BRITISH STANDARD

BS ISO
15190:2003

# Medical laboratories — Requirements for safety

ICS 11.100



BSI
British Standards

# National foreword

This British Standard reproduces verbatim ISO 15190:2003 and implements it as the UK national standard.

The UK participation in its preparation was entrusted to Technical Committee CH/212, IVD's, which has the responsibility to:

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— monitor related international and European developments and promulgate them in the UK.

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INTERNATIONAL STANDARD

**ISO 15190**

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# Medical laboratories — Requirements for safety

*Laboratoires de médecine — Exigences pour la sécurité*

Reference number
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# Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 15190 was prepared by Technical Committee ISO/TC 212, *Clinical laboratory testing and* in vitro *diagnostic test systems*.

# Introduction

This International Standard specifies requirements to establish and maintain a safe working environment in a medical laboratory. As with all such safety guidelines, there are requirements to ensure that there is a named person ultimately responsible and that all employees take personal responsibility for

— their own safety at work and,

— the safety of others who may be affected by it.

Every task requires risk assessment, with the aim that hazards be eliminated wherever possible. Where this cannot be done, the risk from each hazard is reduced to as low a level as practicable, using the following order of priority:

a) by substitution;

b) by containment; or

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

Safety is the primary consideration; cost is of secondary importance.

While this International Standard is intended for use throughout the currently recognized disciplines of medical laboratory services, other services and disciplines may find it useful and appropriate. However, medical laboratories handling human pathogens requiring containment levels 3 and 4 will need to meet additional requirements to ensure safety.

While this International Standard is not intended to provide guidance on accreditation, it may be used for such purposes by a government, professional, or other authoritative body.

International, national or regional regulations or guidelines may apply to specific topics covered in this International Standard.

# Medical laboratories — Requirements for safety

## 1 Scope

This International Standard specifies requirements for safe practices in the medical laboratory.

## 2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 15189:2003, *Medical laboratories — Particular requirements for quality and competence*

## 3 Terms and definitions

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

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

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

[BS 6324-1]

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

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

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

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

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

**3.7**
**decontamination**
procedure that eliminates or reduces microbial or toxic agents to a safe level with respect to the transmission of infection or other adverse effects

**3.8**
**disinfectant**
agent capable of causing disinfection

[BS 6324-1]

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

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

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

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

**3.12**
**hazard**
potential source of harm

[IEC 61010-1:2001]

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

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

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

NOTE Adapted from EN 12469:2000.

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

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

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

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

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

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

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

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

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

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

**3.26**
**tissue**
any coherent collection of animal or plant specialized cells

## 4 Risk group classification

Biological agents are classified into four risk groups:

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

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

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

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

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

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

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

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

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

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

# 5 Management requirements

## 5.1 Management responsibilities

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

## 5.2 Management of staff health

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

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

# 6 Designing for safety

## 6.1 Preliminary considerations

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

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

## 6.2 General design requirements

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

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

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

A water temperature of 45 °C is recommended.

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

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

## 6.3 Physical conditions

### 6.3.1 Lighting

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

### 6.3.2 Temperature

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

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

### 6.3.3 Ventilation

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

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

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

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

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

#### 6.3.4 Noise

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

#### 6.3.5 Ergonomic factors

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

#### 6.3.6 Design for working with viable pathogens

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

#### 6.3.7 Door signs

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

#### 6.3.8 Laboratory security

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

## 7 Staffing, procedures, documentation, inspection and records

### 7.1 Laboratory Safety Officer

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

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

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

### 7.2 Procedures

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

a) arrangements for visitors/contractors;

b) staff health surveillance;

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

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

e) procedures for safe practices in handling hazardous materials;

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

g) methods for identifying training needs and documentation;

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

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

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

k) incident recording/reporting and investigation; and

l) disposal of clinical waste.

