INTERNATIONAL STANDARD

ISO 15190

Second edition
2020-02

Medical laboratories — Requirements for safety

Laboratoires de biologie médicale — Exigences pour la sécurité

Reference number
ISO 15190:2020(E)

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

Page

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).

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).

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.

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.

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;

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.

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).

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

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;

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 member if 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

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.

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;

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;

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;

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).

7 Biosafety and biosecurity hazards

7.1 General

7.1.1 Work Practices

The policies, processes and procedures for handling, examination and disposal of material of biological origin shall utilise good microbiology practice standards.

Work practices shall be such as to reduce the risk of contamination. Work practices in contaminated areas shall be implemented such as to prevent personal and environmental exposure.

7.1.2 Engineering controls

To provide the highest level of hazard control, the laboratory shall implement engineering and administrative controls. Examples of engineering controls include but are not limited to:

a) laboratory design;

b) heating, ventilation and air conditioning systems;

c) use of biological safety cabinets and aerosol reducing equipment;

d) self-sheathing needles;

e) safety-engineered medical sharps;

f) plastic blood collection tubes;

g) sharps disposal containers;

h) engineered transport containers; and

i) aerosol barrier pipette tips.

7.1.3 Administrative controls

Administrative and elimination controls include rules, processes, safe work procedures, training and other processers that shall be put into place by laboratory management and followed or implemented by laboratory staff. Examples include, but are not limited to:

a) elimination or substitution of a biological hazard for one that poses lower risk;

b) immunization programs;

c) accurate hazard assessments;

d) designation of containment levels;

e) procedures that reduce exposure;

f) laboratory signage with hazards identified with symbols or pictograms;

g) decontamination methods (e.g. autoclaves, incinerators);

h) employee training;

i) decontamination and spill response procedures;

j) attention to personal hygiene and housekeeping; and

k) post-exposure protocols.

7.1.4 Biosafety policies

The laboratory shall establish, implement and maintain policies and processes to reduce the exposure to bloodborne pathogens, including but not limited to:

a) when performing phlebotomy, staff shall wear gloves, be prohibited from re-capping needles and dispose of used needles into rigid sharps containers located close by;

b) staff shall use self-sheathing needles, plastic blood collection tubes, sharps disposal containers and needleless systems wherever possible;

c) if samples are damaged or leaking upon receipt, they shall be:

   — opened by trained persons wearing appropriate personal protective equipment in order to avoid spillage or aerosols;

   — opened in a biological safety cabinet; and

   — safely discarded without being opened and the sender informed immediately if contamination is excessive or sample is considered unacceptably compromised;

   When the sample is clinically critical or irreplaceable and the laboratory can choose to process the compromised sample, the final report shall indicate the nature of the problem, and where applicable, that caution is required when interpreting the result.

d) procedures that generate aerosols shall be reduced or eliminated;

e) samples shall be capped for centrifugation;

f) samples shall be opened by placing gauze over top and/or opening in the direction away from the person. Face shields or counter-mounted shields shall also be used;

g) gloves shall be worn as a barrier precaution to prevent contamination of hands while handling primary/secondary samples and aliquots. A risk assessment shall be performed to assess the need for the use of gloves when handling culture material. Wearing gloves shall not be considered as an alternative to thorough handwashing (see 13.6);

h) hands shall always be properly cleaned after gloves are removed;

i) face shields, masks or goggles shall be used for any procedure that can generate splashing;

j) all potentially infectious or toxic quality control and reference materials shall be stored, handled and used with the same degree of caution that would be appropriate to samples of an unknown risk;

   NOTE Many such products are made from pooled material from multiple sources.

k) gowns/laboratory coats shall be:

   — worn at all times while working with samples, serum or cultures;

   — closed at the front and neck;

   — knee-length;

   — have long sleeves which are not to be rolled up;

   — made of moisture-resistant materials or moisture resistant aprons shall be made available for use where required; and

   — laboratory gowns/coats should have closures with snaps for fast removal in case of spills and be closed at the wrist to protect clothing;

l) contaminated gowns or lab coats shall be removed when leaving the laboratory;

m) clean gowns/laboratory coats shall be stored away from used or contaminated coats/gowns; and

n) in microbiology laboratories, where use of disposable loops is not possible, electronic incineration devices preferably should be used for microbiological loop sterilization.

7.2 Hazard groups

Biorisk-related hazards and or threats associated with proposed work procedures shall be identified and documented.

NOTE 1 Biohazard risk can vary substantially from one procedure to another even for handling the same pathogen.

Biosafety directives, operational practices, additional biosafety requirements and containment level shall be based on:

a) non-propagative clinical/diagnostic activities with primary samples;

b) propagative in vitro activities;

c) in vivo activities; and

d) drug resistant samples.

It is presupposed that classification system for bio-risk hazard groups takes into consideration applicable statutory and regulatory requirements.

NOTE 2 Some countries require the laboratory to commence local risk assessment with the risk or hazard group as defined and mandated in the country; while other countries permit the laboratory to undertake independent local risk assessment.

7.3 Containment levels

Containment levels describe the minimum physical features and operational practices needed for the safe handling and storage of biohazards within an identified laboratory area. Physical containment requirements shall focus on the following:

a) site selection;

b) containment barrier (e.g. non-opening windows);

c) access (e.g. lockage doors);

d) surface finishes and case work (e.g. cleanable and non-absorbent);

e) air handling (e.g. minimizes spread of infectious aerosols);

f) facility services (e.g. plumbing, electrical);

g) essential biosafety equipment (e.g. biological safety cabinets); and

h) effluent decontamination systems for specialized circumstances.

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. It is presupposed that these design characteristics are are based on applicable statutory and regulatory requirements.

7.4 Aerosols

Laboratory work practices shall be designed and undertaken in such a way as to reduce the possibility of personal contact with harmful aerosols, whether of chemical or biological origin including:

a) Samples should be centrifuged only in safety-capped enclosures.

b) All samples being vortex-agitated shall be contained in containers with lids.

c) Procedures which can generate infectious aerosols shall be performed in a biological safety cabinet.

d) Local ventilation devices shall be used to capture toxic emissions at the source using a laboratory fume hood or cabinet to transfer and work with organic solvents.

e) The use of localized air containment for large pieces of analytical equipment that could generate aerosols, and the use of custom-built extraction hoods to handle small apparatus manipulation is strongly recommended.

f) Localized air extraction is essential where harmful chemical fumes can be present.

7.5 Decontamination

The organization shall establish and maintain validated procedures to ensure that appropriate methods for decontamination and inactivation are chosen and implemented effectively.

Each laboratory is responsible for routine decontamination. Appropriate decontamination shall be required after routine work, at the completion of a work shift, or in emergency situations, such as spill clean-up. The laboratory may contract out decontamination services.

For decontaminating laboratory waste, the laboratory shall utilize autoclaves, chemical disinfectants or incineration. For decontaminating re-usable laboratory wares, the laboratory shall use autoclaves or chemical disinfectants. For laboratories involved with media preparation or tissue culture procedures, proper sterilization practices shall be implemented using steam autoclaves, gas sterilizers, filtration, dry heat or boiling.

The laboratory shall have procedures in place to:

a) address the hazards associated with the various decontamination devices (e.g. heat/steam-associated injuries, glass breakage, chemical reactions, biological hazard of contaminated material);

b) select appropriate devices for the task (e.g. autoclave chemical disinfectant etc.);

c) prepare items before decontamination;

d) maintain and test equipment;

e) assess whether safety parameters of equipment are operating effectively; and

f) require use of indicators to indicate success of decontamination (i.e. biological or chemical).

Manufacturer's instructions for use for specific equipment shall be followed for cleaning and disinfection.

7.6 Standard precautions, routine practices and additional precautions

Standard precautions, routine practices, and additional precautions shall be used with all patients, all patient samples at all times. These precautions shall include airborne, droplet and contact precautions. In order to prevent exposure to blood, body fluids, secretions and excretions, the following routine practices shall be implemented including:

a) hand hygiene;

b) personal protective equipment;

c) environmental controls; and

d) administrative controls.

All samples, cultures and waste shall be assumed to contain viable biological agents that can be associated with transmission of infectious disease, and shall be handled in a safe manner. (See Annex E)

7.7 Biological safety cabinets

Biological safety cabinets (BSC) are designed to provide partial primary containment for biological hazards and shall be used for procedures involving open vessels of biohazards that:

a) can produce infectious aerosols or aerosolized toxins, when aerosol generation cannot be contained through other methods;

b) involve high concentrations of biohazards; and

c) involve large volumes of biohazards.

The selection, location, design and type of biological safety cabinet utilized shall be appropriate to the level of risk containment required for safe working. These considerations shall be part of the hazard assessment process.

Biological safety cabinets shall:

a) be used in such a manner as to avoid compromising the cabinet's function (e.g. jarring or mishandling the delicate HEPA filters);

b) be appropriately vented to the microbiological risk and be consistent with safety requirements.be frequently monitored to ensure that they function as designed;

c) be tested and certified upon installation, when moved or repaired and annually; records shall be kept of the inspection and any functionality testing results; and

d) have proof of inspection indicated by a certification label displayed on the cabinet.

7.8 Biological spills

All laboratory personnel shall be trained and competent in established response techniques for the effective and efficient control of biological spills.

There shall be easy accessibility to the materials necessary for clean-up and decontamination.

C.3 provides additional details on the decontamination, cleaning and disinfection following a biological spillage.

8 Chemical hazards

8.1 General

Chemicals present a broad range of physical (e.g. flammable, corrosive) and biological (e.g., toxic, radioactive, carcinogenic) hazards. These hazards affect both transport and occupational use. National and local agencies often specify how such hazards are to be designated, with labelling depending on the location or type of exposure risk that the chemical presents in different situations.

In all medical laboratories, the policies and procedures for storage, handling, use and disposal of chemicals shall be in accordance with good chemistry laboratory practice and take into account recognized local, regional and national standards including:

a) the nature and risk of hazards concerning each product shall be marked on every stock container, in conformance with International Standards, as well as in clear, unambiguous labelling of containers of "in-use" products;

b) there shall be adequate control measures available for chemical hazards to reduce exposure to hazardous materials (i.e. engineering controls, the use of personal protective equipment, administrative controls, and hygiene practices);

c) controls shall be routinely monitored to ensure their effectiveness;

d) records of the results of the monitoring process shall be maintained;

e) all personnel shall be required to work according to safe operating protocols, including the use of safety equipment or devices that have been deemed appropriate for the task(s) undertaken; and

f) appropriate protective clothing shall be worn at all times by all personnel within analytical areas, supplemented by appropriate personal protective equipment when indicated by the nature of the activity being undertaken (see Clause 14).

