activity, as the risks are so high as to outweigh any potential benefit.

6.4 Risk reduction

There can never be a total absence of risk in the medical laboratory. The aim shall be to decrease risk as much as possible, taking account of all factors involved.

The risk from each safety hazard shall be reduced to as low a level as practicable and as acceptable, using the following order of priority:

a) by elimination;

b) by substitution; or

c) by containment; or

d) by safe instruction and training; or

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

Action plans shall be prepared and implemented to reduce risk(s) to acceptable levels by an agreed target date by all concerned parties, both within the laboratory and with others affected by its operation.

Decisions made and actions proposed shall be recorded, together with supporting information as to why the action was taken.

There shall be careful monitoring of action-plan implementation and the programme should be one of constant improvement in the risk reduction process. It should involve all laboratory personnel, although the implementation depends on positive leadership by senior laboratory personnel and competent direction from the Laboratory Safety Officer (see 5.5).

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