## 7.3 Safety programme audits and inspection

### 7.3.1 Safety programme audits

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

a) safety and health policy;

b) written work procedures that include safe work practices;

c) education and training of laboratory-associated staff;

d) supervision of workers;

e) regular inspections;

f) hazardous materials and substances;

g) health surveillance;

h) first aid services and equipment;

i) investigation of accidents and illnesses;

j) health and safety committee review;

k) records and statistics;

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

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

#### 7.3.2 Safety inspection

Laboratory management is 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,

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.

It is good practice for the safety committee to participate in safety surveys. Regular safety inspections also serve to remind all personnel of potential hazards, ensure compliance and reinforce supervisor responsibility.

### 7.4 Safety manual

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

a) fire prevention;

b) electrical safety;

c) chemical safety;

d) radiation;

e) microbiological hazards; and

f) 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, MSDS on all chemicals and agents handled in the laboratory and other reference materials including texts and authoritative journal articles.

### 7.5 Records

#### 7.5.1 General

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

#### 7.5.2 Occupational illness, injury, and adverse incident records

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

Personnel training records shall be kept. They should include dates of safety orientation and annual updates of safety preparedness for each employee.

### 7.5.3 Risk assessment records

There shall be a formalized system of risk assessment. In addition to any formal workplace risk assessments that may be required, a safety checklist can be a satisfactory way to record and document the review programme (see 7.3).

NOTE Records of safety audits and examination of trends of incidents can provide mechanisms that help to ensure remedial actions are taken.

### 7.5.4 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 for the period of time required by national or local legislation.

## 8 Identification of hazards

Hazardous areas shall be systematically and clearly identified, and be appropriate to the hazard concerned. In certain circumstances, it may be appropriate to identify the hazardous area using both signs and physical barriers.

Specific hazardous materials to be used within the laboratory or laboratory units shall be clearly identified.

All entrances and exits to work areas shall be marked as to the hazards present within. Special attention shall be paid to fire hazards and flammable materials, and to toxic, radioactive, harmful or biologically hazardous materials. Laboratory managers are responsible for regularly reviewing and updating this hazard-identification system to ensure its relevance to the hazards known to be present. This activity shall be carried out at least annually.

Maintenance personnel who are not part of the laboratory staff, contractors and subcontractors shall be made aware of any hazards they may 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.

## 9 Reporting of incidents, injury, accidents and occupational illnesses

The laboratory shall have a programme for reporting laboratory incidents, injuries, accidents and occupational illnesses, as well as potential hazards.

Reports shall be filed for all incidents, including injuries, and shall include a detailed description of the incident, an assessment of the cause, recommendations for preventing similar incidents, and 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.

## 10 Training

The laboratory director shall ensure that worker safety training programmes are implemented for all laboratory-associated personnel, including transport and cleaning staff.

Training in safe work practices should be emphasized.

A comprehensive training programme begins with a written plan, and should include an introduction for new employees as well as periodic retraining for experienced employees. Employees shall be required to read the appropriate safety manual before beginning to work in an area. Confirmation in writing should 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.

At a minimum, a safety training programme shall address fire prevention and preparedness, chemical and radiation safety, and biological hazards and infection prevention. The curriculum should be tailored according to the employee's job description, and should include appropriate considerations for conditions such as pregnancy, immunodeficiency and physical disability. There should be a system for evaluating each employee's understanding of the information given to them.

## 11 Personnel responsibilities

### 11.1 Food, drink and like substances

Food, drink, and like substances shall be allowed only in areas designated for their preparation and consumption.

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

Refrigerators shall be appropriately labelled to indicate their intended use.

Smoking shall be prohibited in the technical work area.

### 11.2 Cosmetics, hair, beards and jewellery

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

Long hair shall be secured back. It is important to keep hair out of moving equipment. Men with beards shall observe the same precautions provided for hair.