The organization shall ensure there is medical consultation whenever:

a) a person develops signs or symptoms associated with a hazardous chemical;

b) exposure monitoring reveals an exposure level routinely above the action level; and

c) an event takes place in the work area such as a spill, leak, explosion or other occurrence resulting in the likelihood of a hazardous exposure.

8.2 Chemical classification and labelling

8.2.1 Hazard identification and control

Employers shall be responsible for:

a) the education and training of staff on the safe use of hazardous products;

b) ensuring products in use are properly labelled (including workplace labels, if necessary);

c) providing current SDS to workers; and

d) instituting appropriate control measures to protect workers.

Employees shall be required to:

a) participate in the program by attending education and training;

b) use provided control measures; and

c) assist in the identification and control of hazards.

8.2.2 Safety data sheets

Laboratory management shall ensure that there are current safety data sheets (SDS) for any substance entering the workplace and to make SDS readily available to employees who can be exposed to the product. The SDS can be available in a computerized format as long as employees are trained on how to access them, the computers are kept in working order and the employer can provide a hard copy of the SDS on request.

Via the SDS, manufacturers and importers are required to identify the hazards posed by any chemical, whether a unique substance or a mixture, they supply and provide information about the risk the chemical presents with recommendations for measures to ensure safe transport, storage and handling. The supplier needs to update the SDS anytime they become aware of any significant new data that impacts the validity of the contents of the SDS.

NOTE 1 The information for a given chemical, though, can be country- and manufacturer-specific: Specifications or requirements for chemicals can be different from country to country so that a safety data sheet can be specific to a given market, and each manufacturer can make its own assessment of the data for the same substance or mixture even though there is no physical or chemical difference between the products of different manufacturers.

NOTE 2 The Globally Harmonized System of Classification and Labelling of Chemicals (GHS) harmonizes the communication of hazards posed by chemicals in SDS and on labels specifically in those countries that adopt the standard, though the information can be used in any setting. It covers hazards specific to transport as well as in the workplace and to consumers; however, it defers to the labelling requirements of the United Nations Recommendations on the Transport of Dangerous Goods when applicable. The requirement for SDS is based on the chemical either meeting hazardous classification criteria if it is a pure substance or containing at least a minimum percentage of a pure hazardous substance if the chemical is a mixture. Chemicals that meet the criteria for any of the hazard classes are also required to be labelled with signal words, pictograms and hazard statements.

NOTE 3 The United Nations Recommendations on the Transport of Dangerous Goods also includes classifications for toxic/infectious substances and radioactive materials that are not specifically identified in the GHS.

8.3 Toxic chemicals

Laboratory workers shall be informed regarding measures of toxicity (e.g. Lethal Dose 50, Lethal Concentration 50) and exposure limits. Exposure limits are guidelines only and shall be interpreted with caution. These limits shall not be viewed as fine lines between safe and dangerous concentrations nor shall they be used as relative indices of toxicity. Exposure limits have many limitations as they do not account for mixed exposures where the effects could be combined. Another important limitation of occupational exposure limits is their application only to the normal adult population and not children, the elderly or individuals with health conditions.

Laboratory workers shall be informed regarding the potential routes of entry for toxic chemicals and take the necessary precautions to prevent exposure. Inhalation and skin absorption are the two most important routes of entry.

8.4 Oxidizing and corrosive materials

8.4.1 Oxidizing materials

The laboratory shall take the appropriate precautions with using oxidizing materials, including but not limited to:

a) using solutions of oxidizers instead of dry forms to avoid release of dusts;

b) reducing reactivity of solutions by dilution;

c) wearing appropriate skin and eye protection;

d) keeping out of contact with flammable and combustible materials during storage, dispensing and use;

e) keeping containers tightly closed; and

f) following suppliers' instructions for mixing and diluting.

8.4.2 Corrosive materials

The laboratory shall take the appropriate precautions with using corrosive materials, including but not limited to:

a) protecting eyes and skin when handling;

b) using the most dilute concentration needed to achieve desired result;

c) using a fume hood for handling, dispensing mixing or any other manipulation of corrosive materials known to emit vapours or produce hazardous reaction products;

d) transporting in unbreakable containers or place glass containers in safety carriers;

e) storing glass containers of corrosive liquids in spill trays;

f) adding corrosives to water, never the opposite when diluting;

g) irrigating skin and eyes thoroughly for 15 min in the event of contact; and

h) separating stored acids from bases.

8.5 Chemical storage

8.5.1 General

The organization shall ensure that all hazardous chemicals are:

a) stored in a secure location;

b) accessible only to authorized laboratory staff;

c) stored inside a closable cabinet or on a sturdy shelf that is secured to the wall or floor;

d) stored in areas with adequate ventilation; and

e) stored away from direct heat, sunlight or highly variable temperatures.

The laboratory should minimize the quantities of chemicals kept in the laboratory, storing reserves in a chemical storeroom.

An up-to-date chemical inventory list shall be maintained.

Used, surplus, out-of-date or otherwise unwanted materials shall be disposed of on a regular basis.

8.5.2 Organization and segregation

The organization shall ensure that:

a) Chemicals are segregated by reactivity class and flammability:

   — Acids shall be stored in a dedicated acid cabinet. Nitric acid should be stored alone unless the cabinet provides a separate compartment for nitric acid storage.

   — Highly toxic chemicals shall be stored in a dedicated, lockable poison cabinet that has been labelled with a highly visible sign.

   — Volatile and odoriferous chemicals shall be stored in a ventilated cabinet.

   — Flammables shall be stored in an approved flammable liquid storage cabinet.

   — Water sensitive chemicals shall be stored in a water-tight cabinet in a cool and dry location segregated from all other chemicals in the laboratory.

b) Chemicals are organized by compatibility first then alphabetically within compatible groups.

c) Hazardous liquids, such as acids or alkalis, are stored in compartments or devices capable of containing spills (e.g. trays, diked storage vaults or lined storage cabinets) on lower shelves/ cabinets.

d) Large containers are securely stored on lower shelves, near the floor, but at a height that allows for safe ergonomic handling.

e) Chemicals are not stored on tops of cabinets, on the floor, or on bench tops and in chemical fume hoods, except when in use.

f) Chemicals are not stored with food and drink.

g) Shelves used for storing chemicals are:

— equipped with edge guards to prevent containers from protruding over or sliding off the edge;

— sturdy, with a load capacity well in excess of the weight of the chemicals placed upon them; and

— properly assembled by verifying that all clamps, supports and shelf brackets are correctly positioned.

8.6 Chemical spills

Suitable chemical spill measures shall be provided, including neutralizing agents, spill containment, and absorbents appropriate for the chemicals used in the workplace. (see 10.5)

In the event of a spill or leak of a volatile toxic, corrosive or flammable chemical:

a) personnel shall swiftly assess the situation and determine the appropriate action to resolve the situation in accordance with pre-existing, the approved local emergency plan;

b) ignition sources shall be turned off if flammable materials are involved;

c) barriers shall be established and warning signs posted to prevent re-entry into the spill area;

d) staff shall ensure that fume hood and other local exhausts are operating;

e) eyewash facilities shall be provided in all analytical areas where there is potential for eye damage due to chemical contamination; and

f) where the nature of the chemical hazard is such that there can be a risk of gross body contamination, drench showers shall be provided (see 10.4).

8.7 Chemical waste

There shall be a clear written procedure for the discarding and safe disposal of every chemical product used in the laboratory. It is presupposed that chemical waste disposal policies and procedures are developed with an awareness of applicable statutory and requirements. (see Annex F).

9 Physical hazards

9.1 Compressed gases

Appropriate facilities shall be provided for the safe handling, storage and use of compressed gases and cryogenic materials.

Securing devices (e.g. racks, chain and shelving lips) shall be installed to prevent unintended movement of gas cylinders, reagents or glassware.

Gas cylinders shall be secured firmly in an upright position during storage, handling and transport using securing devices. Storage of gas cylinders shall be in a separate area from the laboratory. Only gas cylinders connected to equipment shall be present in the laboratory.

Local fire codes shall be consulted prior to installation of cylinders of flammable gases or liquids.

Systems shall be checked for leaks by applying a soap solution to all connectors (see Annex G).

9.2 Ventilation and indoor air quality

9.2.1 General

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

Local natural or mechanical ventilation shall be in place where unpleasant or nauseous odours could arise from certain processes.

Controlling exposure to airborne substances shall be achieved by capturing and removing emissions from the source by way of local exhaust ventilation. EXAMPLES: Common local laboratory exhaust ventilation devices include:

a) chemical fume hoods;

b) canopy hoods;

c) slotted hoods;

d) biological safety cabinets (see 7.7); and

e) direct connections (e.g. flammable liquid storage cabinets equipped with ports that enable direct connection to an exhaust vent).

Measures shall be taken to ensure that potentially contaminated air carried by exhaust ventilation ducting cannot re-enter internal building spaces.

To ensure the quality of the indoor air is maintained, the laboratory shall ensure they are performing required preventive maintenance on ventilation devices (e.g. measuring air flow, replacing filters, cleaning ducts, replacing damaged insulation).

To assist with the prevention of microbial contamination, the laboratory shall:

a) promptly clean sources of water collection or leakage;

b) remove and discard contaminated porous organic materials;

c) clean and disinfect nonporous surfaces where microbial growth has occurred; and

d) maintain indoor relative humidity less than 60 %.

9.2.2 Chemical fume hoods

Fume hood air flowrates shall be monitored regularly to ensure adequate ventilation and shall be engineered to avoid dispersion of potentially infectious agents and toxic fumes.

Defective hoods shall be labelled appropriately or have access locked out to ensure that they are not used by laboratory personnel.

Only materials required for use shall be kept inside the fume hood so as not to disturb the air flow (i.e. do not use as a storage location).

Cabinets and chemical fume hoods shall be installed and monitored annually against applicable requirements.

Fume hoods may be either vented (ducted) or recirculating (ductless); recirculating systems use a filter in the exhaust that removes the hazardous material within the air flow. Since filters are specific for given hazards, recirculating fume hoods either shall be dedicated to a specific task or chemical hazard or shall have interchangeable filters that are inserted based on the task/hazard presented by the work being done in the hood at the moment.

Recirculating hoods should generally not be used in laboratory settings where a variety of hazardous or noxious chemicals can be used.

The laboratory shall ensure that the recommended sash height for use is followed (i.e. as low as possible). When testing such hoods to verify air flow through the ventilation system, the sash shall be properly positioned at a designated height so that the reading is accurate.

Consideration shall be given to the work to be done in the hood to ensure that the hood is appropriate to the task.

9.2.3 Canopy hoods

Canopy hoods used to capture heat or contaminants from machines (e.g. autoclaves, atomic absorption spectrophotometers) or processes shall not be used as a substitute for chemical fume hoods. Canopy hoods shall not be used a personal work station for handling of hazardous substances.

9.2.4 Slotted benches

Slotted benches (i.e. one or more narrow horizontal openings at the rear of a work bench connected to an exhaust ducts) shall only be used for processes involving low-to-moderate toxicity and small quantities of materials.

9.2.5 Biological safety cabinets

Biological safety cabinets (BSC) that rely on mechanical HEPA filtration and include some recirculation of air within the cabinet, unless specifically designed for such purposes, shall not be used for work with hazardous chemicals (see 7.7.)

9.3 Electrical

Electrically operated equipment used in the laboratory shall:

a) be designed and manufactured to comply with appropriate safety requirements;

NOTE Recognized standards include the ISO/IEC 61010 series, (see Bibliography).

b) be used in accordance with the particular requirements;

c) be connected to an uninterruptible power supply (UPS) where required to ensure safety of the equipment; and

d) not be put into use if modified or repaired, until a competent person (e.g. a qualified electrician or biomedical engineer) has carried out electrical safety tests and is satisfied that the equipment is safe for use.

The organization shall ensure that:

a) users of electrical equipment shall be trained in its proper use;

b) electrical equipment is handled in such a way that electrical safety is not compromised;

c) splash-proof or non-sparking equipment is provided where required for some applications;

d) users of electrical equipment routinely inspect the equipment for damage that could lead to electrical fault;

e) the use of extension cords and multiple adaptors is avoided;

f) if conducting liquid is accidentally spilt on equipment, the latter shall:

— be disconnected from the electrical supply and carefully dried;

— not be reused until a competent person has approved it for use; and

— decontaminated to reduce the risk of chemical or biological contamination exposure to the maintenance personnel (see also 7.5, Annex A and Annex C);

g) only competent persons shall be permitted to carry out work on electrical equipment and circuitry; and

h) unauthorized work is forbidden.

9.4 Radiation safety

9.4.1 Use of radionuclides

The laboratory director shall assess the justification for, extent of, and location of proposed use before permitting work with radionuclides. The laboratory shall ensure that:

a) adequate records of radionuclide acquisition, use and disposal are kept;

b) all radiochemicals are safely and securely stored;

c) all laboratory personnel who work with or have exposure to radionuclides be instructed and trained in radiation-based and associated techniques and in radiation protection, and comply with radiation safety policies and procedures;

d) the laboratory has written standard operating procedures and local rules appropriate and sufficient for the work;

e) procedures include clear instructions, a summary of which is displayed prominently in the workplace where radionuclides can be used, detailing the actions to be taken to deal with radiation accidents and spills;

f) the procedures detail methods of safe disposal of unused radioactive materials and materials that have been mixed with or contaminated by radioactive materials; and

g) appropriate approved warning and prohibition signage is displayed.

9.4.2 Radiation protection personnel

Where work with radionuclides is undertaken, the laboratory shall seek the advice of the local authorized radiation protection advisor (RPA) on radiation protection practice and regulatory requirements. It is presupposed that the laboratory takes into account applicable statutory and regulatory requirements, including any required laboratory design and equipment standards.

The laboratory shall appoint specific individual (s) who shall report to the RPA (e.g. radiation protection officer). These individuals shall:

a) have particular responsibilities for the design of the operational radiation protection programme, its implementation, and maintenance; and

b) report managerially to the laboratory director and professionally to the radiation protection adviser.

The laboratory shall appoint individuals who are directly responsible for the day-to-day supervision of work with ionizing radiation to ensure the use of good radiation practice (e.g. radiation protection supervisor).

Local rules shall dictate the availability, roles and responsibilities of all individuals assigned to radiation protection roles.

The formation of a radiation safety committee is strongly recommended where this is not already a statutory requirement.

NOTE The radiation protection adviser is a suitably qualified person often occupying a post of equivalent standing to that of the laboratory director. Information and advice is shared on an expert consultancy basis.

9.4.3 Workplace monitoring for ionizing radiation

A programme of systematic monitoring for ionizing radiation shall be established to ensure that comprehensive and frequent monitoring of the workplace is undertaken including:

a) maintenance of monitoring records;

b) wearing of appropriate film badges or thermos luminescent dosimeters, as prescribed by license requirements by all staff handling or working with radioactive materials;

c) design and adoption of a protocol for routine cleaning and decontamination;

d) regular review of the use of radionuclides, frequent monitoring of work practices and modifications as dictated by the RPA and RPO;

e) recording and retention of remedial action or procedural changes for the period of time dictated by statute or locally agreed rules;

f) labelling and holding of radioactive waste in a secure and radiation-protected storage dedicated for this sole purpose, in such a way that there are clear indications of the nature and level of risk in each discarded package; and

g) determination of storage and disposal.

9.5 Non-ionizing radiation

9.5.1 Ultraviolet and laser light sources

Wherever ultraviolet (UV) and laser light sources are used, suitable and adequate personal protective equipment shall be provided, appropriate approved signs displayed, and training provided for the safe use of equipment. These light sources shall be used only for their designed purpose.

Housing for such light sources shall be opened only by maintenance staff qualified to service such equipment.

9.5.2 Microwave equipment

Microwave equipment shall be regularly inspected, monitored and serviced to ensure that performance and safety standards are maintained.

Where high-powered microwave and radiowave devices merit additional precautions, they shall include extra shields and protective covers. The possibility of interference with the performance of other pieces of equipment should be considered when locating such devices. Signs shall be posted to warn of the effects such devices can have on people wearing pacemakers. Personnel who have pacemakers fitted shall be prohibited from the immediate location of high-powered microwave and radiowave devices.

Flammable substances shall not be placed in microwave equipment. All substances, biological and/or chemical that are potentially hazardous to personnel or the environment shall be placed in secondary containment when utilizing microwave equipment.

9.6 Temperature and humidity

Ambient temperature and humidity in the laboratory shall be controlled as far as possible to a level compatible with laboratory worker comfort and equipment function including:

a) ambient humidity and changes of air in the laboratory shall be made compatible with laboratory worker comfort and safety;

b) any equipment generating excessive heat or chill shall be controlled; and

c) personal protective equipment, including thermal protective gloves and appropriate clothing, shall be provided to allow for personnel safety and comfort.

9.7 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 including but not limited to:

a) evaluation of noise levels of equipment before purchasing and selecting equipment with quiet operation whenever available;

b) placing noise-generating equipment as far away from work stations as feasible;

c) maintaining equipment properly; and

d) using absorptive material on walls, ceilings, noise barriers or baffles, or enclosures to reduce noise.

9.8 Pressure

Pressure differences between laboratory apparatus and atmospheric pressure cause a significant hazard and shall be mitigated. Hazards of pressure or vacuums shall be reduced by:

a) only using apparatus approved for work under high pressure or vacuum;

b) using apparatus with pressure limiting or pressure relief mechanisms;

c) letting pressures return to atmospheric prior to opening a vacuum desiccator or after the removal of a sample container from a cryogenic liquid;

d) allowing heated or cooled containers to return to room temperature prior to opening;

e) wearing appropriate eye and face protection when handling apparatus under vacuum or under pressure; and

f) opening containers slowly to allow pressure to equilibrate.

10 Emergency preparedness and response

10.1 General

The laboratory shall:

a) have emergency response plans in place to mitigate any potential emergency;

b) ensure emergency preparedness and response covers preparedness for natural disasters such as earthquakes, hurricanes, flooding etc.;

c) ensure all staff are well versed in the plans;

d) conduct practice drills periodically;

e) make emergency response equipment available in accordance with standard operating procedures; and

f) post the emergency plan in conspicuous locations throughout the laboratory.

10.2 First aid equipment and procedures

The following facilities andequipment for first-aid and emergency procedures shall be readily accessible within the laboratory at all times:

a) a first aid box so labelled;

b) first aid equipment (e.g. sterile dressings);

c) eye irrigation/washing equipment;

d) antidotes to poisonous chemicals used in the laboratory, and instructions for their use;

e) protective clothing and safety equipment for the person rendering first-aid; and

f) provision for summoning medical assistance and prompt transfer to an emergency room or a hospital when required.

NOTE The contents of the kits are generally specified in local, regional or national health and safety statutory and regulatory requirements.

10.3 Eyewash facilities

10.3.1 General

All employees who can be exposed to hazardous materials shall be instructed in the location and proper use of emergency wash facilities.

10.3.2 Facilities

Eyewash facilities shall be:

a) conveniently located wherever acids, caustics, corrosives and other hazardous chemicals or hazardous biological materials are in use, or where work with radioactive materials is undertaken; and

b) of an approved fixed design or be a simple, approved spray-type device attached to the water, or isotonic saline supply by a flexible hose.

NOTE Simple spray devices with ample supply of easy-open containers of sterile water are an acceptable alternative in facilities where the risk of splashes exists and access to plumbing is not available.

10.3.3 Water supply

Devices attached to the water supply shall be:

a) tested at regular frequencies to ensure proper functioning and to flush out stagnant water; and

b) inspected annually.

Portable eyewash bottles are usually designed to use on one eye and do not deliver the quantity of flushing solution required and do not stay open permitting continuous flushing. These units shall be well maintained to prevent contamination.

10.4 Emergency/drench showers

a) Emergency showers shall be available and convenient to locations identified through the risk assessment process (e.g. where caustic and corrosive chemicals are used).

NOTE 1 The number of such emergency showers depends on the complexity and extent of the laboratory.

NOTE 2 Floor drains are normally provided in proximity to such emergency showers.

NOTE 3 In specific laboratory facilities, including high-level containment facilities, floor drains can compromise containment and thus their installation can be inappropriate.

b) These devices shall be:

— tested at an appropriate frequency (e.g. weekly activation) to ensure they are properly functioning; and

— inspected annually.

c) Comfortable water temperatures shall be provided where possible.