Rings, earrings, wristwatches, bracelets, necklaces and other jewellery shall not be worn in laboratory technical areas if there is any danger of them being caught in equipment or contaminated by infectious substances or chemicals.

NOTE 1 Hand creams may be used.

NOTE 2 Disposable hair- and beard-covers may be used.

### 11.3 Immunization status

All laboratory workers should be strongly encouraged to have immunizations to prevent infections associated with organisms to which the person is likely to be exposed.

All personnel working with or handling human blood, sera, body fluids or human tissue should be offered hepatitis B vaccine. Records of immunizations should be kept in accordance with national, regional and local requirements.

The immunization programme for a given laboratory should be based upon a documented laboratory infection-risk assessment, and on advice from local public health officials. International, national or regional regulations or guidelines may apply.

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.

### 11.4 Personal property

Personal property, clothing and cosmetics shall not be placed in designated areas where contamination can occur.

Secure storage such as lockers should be provided.

### 11.5 Festive decorations

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

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

## 12 Clothing and personal protective equipment (PPE), including gloves, eye, face, foot and respiratory protection

### 12.1 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.

When not in use, *clean* protective clothing shall only be hung on hooks provided for that purpose. These hooks shall be away from radiators, steam pipes, heating instruments, and open flames. Contaminated protective clothing should be placed and transported in appropriately identified bags that prevent leakage. They should 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.

NOTE 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 worker or visitor. Other personal protective equipment, such as gloves, goggles, masks, capes and face shields may also be required in these situations.

### 12.2 Protective clothing outside the laboratory

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

### 12.3 Face and body protection

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

Aerosol-generating procedures performed on samples potentially containing microorganisms should be performed within a microbiological safety cabinet.

Approved safety glasses, facial shields or other eye and face protection shall be available to be worn when handling hazardous materials.

Contact lenses offer no protection from splashes. Additional eye protection shall be worn with contact lenses.

### 12.4 Gloves

Gloves shall 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.

Gloves shall meet comfort, fit, flexibility, grip, abrasion resistance, puncture resistance and tear resistance requirements for the type of manipulation performed, and shall adequately protect from the hazards involved. Laboratories shall provide unpowdered 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.

Gloves should be

a) inspected for leakage before wearing,

b) worn to completely cover the hands and wrists and, where appropriate, overlap the laboratory gown or coat sleeve.

c) replaced if torn, damaged, or if internal contamination is suspected, and

d) use of gloves should be task-specific, i.e. they are only to be used during contact with potentially contaminated material and are to be removed and disposed of in accordance with local safe practices when the task is completed or interrupted.

Soiled gloves shall be removed before handling reference materials, telephones, keyboards, etc.

### 12.5 Footwear

Footwear shall be comfortable, with nonslip soles. Open-toed sandals are inappropriate as laboratory footwear. Leather or synthetic, fluid-impermeable footwear is recommended. Disposable, fluid-resistant shoe covers may be worn for jobs where splashing is anticipated.

For routine work in the laboratory, flat ergonomically comfortable shoes are recommended.

NOTE 1 Special footwear (e.g. disposable or rubberized boots) may be required for specific laboratory areas including high infection containment facilities.

NOTE 2 Approved safety shoes may be required for work with bulk chemicals, during hazardous activities, or in histopathology areas where knives or other sharp instruments are regularly used.

### 12.6 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 training.

Arrangements should also be made for workplace monitoring, medical evaluation, and for respirator users' supervision to ensure the equipment is being used correctly. Respirators may require individual-fit testing. Personnel with beards cannot be fully protected by respirators.

### 12.7 Handwashing

Laboratory workers shall wash hands immediately after actual or possible contact with blood, body fluids or other contaminating materials, even if gloves have been worn.

Hands should be routinely washed after removing gloves, before and after using the toilet, before leaving the laboratory, before eating or smoking, and before and after contact with each patient.

All personnel working in or visiting the laboratory shall wash hands whenever they have been contaminated, as well as at all times prior to leaving the technical area.