10.5 Spill response

All spills of samples, chemicals, radionuclides, or cultures shall be cleaned up and the area decontaminated after risk assessment (see Annex C on decontamination of spills). Approved safety precautions, safe methods, and personal protective equipment shall be used during clean-up. The laboratory director should be notified of the incident in writing. The laboratory shall ensure the availability of appropriate types of spill kits.

All personnel dealing with spills shall be trained in spill response procedures and the correct equipment to use.

Some incidents of spillage can require the immediate evacuation of all personnel from the area. The impact of these spills may be affected by both the amount and nature of the agent concerned. The safety manual protocol for dealing with such events shall be utilised.

Specific protocols shall be established for the decontamination, cleaning, and disinfection of each piece of equipment in case of accidents or spills that result in biological, chemical, or radioactive contamination, and also prior to equipment being serviced or repaired (see Annex C for more information on decontamination, cleaning and disinfection of equipment).

Only appropriately trained personnel wearing appropriate personal protective equipment shall undertake cleaning procedures.

11 Fire safety

11.1 Fire prevention and control

11.1.1 Construction

Architectural specifications shall be based upon the type of laboratory hazard to be contained. Primary exit routes shall be designated. All construction plans shall determine the applicability of local regulation.

Medical laboratories within inpatient facilities should be separated from medical areas by fire resistant construction, with a minimum rating of one hour and all openings protected by 45 min-rated assemblies. Freestanding laboratories and those part of inpatient medical centres, but are located in their own buildings, should conduct a fire risk assessment and refer to local fire regulations.

Secondary exits shall be provided for the laboratory. Laboratory corridors that are also an access to an exit shall be maintained clear and unobstructed at all times.

Where flammable gases are stored, spark-proof or spark-protected lights and switches should be installed. Electrical equipment shall be specially designed for use within such areas.

11.1.2 Flammable material storage

Containers for flammable liquids and gases shall be:

a) kept as small as possible;

b) compatible with laboratory needs; and

c) kept closed except when in use.

Flammable liquids and gases shall be stored only in approved cabinets or stores.

Refrigerated flammable liquids shall be stored only in "explosion-safe" non-sparking refrigerators.

NOTE Domestic refrigerators are not suitable for this purpose.

Metal storage containers for bulk flammable liquids shall be bonded and grounded to a common site to avoid static charge.

Portable safety containers shall be used for storing, transporting and dispensing flammable liquids.

Decanting or transferring combustible liquids from stock drums to small containers should be done within a storage room especially reserved for this purpose or within a chemical fume hood. Proper grounding of metal containers is required.

11.1.3 Alarm systems

An automatic smoke-detection, heat-detection, and alarm system:

a) shall be provided for every laboratory area that stores flammable or combustible liquids or gases, or whose size or configuration is such that the fire itself cannot constitute adequate warning;

b) should alert local emergency responders or the public fire department;

c) should connect with the facility's overall detection and alarm system, if such a system exists;

d) shall be audible in all areas of the laboratory, including storage rooms, lavatories, and dark rooms;

e) shall be regularly tested to ensure their function; and

f) personnel shall be trained in how to use the fire alarm system.

A visual alarm is needed in areas in which personnel use headphones (e.g. client services, transcription) or when an employee can have a hearing disability.

11.1.4 Fire risk reduction strategies

The organization shall determine the applicability of local, regional and national fire statutory and regulatory requirements and implement the following fire reduction strategies:

a) only minimum quantities of flammable gases and liquids shall be kept in the technical areas of the laboratory;

NOTE In some jurisdictions, "minimum quantity" is interpreted as one working day's consumption.

b) potential sources of ignition should be minimized;

c) flammable gases and liquids shall be used only in well-ventilated areas;

d) work involving release of flammable vapours shall be conducted only in a laboratory fume hood or cupboard;

e) flammable liquids and gases shall be kept away from heat and sources of ignition, including electric motors and direct sunlight;

f) piped-in gas supplies require the installation of emergency shut-off valves and pipework which considers national, regional or local statutory and regulatory requirements;

g) spill kits shall be immediately available to contain small quantities of flammable spillage; and

h) in the case of a large or uncontrollable spill, fire department assistance shall be sought immediately.

11.1.5 Fire prevention and training programs

11.1.5.1 Training program

A training program in fire safety shall:

a) be provided for new employees and updates provided to current employees as needed; and

b) include recognition and evaluation of fire hazards, planning to reduce the risk of fire and all actions to take when fires occur. (See 5.9.1).

11.1.5.2 Evacuation Plan

Periodic fire drills following the local fire evacuation plan shall be held on the advice of local statutory and regulatory requirements.

The local fire evacuation plan shall:

a) address how to assist disabled persons;

b) address handling of patients and visitors unfamiliar with the exit procedure; and

c) include a triage location that does not interfere with emergency personnel and vehicles.

11.1.6 Firefighting equipment

11.1.6.1 General

Appropriate equipment shall be in place to extinguish containable fires, and to assist in the evacuation of personnel from the vicinity of a major fire.

11.1.6.2 Portable fire extinguishers

Portable fire extinguishers (PFEs) shall be:

a) properly installed and maintained;

b) inspected monthly to ensure they are charged;

c) have maintenance performed annually; and

d) appropriate for the country in which it is being used.

All personnel shall be trained in the use of PFEs prior to fire emergencies including the potential hazards of incorrect use (see Annex H).

Depending on the type of fire that can develop, the appropriate PFE type needs to be available.

NOTE 1 PFEs are specific for one or more classes of fire.

The common fire classes relevant to the laboratory are:

a) organic solids such as paper, wood and some plastics;

b) flammable or combustible liquids;

c) flammable gases; and

d) electrical equipment/appliances.

NOTE 2 National, regional and local labelling schemes for different classes of fires can vary .

11.1.6.3 Use of fire blankets

Fire blankets should:

a) be used to cover a burning area (including workers doused with burning liquid or with clothes on fire); and

b) not be considered if the combustible material burns in the absence of oxygen, there is an alternate oxidizer source within the burning area or he fire is too large to be adequately covered by the blanket.

Selection, location and maintenance of extinguishers and fire blankets shall be appropriate for the types of fire possible within the laboratory, and in accordance with the local fire authorities.

It is the responsibility of laboratory personnel to ensure people's safety by orderly evacuation rather than by attempting to extinguish fires.

11.1.6.4 Automatic systems

Automatic sprinkler or other extinguishing systems shall be:

a) implemented for the clinical laboratory that uses or stores flammable or combustible liquids or gases;

b) regularly inspected; and

c) maintained with an awareness of local fire statutory and regulatory requirements.

11.2 Emergency exits and evacuations/Egress

The laboratory shall be aware of all aspects of emergency exits and evacuations/egress advised in local, regional and national statutory laws and regulations including:

a) identification at each entrance and exit point, with emergency exits marked so as to distinguish them from normal exits;

b) provision of secondary exits to ensure safe evacuation of personnel from the laboratory;

c) verification that designated fire exits open into a fire-protected area with exit routes and fire egress doors clearly identified;

d) development of an action plan for emergency evacuation (see Annex A for more information on development of action plans);

e) As an alternative, the plan considers chemical, fire and microbiological emergencies, including measures to be taken to leave the unoccupied building in as safe a state as possible;

f) making all personnel, including visitors, aware of the action plan, routes of exit, and assembly points for emergency evacuation; and

g) placing maps illustrating evacuation routes at regular intervals throughout the building.

12 Laboratory ergonomics

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.

Employers should be responsible for:

a) performing a task analysis to review how work is done and what motions are required and to evaluate problems associated with awkward or repetitive motions;

b) including ergonomic considerations in purchasing requirements or standards;

c) considering the various types of workers who will be working at a workstation for proper workstation design;

d) considering the use of adjustable equipment, benches, and work stations to facilitate flexibility to various body types; and

e) training workers, particularly in proper body mechanics to ensure good ergonomics in the laboratory.

NOTE Common ergonomic challenges in the laboratory include, but are not limited to:

a) frequent pipetting;

b) use of optical microscopes for prolonged periods;

c) computer workstations;

d) microtomes;

e) biological safety cabinets; and

f) physiological testings such as ultrasonography and ECG can have high prevalence rates of exertion including bending, lifting, pushing and pulling.

13 Equipment safety

13.1 General considerations

For all equipment, the manufacturer's instructions and safety notifications shall be reviewed to ensure proper set up and use. All manufacturer's documentation and instructions shall be retained. A preventive maintenance program shall be set up and implemented in accordance with all manufacturer's recommendations. All equipment shall be decontaminated prior to servicing or disposal.

13.2 Centrifuges

To prevent physical hazards due to mechanical failure and contact hazards from spilled chemical or biological material and biological hazards resulting from the creation of aerosols of biological hazards, the laboratory shall ensure that:

a) users are properly trained;

b) centrifuges are properly balanced with carefully matched rotors and tubes;

c) the lid is opened only after the rotor has come to a complete stop;

d) centrifuge parts are regularly cleaned, dried and inspected;

e) rubber O-rings and tube closures are inspected for deterioration;

f) only tubes with tops or stoppers are used;

g) tubes are not filled to the rim as liquids can become trapped in the threads of screw tops; and

h) sealed centrifuge cups or rotors which can be loaded and unloaded in a BSC are used when required.

13.3 Water baths

The continuity to ground in the plug to the water bath case shall be regularly verified to prevent electrical shock. Microbiological contamination in water baths shall be prevented by adding disinfectant (e.g. phenolic detergent). Water baths shall be unplugged prior to filling or emptying.

13.4 Mixers, blenders, sonicators, grinders and lyophilizers

To minimize the release of hazardous aerosols or biological hazards, the laboratory shall:

a) operate and load equipment inside a BSC;

b) during blender operation, cover the top of the blender with a towel soaked in disinfectant; and

c) filter vacuum pump exhaust.

13.5 Pipettes and pipettors

Mechanical pipetting devices shall be used for all work with chemical and biological agents.

NOTE The use of mechanical pipetting devices does not completely eliminate all hazards associated with pipetting.

The following shall be taken as precautionary measures:

a) When using automatic pipettors, pipettes or tips, use ones that hold a larger volume than the volume needed to be pipetted.

b) Perform pipetting of biological hazards in a BSC and pipetting of toxic materials in a fume hood.

c) Place used pipettes in disinfectant solution.

d) Disinfect pipettors or pipetting aids when contaminated and on a regular basis.

e) Use plastic Pasteur pipettes when possible.

f) Use pipettes plugged with cotton when working with potentially biological hazards.

g) Use mark-to-mark pipettes to avoid expelling the last drop.

h) Expel liquids slowly down the sides of a tube to avoid aerosol creation by splashing.

13.6 Microscopes

The following shall be taken as precautionary measures applicable to microscopes:

a) To reduce injuries related to frequent microscope use, workstations should be set up ergonomically with microscope work being alternated with other tasks where possible (see Clause 12).

b) Ergonomically-designed microscopes should be utilised.

c) For electrical safety, cords, plugs and connections shall be regularly inspected for deterioration or corrosion.

d) When using fluorescent microscopes, proper shielding should be in place during operation and alignment.

e) A face shield and gloves should be worn when changing a fluorescent high-pressure mercury bulb.

f) Stage, eyepieces, knobs and any other parts of the microscope which can become contaminated shall be disinfected after use (a 1:16 sporicidin solution is recommended).

g) Radiation dosimeters as well as personal protective equipment should be worn by users of electron microscopes as necessary for work with the hazardous chemicals uses as fixatives or preparatory agents.

13.7 Automated analysis equipment for sample examinations

The following shall be taken as precautionary measures applicable to automated analysis equipment:

a) ensuring all reagents are stored according to requirements;

b) checking that all tubing and connections are in place prior to operating equipment;

c) using clear plastic safety shields in front of sample probes;

d) ensuring that only authorized and knowledgeable workers service equipment when it malfunctions;

e) reviewing local regulations for all waste line discharges and receptacles;

f) using closed sampling instruments whenever possible;

g) keeping drip trays clean;

h) avoiding overfilling sample cups; and

i) transferring required aliquots using a pipettor.

13.8 Microtomes and cryostats

The following shall be taken as precautionary measures applicable to the use of microtomes:

a) ensuring that microtomes are in the locked position when positioning paraffin blocks;

b) only handling microtome knives by the knife handles;

c) avoiding the use of fingers to remove sections from the knife;

d) using a brush, forceps and a microscope slide to remove sections from the knife; and

e) sterilization of knives and section flattening devices after use by autoclaving.

For freezing microtomes:

a) the carbon dioxide cylinder shall be secured near the microtome; and

b) surgical masks shall be worn when using freezing microtomes to avoid exposure to lyophilized tissue dusts.

Personal protective equipment such as gowns, puncture and penetration resistant gloves, eye protection shall be worn in the frozen section laboratory due to the high level of potential infection exposure from samples in the fresh state.

Automated microtomes should be utilized wherever possible.

General precautionary measures applicable to the use of cryostats that shall be taken include but are not limited to:

a) keeping the cover closed during cutting;

b) routinely decontaminating with 75 % to 100% alcohol after the removal of tissue debris and at the end of each day of use;

c) decontaminating with tuberculocidal disinfectant for suspected tuberculosis cases and sodium dodecyl sulfate (SDS) after suspected Creutzfeldt-Jakob disease (CJD) cases;

d) defrosting and decontaminating the cryostat weekly;

e) handling knives cautiously;

f) locking the hand wheel and placing a guard over the knife when changing blocks; and

g) wearing metal mesh gloves when changing knife blades.

13.9 Mass spectrophotometers

Because mass spectrophotometry entails the use of flammable and toxic chemicals and compressed gas, training for a mass spectrophotometer shall be performed by an authorized trainer. (See 8.3 and 9.1).

Gas, pump, exhaust and drain system tubing and connections shall be verified to ensure they are correct prior to each use. Pumps shall be vented to outside the laboratory as pump exhausts can contain traces of the samples being analysed, solvents or reagent gas.

13.10 Flow cytometers

Because flow cytometer users are subjected to occupational exposure through accidental inoculation, droplets or aerosols,precautionary measures that shall be taken include but are not limited to:

a) implementing a rigorous sorter preventive maintenance schedule;

b) using protective covers for computer control surfaces, including keyboard and computer mouse;

c) ensuring sample preparation steps minimize potential aerosol formation;

d) preparing samples that need to be sorted as single cell suspensions as aggregated cells can partially or completely clog sort nozzles resulting in aerosols from stream deviation;

e) equipping cell sorters with an aerosol management system (AMS) designed to evacuate the sort chamber and sort collection area of the cytometer. The AMS shall be operated during sort operations; and

f) determining user-specific personal protective equipment following a risk assessment which accounts for the risk group of the biological samples being tested.

14 Safe personnel work practices

14.1 Food, drink and like substances

Consumption of food, drink, and like substances (e.g. chewing gum, medication) shall not be allowed in laboratory areas.

Food and drink for consumption shall be stored only in specifically designated refrigerators located in non-laboratory areas. Food shall not be stored where reagents, blood or other potentially infectious material are stored.

Refrigerators, freezers, microwave ovens and ice machines shall be appropriately labelled to indicate their intended use.

14.2 Cosmetics, hair, jewellery

14.2.1 Cosmetics and contact lenses

Application of cosmetics and the handling of contact lenses shall be prohibited in technical work areas.

Hand creams may be used.

NOTE Oil-based hand creams or lotions can cause deterioration of some glove material.

14.2.2 Hair

Long hair shall be secured back and off the shoulders to prevent it from contact with contaminated materials or work surfaces, prevent shedding organisms into the work area, and be kept out of moving equipment.

Men with beards shall observe the same precautions provided for hair.

Disposable hair- and beard-covers may be used.

14.2.3 Jewellery

Jewellery and other accessories that can interfere with work procedures or safety practices shall not be worn in the laboratory.

NOTE This includes rings, earrings, wristwatches, bracelets, necklaces and other jewellery where there is danger of them being caught in equipment or contaminated by infectious substances or chemicals.

14.3 Smoking

All forms of smoking shall be prohibited in the technical work area including electronic cigarettes/ vapours.

14.4 Personal property

14.4.1 General considerations

Personal property such as portable electronic devices, clothing, cosmetics, and beverage containers shall not be placed in areas where contamination can occur.

For security and infection prevention and control purposes, these items should be kept in a secure storage area such as lockers.

14.4.2 Personal electronic devices

Personal electronic devices (e.g. cell phones, personal digital assistants, wireless communication devices, portable music players, and radios with headphones) shall not be used in the technical work area in the following circumstances:

a) When working with hazardous materials of any category (chemical or biological).

b) When wearing gloves or other personal protective equipment with the exception of a lab coat.

c) While performing work in laboratory samples, data or process that can affect testing outcomes.

d) When in an area in which they might distract or interrupt others.

e) When in an area in which accidental release of protected health information could occur.

f) If they interfere with an employee's ability to detect potential hazards, such as hearing an alarm or an approaching obstacle.

All personal electronic devices should be protected from laboratory hazards and possible contamination.

14.5 Festive decorations

Festive and other decorations that present potential contamination and/or fire hazards shall not be used in technical work areas.

Decorations shall never be attached to lights, light fixtures or technical instruments.

14.6 Hand hygiene

General precautionary hand hygiene measures shall be implemented, including but not limited to:

a) during the delivery of healthcare, workers should avoid unnecessary touching of surfaces in close proximity to patients to prevent both contamination of clean hands from environmental surfaces and transmission of pathogens from contaminated hands to surfaces;

b) laboratory personnel shall perform hand hygiene:

   — before and after having direct contact with patients;

   — immediately after actual or possible contact with blood, body fluids or other contaminating materials, even if gloves have been worn;

   — after contact with inanimate objects (including medical equipment) in the immediate vicinity of the patient;

   — after removing gloves;

   — before and after using the toilet;

   — before leaving the laboratory technical area; and

— before eating or smoking;

c) alternative materials shall be provided for handwashing for workers who suffer from allergies or other reactions to specific compounds contained in certain antiseptic agents;

d) hypoallergenic skin lotion should be provided at all wash stations;

e) sinks for handwashing shall not be used for disposal of blood and body fluids; and

f) artificial fingernails or extenders shall not be worn if duties include direct contact with patients.

NOTE In locations where access to handwashing sinks is limited, use of alcohol-based "waterless" hand-cleansing products can be acceptable alternative to traditional handwashing depending on the nature of the activity in the area.

14.7 Mouth pipetting

Mouth pipetting shall be prohibited.

14.8 Sharps

Laboratory workers shall be trained in safe handling and use of sharp instruments and devices including but not limited to:

a) Sharps, including used needles, shall not be sheared, bent, broken, recapped or re-sheathed by hand, or manually removed from syringes or holders.

b) Reviews of working practices should include the objective to reduce the use of sharps wherever possible.

c) Sharp objects for disposal, including needles, glass and disposable scalpels shall be placed in specified puncture-resistant containers immediately after use.

d) Sharp containers shall be placed within arm's reach, below eye level and not be filled to more than two-thirds of their capacity before replacement.

e) Procedures for the safe disposal of the used containers and their contents shall take into account applicable local, regional and national statutory and regulatory requirements.

15 Personal protective equipment

15.1 General considerations

The organization/laboratory shall have a personal protective equipment (PPE) plan which incorporates institutional policy and determines the PPE required for performing various tasks and diagnostic procedures including:

a) consistent application of PPE policy to all personnel, service employees as well as visitors;

b) selection of PPE based on the nature of the patient interaction and/or the likely mode(s) of transmission;

c) use of designated containers for used disposable or reusable PPE;

d) placement of designated disposal containers in a location that is convenient to the site of removal to facilitate disposal and containment of contaminated materials;

e) performance of hand hygiene as the final step after removing and disposing of PPE;

f) requirement for institutions to launder garments used as PPE and uniforms visibly soiled with blood or infective material; and

g) training of all employees in the use of PPE. (See 5.9).

15.2 Protective clothing in the laboratory

The laboratory shall ensure that an ample supply of clean protective clothing (e.g. coats and gowns), appropriate to the level of risk, is available for those working in or visiting within the laboratory.

NOTE Home-laundering is not an acceptable practice.

When not in use, clean protective clothing shall only be hung on suitable devices provided for that purpose. These hooks shall be away from radiators, steam pipes, heating instruments, and open flames. Contaminated protective clothing shall be placed and transported in appropriately identified bags that prevent leakage. They shall be appropriately washed to ensure chemical and biological decontamination.

Protective clothing shall be changed at appropriate intervals to ensure cleanliness and shall be changed immediately if it is known to be contaminated with hazardous materials.

Protective clothing shall be removed before leaving the laboratory area.