Laboratories should provide alternative materials for handwashing for workers who suffer from allergies or other reactions to specific compounds contained in certain antiseptic agents. Hypoallergenic skin lotion should be provided at all wash stations.

Sinks for handwashing should not be used for disposal of blood and body fluids.

NOTE In locations where access to handwashing sinks is limited, use of alcohol-based “waterless” hand-cleansing products are an acceptable alternative to traditional handwashing.

## 12.8 Training

The laboratory shall ensure that there are personnel trained in first aid. Materials and procedures shall be provided to mitigate adverse effects and incidents occurring to people within the laboratory involving chemical, toxic or potentially infectious materials. 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 should be familiar with the procedures to be taken following needlestick injuries.

NOTE See Annex B for general and specific guidelines for management of first aid.

## 12.9 Equipment

The laboratory director shall ensure that, at a minimum, the following facilities for first-aid and emergency procedures are available within the laboratory:

a) a first aid box;

b) first aid equipment;

c) eye irrigation 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 a hospital when required.

## 12.10 Eyewash stations

Eyewash stations shall be 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. These eyewash stations shall be 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. 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.

Devices attached to the water supply should be tested each week to ensure proper functioning and to flush out stagnant water.

## 12.11 Emergency showers

Emergency showers shall be available and convenient to the location where caustic and corrosive chemicals are used.

These devices should be tested periodically for proper function. The number of such emergency showers depends on the complexity and extent of the laboratory. Comfortable water temperatures should be provided where possible. Floor drains should normally be provided in proximity to such emergency showers.

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

## 13 Good housekeeping practices

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

Work areas shall be kept tidy and uncluttered at all times.

Storage of large amounts of disposable materials that may result in obstruction and trip hazards in the workplace should be prohibited.

All equipment and work surfaces that are used for processing contaminated materials shall be cleaned and disinfected with appropriate agents at the end of each working shift and whenever spills or other contamination has occurred.

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.

Changes in housekeeping practices or materials shall be communicated with the laboratory director to ensure that unintended risks or hazards can be avoided.

Changes in laboratory practices, working habits, or materials that may result in potential hazards to housekeeping and/or maintenance staff shall similarly be communicated with the laboratory director and in writing to the managers of the housekeeping and maintenance staff.

Some incidents of spillage may 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 should be utilised (see Annex A for more information on developing action plans for spills).

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).

NOTE Appropriate personal protective equipment may be required during the cleaning procedure.

## 14 Safe work practices

### 14.1 Safe work practices with all material of biological origin

In all medical laboratories, the policies 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 exposure.

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

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. Such containers should be opened in a microbiological safety cabinet. If contamination is excessive, or the sample is considered unacceptably compromised, it should be safely discarded without being opened. The sender should be informed immediately.

Mouth pipetting shall be prohibited.

Laboratory workers shall be trained in safe handling and use of sharp instruments and devices.

Sharps, including used needles, shall not be sheared, bent, broken, recapped or resheathed by hand, or manually removed from syringes. Reviews of working practices should include the objective to reduce the use of sharps wherever possible.

Sharp objects for disposal, including needles, glass and disposable scalpels shall be placed in puncture-resistant containers immediately after use. National, regional or local regulations may apply.

Sharp containers should not be filled to more than two-thirds of their capacity before replacement. Safe disposal of the used containers and their contents should be in accordance with local guidelines. National, regional or local regulations may apply.

NOTE 2 Special conditions can apply to certain blood collection systems.

### 14.2 Special requirements for working in microbiology laboratories

These requirements should normally be applied to other medical laboratory disciplines whenever practicable.

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.

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.

Gowns may be worn at all times while working with samples, serum or cultures. Gowns should be closed at the front and neck, and have long sleeves with cuffs.

Preferably, gowns should be made of moisture-resistant materials.