Disposable plastic aprons or fluid-resistant gowns can be required if there is a significant probability that potentially hazardous substances will be splashed on the patient, worker or visitor. Other personal protective equipment, such as gloves, goggles, masks, capes and face shields can also be required in these situations.

15.3 Protective clothing outside the laboratory

Phlebotomists and other workers whose duties take them out of the laboratory shall be required to wear clean coats, gowns or tunics while working with patients.

15.4 Face and body protection

Approved safety glasses, goggles, facial shields or other eye and face protection shall be available and worn when handling hazardous materials. The personal protective equipment and combinations of each shall be in accordance to the need anticipated by the task performed.

Splash guards or similar devices shall be available for use if there is the potential for splashing of samples or reagents to occur.

Additional eye protection shall be worn with contact lenses.

NOTE Personal eye glasses and contact lenses are not considered adequate protection from splashes.

15.5 Gloves

Gloves shall:

a) be available for use in laboratory operations to provide protection from chemicals, biological hazards, radioactive contamination, cold and heat, product contamination, sharp edges and abrasions;

b) meet comfort, fit, flexibility, grip, abrasion resistance, puncture/tear resistance and chemical resistance requirements for the type of manipulation performed;

c) adequately protect from the hazards involved;

d) only be used during contact with potentially hazardous and/or contaminated material;

e) be inspected for leakage before wearing;

f) be worn to completely cover the hands and wrists and, where appropriate, overlap the laboratory gown or coat sleeve;

g) be removed and disposed of in accordance with local safe practices when the task is completed or interrupted;

h) be changed between patients;

i) be replaced if torn, damaged, or if internal contamination is suspected; and

j) be removed if soiled, where there is a possibility of cross-contamination with clean areas or materials.

NOTE All telephones, doorknobs and handles, computer keyboards, keyboards, etc. are considered contaminated unless these areas/items are protected by a barrier that allows for decontamination.

Gloves shall not be washed for the purpose of reuse as this practice is associated with the transmission of pathogens. The laboratory shall provide un-powdered gloves and/or alternative materials for workers who suffer from allergies and other reactions, e.g. reaction to natural latex, talc, starch or vinyl.

Laboratory workers shall be trained in glove selection, fitting and removal before and after appropriate use.

15.6 Footwear

Footwear shall be comfortable, with nonslip soles. Shoes shall cover the foot to include heel, toes and instep.

Leather or synthetic, fluid-impermeable footwear is recommended.

Disposable, fluid-resistant shoe covers can be worn for jobs where splashing is anticipated. Some tasks, such as transporting large compressed gas cylinders require additionally protective shoes (steel-toed).

For routine work in the laboratory, shoes should be flat and ergonomically comfortable.

Special footwear (e.g. disposable or rubberized boots) can be required for specific laboratory areas including high infection containment facilities.

Approved safety shoes can be required for work with bulk chemicals, during hazardous activities, or in histopathology areas where knives or other sharp instruments are regularly used.

15.7 Respiratory protection

Where respiratory protection devices (e.g. masks, personal respirators) are required for use during a technical activity, instructions on their use and maintenance shall be included in the text of the safe operating procedure for that activity. Respirators shall be used only in accordance with instructions and appropriate training.

Arrangements should also be made for workplace monitoring, medical evaluation, and for respirator users' training to ensure the equipment is being used correctly. Respirators can require individual-fit testing.

16 Transport of samples and hazardous materials

For transport of specimens inside the facility, engineering controls such as carts, leak-proof carrying containers, and absorbent materials shall be implemented. Personnel transporting specimens shall use the appropriate personal protective equipment for the materials they are handling.

All samples shall be transported to the laboratory in such a manner as to prevent contamination of workers, patients, or the environment. It is presupposed that laboratories are aware of applicable statutory and regulatory requirements for specimen transport.

Samples shall be transported in approved, inherently safe, leak proof containers.

Samples, cultures and other biological material transported between the laboratory or other facilities shall be sent in a manner compliant with facility safety rules so as to ensure the integrity of the sample and the safety for the carrier, the general public and the receiving laboratory.

17 Waste disposal

17.1 General considerations

It is presupposed that laboratory waste disposal policies and procedures are developed with an awareness of applicable statutory and regulatory requirements (see 5.8.3).

17.2 Waste management objectives

Laboratory waste management shall have the following objectives:

a) minimizing the risks in handling, collecting, treating, transporting, storing, treating and disposing of waste;

b) minimizing harmful effects to the environment;

c) accident prevention; and

d) ensuring that hazardous waste is handled only by appropriately trained personnel using appropriate personal protective equipment.Hazardous and non-hazardous waste.

17.3 Hazardous waste

General precautionary waste disposal measures for hazardous waste shall be implemented, including but not limited to:

a) All samples, cultures and other biological material no longer required shall be discarded in containers specifically designed, intended and marked for disposal of hazardous waste.

b) Biological waste containers shall not be filled beyond their designed capacity.

c) All sharp objects shall be discarded directly in puncture-resistant containers.

d) Certain regulated sharps, including needles and scalpels shall be discarded into approved sharps containers.

e) Loose sharps (pipettes, syringes, broken glass) shall not be placed inside non-hazardous waste receptacles.

f) All discarded microbiology laboratory samples, cultures and contaminated waste shall be made biologically safe before being taken from the laboratory facility.

NOTE Biological safety can be realized processing by autoclave, or other approved technology, or by packaging in appropriate containers.

g) Transport of waste that has not been treated can be allowed, provided that the material is packaged and transported in a manner which considers hazardous waste statutory and regulatory requirements.

17.4 Non-hazardous waste

General precautionary waste disposal measures for non-hazardous waste shall be implemented, including but not limited to:

a) Rubbish and laboratory waste shall not be allowed to accumulate.

b) Filled containers shall be removed from work areas on a regular basis and be held in a designated secure place, normally within the laboratory area, prior to decontamination or final disposal.

c) Laboratory rubbish and routine paper waste that has not been contaminated with reagents or body fluids can be handled and processed as non-hazardous waste.

d) Appropriate and safe disposal should occur at least daily.

e) Laboratory waste that is known to be contamination-free (e.g. paper, plastic, textiles etc.) can be handled and processed as non-hazardous waste.

f) Laboratories shall ensure that non-hazardous waste being removed by custodial personnel is clearly identified as such and kept well separate from hazardous waste receptacles.

18 Housekeeping practices

Housekeeping activities shall be well maintained to ensure safety for all workers. This includes janitorial staff that can have some level of housekeeping duties in the laboratory. Laboratory staff shall however, have the primary responsibility on maintaining order including but not limited to:

a) maintaining proper storage of all materials (i.e. avoiding obstructions and tripping hazards);

b) cleaning and disinfecting all equipment and work surfaces that are used for processing contaminated materials with appropriate agents at the end of each working shift and whenever spills or other contamination has occurred;

c) keeping aisles, passageways and doors unobstructed;

d) protecting access to emergency eyewashes and showers, first aid kits and fire extinguishers;

e) securing all equipment;

f) properly disposing of sharps and broken glass for disposal segregating and labelling of hazardous waste;

g) decontaminating equipment;

h) flushing and/or decontamination of sinks;

i) proper labelling of hazards; and

j) maintaining an orderly, uncluttered work area at all times.

There shall be oversight and supervision of janitorial activities (e.g. periodic cleaning of floors, removal of non-hazardous waste). Dusting, dry sweeping or vacuuming shall be avoided so as not to produce aerosols. Wet cloths, vacuum cleaners with high efficiency filters and sweeping compounds should be considered to minimize aerosol formation.

A person shall be designated to oversee good housekeeping practices. The laboratory shall designate technical areas as either clean or contaminated.

Changes in housekeeping practices or materials shall be communicated with the laboratory safety officer (see 5.5) to ensure that unintended risks or hazards can be avoided.

Changes in laboratory practices, working habits, or materials that can result in potential hazards to housekeeping and/or maintenance staff shall similarly be communicated with the laboratory safety officer (see 5.5) and in writing to the managers of the housekeeping and maintenance staff.

19 Incidents, injury, accidents and occupational illnesses

The laboratory shall have a programme for reporting laboratory incidents, injuries, accidents, near misses and occupational illnesses, as well as potential hazard, with responsibilities of the laboratory staff, laboratory safety officer (see 5.5) and the laboratory management clearly specified.

Employers shall promote a safe work place environment by facilitating a 'blameless' reporting culture. Employees have a responsibility to report unsafe working conditions and any accident or incident involving hazards.

NOTE 1 Injuries due to needles and other sharps have been associated with transmission of HBV, HCV and HIV to healthcare personnel.

NOTE 2 Exposure of mucous membranes of the eyes, nose and mouth to blood and body fluids has been associated with the transmission of bloodborne viruses and other infectious agents to healthcare personnel.

Reports for all incidents, including injuries shall:

a) be filed at the time of, or immediately after, each incident;

b) include a detailed description of the incident;

c) include an assessment of the cause(s);

d) include recommendations for preventing similar incidents; and

e) include actions taken to implement the recommendations.

Incident reports, including remedial actions, shall be reviewed by a senior manager, the safety committee or the laboratory safety officer (see 5.5). The review shall assess these opportunities for improvement and the need for any changes to policy, process or procedures.

Annex A
(informative)

Action plan outline for implementation of this document

A.1 Introduction

This document is intended for use in all types of medical laboratories, from field laboratories with limited resources to major research and teaching institutions. This annex is intended as a guide for implementing this document, particularly for those with limited resources. Often many of the steps needed to improve safety cost very little, involving only minor changes in operating practices. Rarely are radical high-cost solutions required. Logical decision-making supported by professional expertise can establish and maintain a safe system of work.

A.2 Establishing the safety system

Identify a laboratory safety officer with sufficient experience to take the lead on safety issues. This individual should be given sufficient time to establish the safety system. In a small laboratory, this time commitment can be minimal, but it can increase with laboratory complexity.

A.3 Maintaining the established safety system in the laboratory

Regular safety awareness training for laboratory personnel is recommended. Attendances and programme records should be kept.

Regular programmed safety audits and/or inspections of the workplace (both analytical and non-analytical areas) are recommended. These should not be less than annually, and in areas of increased risk at more frequent intervals. Careful documentation should be kept. The annexes of this document contain itemized checklists to assist this process.

Instruction manuals, methods and operational guidance documentation should include relevant safety information that is both practical and fully operational. This information should be kept current.

All new equipment and processes should be assessed for risk both before and after commissioning, and appropriate risk-reduction strategies implemented.

Untoward incidents and accidents should be fully investigated, documented, and subsequent steps taken to reduce the possibility of recurrence.

All personnel should be encouraged to identify potential hazards and to work in a manner so as not to put themselves or others at risk.

Annex B
(informative)

Laboratory safety audit

B.1 General

The following tables are itemized checklists intended to assist the audit process.

Tables B.1 to B.4 assist with conformity with standards, and are focussed towards the laboratory management personnel.

Tables B.5 to B.10 help to audit the breadth of safety knowledge and safe working practices among operational staff.

B.2 Instructions

a) Follow instructions on each page:

- indicate Y (yes), N (no) or NA (not applicable) in the second, third or fourth column;
- answer all questions; and
- list, explain and/or clarify responses in the last column.

b) If there is insufficient space on the form for all of the required information:

- include the information on a separate page;
- attach it to this form; and
- indicate on the form that there is additional information attached.

c) You will need to update your policies and procedures in the following situations:

- when you add new tasks and procedures that affect occupational exposure; or
- when you change or modify tasks and procedures that affect occupational exposure.

Make sure that you are in conformity with every item you check or date in this audit.

Table B.1 — Work practice/engineering controls

The following work-practice/engineering controls are in place in this department	Y	N	NA	Comments/Explanations
1 Handwashing sinks are available for staff use in work areas where exposure to blood/body fluids can occur.				
2 In instances where handwashing facilities are not readily available, antiseptic hand cleanser and clean disposable paper towels or tow-elettes are available. Indicate method used.				

Table B.1 *(continued)*

The following work-practice/engineering controls are in place in this department	Y	N	NA	Comments/Explanations
3 Handwashing is required in the following instances: — if hands become contaminated with blood or body fluids; — when gloves are removed; and — between patient contacts. Is this policy being followed? If not, please explain.				
4 Is recapping of sharps and bending and breaking of needles prohibited under all circumstances in this department				
5 Leakproof, puncture-resistant sharps containers, with appropriate labels or colour coding, are readily available for disposal of used sharps. If not, please explain.				
6 Are there any reusable sharps used in the lab? Please list them.				
6 a) Reusable sharps contaminated with blood or other infectious materials are processed and stored so that personnel are not readily able to reach into these sharps containers.				
7 Handling of sharps: After use, all sharps (needles, scalpels, capillary pipettes, slides, coverslips, disposable pipettes, and other sharps) are placed in appropriate puncture-resistant containers for reprocessing or disposal. Employees have been trained in these procedures and have been instructed not to overfill containers.				
8 Eating, drinking, applying cosmetics, smoking and handling contact lenses is prohibited in work areas where there is any risk of occupational exposure. Employees have been informed of this rule and are in compliance.				
9 Mouth pipetting is prohibited in the laboratory.				
9 a) Mechanical pipetting devices are available in the laboratory.				
10 Storage of food and drink for consumption is prohibited in places where blood or other potentially infectious materials are kept. This applies to refrigerators, freezers, shelves, cabinets, countertops and benchtops. Employees have been informed of this rule and are in compliance.				
11 Sample handling: Leakproof primary containers are used for all samples.				
11 a) All samples (blood or other potentially infectious materials) are placed in leakproof secondary containers during transport. Requisitions are attached to the outside of the secondary container.				

Table B.1 *(continued)*

The following work-practice/engineering controls are in place in this department	Y	N	NA	Comments/Explanations
11 b) When packages that contain blood or other potentially infectious materials are shipped from the laboratory to another mailing address, they are appropriately packaged and a biohazard label is affixed to the outside of the package.				
11 c) Pneumatic tube system: Employees are instructed on the proper packaging of the carriers to transport samples without leakage.				
12 Equipment that becomes contaminated with blood or other potentially infectious materials is decontaminated immediately or as soon as possible.				
12 a) Equipment is also inspected before it is repaired or shipped, and decontaminated if possible. If it cannot be decontaminated before repair or shipment, staff have been instructed to attach a biohazard label that clearly identifies the site(s) of contamination.				
13 Regulated waste: Closable leak-proof containers with the appropriate colour coding or labelling are available.				
13 a) Bulk body fluids (urine, vomitus, faeces, etc.) are disposed of properly through a sanitary sewer system.				
13 b) Containers of body fluid (pleurevacs, blood bags, suction liners, etc.) are placed in biohazard waste containers for incineration or other approved disposal.				
13 c) Laboratory samples are disposed of in biohazard bags (autoclavable, if appropriate) in leakproof containers with tight-fitting covers.				
13 d) Laboratory samples are autoclaved before disposal when applicable.				
13 e) If autoclaves are used for treatment of waste, they are monitored with biological indicators on a regular basis. Please define how often.				
13 f) Tissues, organs and other body parts are placed in biohazard waste containers and sent for incineration or other approved disposal.				
14 Other solid waste (gloves, dressings, etc.) is placed in sturdy plastic bags and is tightly closed for transport.				
15 Procedures that can cause splashing, spraying or splattering of blood or body fluids are performed in a biological safety cabinet or behind an appropriate protective shield. Please list procedures.				
15 a) Biological safety cabinets are inspected on an annual basis.				
16 Written laboratory biological/infection control safety policies are readily available to employees.				

Table B.1 *(continued)*

The following work-practice/engineering controls are in place in this department	Y	N	NA	Comments/Explanations
16 a) The laboratory or hospital exposure control of infection plan is readily available to employees.				
16 b) A copy of an appropriate local, regional, national or international publication covering the protection of laboratory workers from occupationally acquired infections is readily available to all employees.				

Table B.2 — Personal protective equipment (PPE)

The following fluid-resistant PPE is available to employees of this department free of charge	Y	N	N/A	Comments/Explanations
1 Disposable gloves, in appropriate sizes, are available to all at risk of exposure, for either discretionary use or as needed.				
1 a) Are gloves worn: — during contact with blood or body fluids, mucous membranes or the non-intact skin of patients? — when handling items or surfaces soiled with blood or body fluids? — when performing vascular-access procedures (phlebotomy)?				
2 Hypoallergenic gloves and liners are available to workers who are allergic to latex gloves.				
3 Utility gloves are available when indicated, checked before use, and replaced as necessary.				
4 Is face protection needed?				
4 a) If face protection is needed/required, the type(s) of face protection available are as follows (indicate all that apply): — mask with glasses with solid side-shields — mask and goggles — mask with splash shield — chin-length face shield List other face protection available if not listed.				
5 Is protective body clothing required? 5 a) Type(s) of protective body clothing available (indicate all that apply): — clinic jackets — gowns — laboratory coats — aprons List any other protective body clothing that is available.				
6 Is footwear and headgear required?				

Table B.2 *(continued)*

The following fluid-resistant PPE is available to employees of this department free of charge	Y	N	N/A	Comments/Explanations
6 a) Type(s) of footwear and headgear available are as follows (check all that apply): — surgical caps/hoods — shoe covers — short — knee-high List other footwear and headgear available.				
7 Is reusable protective clothing being reprocessed by either of the following? — hospital laundry services — outside laundry services If an outside laundry service is used, provide the following information: name of service; address; items processed by service; and whether the service meets appropriate standards.				
8 Is resuscitation equipment required? 8 a) Types of resuscitation equipment available are: — mouthpieces — resuscitation bag List other available equipment.				
9 The PPE mentioned above is available in all work areas where needed and is maintained on a regular basis.				

Table B.3 — Housekeeping

Item	Y	N	N/A	Comments/Explanations
1 Employees decontaminate work surfaces with an appropriate disinfectant, immediately after completion of procedures, after their work shift, and as soon as feasible when contaminated with blood or body fluids.				
2 Blood and body fluid spills: 2 a) Broken glass: Staff have been instructed never to pick up by hand any broken glassware that might be contaminated.				
2 b) A brush, dust pan, forceps and/or tongs are available for picking up broken glassware.				

Table B.3 *(continued)*

Item	Y	N	N/A	Comments/Explanations
2 c) Are the following procedures routinely used for spill clean-up? — soak up spills with absorbent material (paper towels) — decontaminate the area with an appropriate disinfectant — dispose of contaminated materials appropriately				
3 Disinfectant is ready and available for use at all times. Please list the disinfectant used to decontaminate blood or body fluids in this laboratory.				
4 Laundry: staff have been instructed to consider all used linen as potentially infectious and to wear appropriate PPE when handling used laundry.				
4 a) Staff have been instructed to handle contaminated laundry as little as possible.				
4 b) Staff have been instructed to place laundry directly in the standard laundry bag.				
4 c) Staff have been instructed to double bag as necessary to prevent leakage.				
5 Biohazard warning signs are used to identify the following contaminated materials: — containers used to store or transport contaminated materials, including pneumatic tube carriers; — containers used to store or transport regulated medical waste; and — refrigerators or freezers that hold potentially infectious materials.				
5 a) Biohazard warning signs are posted on laboratory entrances.				
5 b) Biohazard labels are placed on generally accessible equipment (telephones, computer terminals, etc.) used by personnel wearing gloves. No one shall use this equipment without wearing gloves.				

Table B.4 — Exposures

Item	Y	N	N/A	Comments/Explanations
1 Do employees know what to do if they sustain percutaneous exposure via non-intact skin, or mucocutaneous exposure?				
1 a) Is a written protocol available for exposure follow-up, i.e. part of the Exposure Control Plan, or the Laboratory/Hospital Infectious Control Manual?				

Table B.5 — Exposure determination/training/vaccine compliance

Item	Y	N	N/A	Comments/Explanations
1 Have you received and reviewed the blood-borne pathogen programme compliance summary distributed by the occupational or environmental safety departments for documentation of exposure determination, training, and vaccine compliance?				
1 a) If you answered "yes", have you taken the steps to ensure compliance for all your employees?				

Table B.6 — Information and training

Item	Y	N	N/A	Comments/Explanations
1 Are you familiar with the location and contents of the following items? — Chemical safety plan — Blood borne pathogen or biological safety plan — Chemical safety poster — Safety data sheets — Emergency response guide				
2 Has laboratory safety/health training been provided?				

Table B.7 — Standard operating procedures

Procurement	Y	N	Comments
1 When procuring chemicals, do you consider: — potential hazards of the chemicals? — selecting the least hazardous chemicals for the procedure? — ensuring that all chemical containers are properly labelled?			
2 To reduce accidents during transport, do you: — use a transport vessel or secondary container? — use the least-trafficked routes? — use correct PPE, when indicated?			
Storage	**Y**	**N**	**Comments**
3 Do you: — understand and follow chemical storage colour coding recommendations on the container labels? — store chemicals according to hazard class? — avoid storing chemicals in an open area or in corridors, passages and stairs?			

Table B.7 *(continued)*

Procurement	Y	N	Comments
4 Do you know the reason(s) that you need to store chemicals according to hazard class?			
5 Do you know why it is not a good idea to store chemicals in the chemical fume hood?			
Disposal	**Y**	**N**	**Comments**
6 Do you comply with the hospital/laboratory waste policy?			
7 If not, how do you dispose of hazardous waste in the laboratory?			
Potentially high-risk procedures	**Y**	**N**	**Comments**
8 Do you perform any of the following in your laboratory? — weighing/preparing stock solutions; — handling of concentrated acids/bases; — pressurization activities; — rinsing with solvents; — heating/cooling chemicals; — use of reactive chemicals; and — handling of particularly hazardous substances.			
9 If yes, list what safety precautions you take.			
10 Do you maintain an up-to-date inventory of particularly hazardous substances?			
11 Do you ensure that the following safety controls are in place when working with particularly hazardous substances? — a designated work area has been established; — containment devices are available and used; — appropriate and safe waste-removal procedures are in place; — appropriate authorities have been notified; — appropriate and explicit signs are displayed; and — appropriate steps to prohibit entry of unauthorized persons into the vicinity of the hazardous substance.			

Table B.7 *(continued)*

Procurement	Y	N	Comments
High-risk protocols	**Y**	**N**	**Comments**
12 Are you aware that these activities require prior training and approval? — work with severely/extremely toxic inhalation hazards, both inside and outside of containment devices; — work with highly reactive/unstable compounds; and — work with "known carcinogens" IARC group 1A & 1B.			

Table B.8 — Controlling exposures

Hazard potential	Y	N	Comments
1 Do you work with highly volatile chemicals and/or finely divided powders?			
2 If yes, are you aware of the hazard potential?			
Control measures	**Y**	**N**	**Comments**
3 Do you use any of the following engineering controls? — chemical fume hood; and — other local exhaust ventilation.			
4 Does your chemical fume hood have a performance indicator?			
5 If yes, do you know how to use and interpret the chemical fume hood performance indicator?			
6 Do you know how to inform the maintenance department when the hood is outside its normal operating parameters?			
7 Do you maintain the sash height as low as possible?			
9 Do any procedures in the laboratory require the use of respiratory protection?			
10 Are you currently participating in the hospital/laboratory protection programme?			
PPE: Gloves	**Y**	**N**	**Comments**
11 Do you use a glove permeability chart to select the most appropriate glove material to wear for specific procedures?			
12 Do you remove gloves in the following situations? — when the glove material has been contaminated or compromised; — answering the phone; — opening laboratory doors; and — leaving the laboratory environment.			

Table B.8 *(continued)*

Hazard potential	Y	N	Comments
PPE: Laboratory coat and gown	**Y**	**N**	**Comments**
13 Do you remove your laboratory coat or gown when leaving the laboratory environment?			
PPE: Eye/face protection	**Y**	**N**	**Comments**
14 Have provisions been made for an emergency eyewash station located within no more than 10 seconds walking distance (approximately 17 m) away from every area of the laboratory in which hazardous chemicals are used?			
15 Do you know the proper type of eye and face protection to use for a specific procedure?			

Table B.9 — Exposure determination

Item	Y	N	Comments
1 What would you do if you developed the following symptoms? — skin/eye irritation; — respiratory distress or felt unwell in other ways while working with chemicals; and — skin rashes.			
2 Do you use your sense of smell to assess chemical concentrations?			
3 Do you know what threshold limit values and permissible exposure limits are?			
4 Do you know that the occupational environmental safety office or similar organizations are available to assess work practices and conduct air monitoring for hazardous chemicals?			
5 Do you know that you are entitled to an evaluation of your laboratory environment any time you have a concern about work with hazardous chemicals?			
6 Do you know what procedures to follow when you have a chemical spill in the area?			

Table B.10 — Medical consultation

Item	Y	N	Comments
1 Do you know that you are entitled to a medical examination under the following circumstances? — if you experience signs or symptoms of exposure to chemicals; — if you are present during a chemical spill, leak, explosion, or accidental release; and — if you are exposed to a chemical above its regulated level.			

Annex C
(informative)

Decontamination, cleaning and disinfection following spillage

C.1 General

This annex is intended to assist in developing specific protocols for the decontamination, cleaning and disinfection where accidents or spills have resulted in contamination. This annex can also assist in developing suitable protocols for preparing and making equipment biologically safe before service or repair.

C.2 Chemical spills

In the event of a spill or leak of a volatile toxic, corrosive or flammable chemical, the following steps are to be performed by trained personnel:

a) Select the appropriate eye, skin and respiratory protective equipment required for safe re-entry into spill area — refer to the SDS, suitable reference, product supplier or other resource person.

b) Determine the methods and materials required to clean up the spill as demonstrated in Table C1.

c) When applying adsorbents or neutralizers, start slowly and from the perimeter of the spill working inwards in order to contain the spill and to minimize the surface area.

d) Continue until the entire spill has been adsorbed or neutralized.

NOTE pH paper is useful in verifying whether neutralization of a corrosive spill is complete.

e) Wash spill area to remove any residues.

f) Package all contaminated materials in a suitable container, attach a label and submit for waste disposal.

Table C.1 — Spill clean-up

Spill Type	Spill Control Pillows	Activated Charcoal	Acid Neutralizer	Caustic Neutralizer	Mercury Vacuum or spill kit
Solvents	X	X			
Acids	X		X		
Caustics (Bases)	X			X	
Other liquids	X				
Mercury					X

NOTE This table is based on the Laboratory Safety CSMLS Guidelines — Eighth edition.

C.3 Biological spills

C.3.1 General

The following procedures are recommended for decontaminating spills of blood, body fluids or other infectious materials (including culture materials) that occur in the medical laboratory. Spills in other sites can require modification of these procedures.

C.3.2 Decontamination of spills

The factors which influence decontamination procedures are:

a) volume of spill;

b) which body fluid is spilled;

c) protein content;

d) infectious agent present;

e) concentration of infectious agent; and

f) nature of the surface (porous vs. water-resistant).

C.3.3 Personal protective equipment

Wear gloves, gown and facial protection. As aerosols inevitably exist, or are created during spill clean-ups, respiratory protection is strongly advised. Heavyweight, puncture resistant utility gloves such as those used for house-cleaning and dishwashing are recommended.

If the spill contains broken glass or other objects, these should be removed and discarded without contact with the hands. Rigid sheets of cardboard or disposable plastic scoops with a pusher component used as a "pusher" and "receiver" may be used to handle such objects; or tongs and forceps may be used. These should be discarded, along with the objects themselves, into an appropriate puncture-resistant biohazard container.

If the spill is large and/or the worker's shoes could potentially be contaminated, water-impermeable shoe covers should be worn.

With spills of culture media and materials, the site should be covered completely with an absorbent material (see C.4). After a period of 10 min, the clean-up procedure as described below should be initiated. If droplet formation is likely to have occurred (e.g. breakage within a centrifuge), the equipment should remain closed for at least 30 min to allow blood/body fluid droplets to settle before decontamination begins.

C.3.4 Measures to absorb the spill

Since most disinfectants are less active or even ineffective in the presence of high concentrations of protein as are found in blood and serum, the bulk of the spilled liquid should be absorbed prior to decontamination.

Absorb the spilled material with disposable absorbent material (e.g. paper towels, gauze pads or tissue paper wipes). If the spill is large, granular absorbent material such as that used to absorb caustic chemical spills may be used to absorb the liquid. Finely granulated silica gels are available which, when sprinkled on a spill, congeal the liquid immediately. The gelatinous mass may then be scraped up rather than blotted. Absorbent granular materials and silica gels containing a chemical which releases chlorine upon wetting are available. The efficacy of such material in decontamination is not known, and therefore they should not be relied upon to decontaminate a spill. After absorption of the liquid, all contaminated materials should be discarded in the biohazard waste container.

C.3.5 Decontamination of the spill site

Decontaminate the spill site using an appropriate hospital disinfectant, such as a 1 to 10 aqueous dilution of household bleach. Flood the spill site, or wipe down the spill site with disposable towels soaked in disinfectant to make the site "glistening wet" and then allow the site to dry.

Do not use low-level disinfectants, such as quaternary ammonium compounds. Phenolic disinfectants are not recommended for use on contaminated medical devices which come into contact with unprotected patients or laboratory workers, but may be used on laboratory devices, floors and counter tops.

Absorb the disinfectant solution with disposable material. Alternatively, the disinfectant may be permitted to dry.

C.3.6 Cleaning of the spill site

When the spilled material is seen to be dry, fully absorbed, and has been decontaminated, clean the site to make it safe.

Rinse the spill site with detergent and water to remove any noxious chemicals or odours.

Dry the spill site to prevent slipping.

Place all disposable materials used to decontaminate the spill into a biohazard container. Handle the material in the same manner as other infectious waste. Any reusable materials should be decontaminated prior to storage.

A "biohazard spill kit" containing all the materials and protective equipment needed should be prepared and made readily available in all areas where spills are likely to occur. A portable "biohazard spill cart" should be available for transport to areas remote from the laboratory (e.g. the patient's bedside in case a spill occurs during phlebotomy).

C.4 Eye exposure to hazardous chemicals

Flush the eye immediately with water while holding the eye open with fingers.

If wearing contact lens, remove and continue to rinse the eye with water.

Continue to flush the eye and seek immediate medical attention.

C.5 Acid/base spills

For a spill, not directly on human skin, do the following:

Neutralize acids with powdered sodium hydrogen carbonate (sodium bicarbonate/baking soda), or bases with vinegar (5 % acetic acid solution).

Avoid inhaling vapours.

Spread diatomaceous earth to absorb the neutralized chemical.

Sweep up and dispose of as hazardous waste.

For spills directly on human skin, do the following:

Flush area with copious amounts of cold water from the faucet or drench shower for at least 5 min.

If spill is on clothing, first remove clothing from the skin and soak the area with water as soon as possible.

Arrange treatment by medical personnel.

C.6 Mercury spills

Evacuate the affected area.

Close off interior doors and windows, and heating and air conditioning vents in the incident room.

Open exterior doors and windows to move the inside air outside.

Review and follow specific clean-up instructions advised by the local or national authority.