Gloves shall be worn as a barrier precaution to prevent contamination of hands while handling samples and cultures. However, gloves should be removed at the completion of work to avoid contaminating the workspace. Wearing gloves shall not be considered as an alternative to thorough handwashing (see 12.7).

Hands should always be thoroughly washed when gloves are removed.

Electronic incineration devices preferably should be used for microbiological loop sterilization.

## 15 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.

Samples should be centrifuged only in safety-capped enclosures.

All samples being vortex-agitated should be contained in containers with lids.

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. Localized air extraction is essential where harmful chemical fumes may be present.

## 16 Microbiological safety cabinets, chemical safety hoods and cabinets

Where laboratory staff works with samples of Risk Groups I and II, recirculation of air from biological safety cabinets is permitted, provided the air is passed through high efficiency (HEPA) filters before being discharged. Where laboratories work with cultures that may contain microorganisms of Risk Group III or above, recycling of air shall be prohibited.

In some jurisdictions, double HEPA filters are required.

Biological safety cabinets and chemical safety hoods shall be installed and certified annually by a competent individual.

Biological safety cabinets shall be frequently monitored to ensure that they function as designed. Records shall be kept of the inspection and any functionality testing results. Proof of inspection should be indicated by a certification label displayed on the cabinet.

The location, design and type of biological safety cabinet utilized shall be appropriate to the level of risk containment required for safe working.

All biological safety cabinets shall be used in such a manner as to avoid compromising the cabinet's function.

Venting of biological safety cabinets, chemical safety hoods and cabinets shall be appropriate to the microbiological and/or chemical risk and be consistent with safety requirements.

## 17 Chemical safety

### 17.1 Measures to avoid chemical contamination

In all medical laboratories, the policies and procedures for storage, handling, use and disposal of chemicals shall always be in accordance with good chemistry laboratory practice standards.

The nature and risk of hazards concerning each product shall be marked on every stock container, in compliance with International Standards, as well as in clear, unambiguous labelling of containers of "in-use" products.

There shall be adequate control measures available for chemical, physical and fire hazards. These controls shall be routinely monitored to ensure their effectiveness. Records of the results of the monitoring process shall be maintained.

Hazardous liquids, such as acids or alkalis, shall be stored below eye level. Large containers shall be securely stored near the floor, but at a height that allows for safe ergonomic handling.

Appropriate facilities complying with national, regional or local requirements shall be provided for the safe handling, storage and use of compressed gases and cryogenic materials.

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

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.

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 12).

### 17.2 Emergency measures applicable when chemical contamination has occurred

Eyewash facilities shall be provided in all analytical areas where there is potential for eye damage due to chemical contamination.

Where the nature of the chemical hazard is such that there may be a risk of gross body contamination, drench showers shall be provided (see 12.11).

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

### 17.3 Discarded chemicals

There shall be a clear written procedure for the discarding and safe disposal of every chemical product used in the laboratory. This shall include sufficient details of the local regulatory process to enable full compliance with the mechanisms through which such materials can be safely and legally released from the laboratory's control.

## 18 Radiation safety

### 18.1 Radionuclides

The Laboratory Director shall assess the justification for, extent of, and location of proposed use before permitting work with radionuclides.

The laboratory shall keep adequate records of radionuclide acquisition, use and disposal. All radiochemicals shall be safely and securely stored.

All laboratory personnel who work with or have exposure to radionuclides shall be instructed and trained in radiation-based and associated techniques and in radiation protection, and shall comply with radiation safety policies and procedures.

The laboratory shall have written standard operating procedures and local rules appropriate and sufficient for the work.

These procedures shall include clear instructions, a summary of which shall be displayed prominently in the workplace where radionuclides may be used, detailing the actions to be taken to deal with radiation accidents and spills.

The procedures shall detail methods of safe disposal of unused radioactive materials and materials that have been mixed with or contaminated by radioactive materials.

Appropriate approved warning and prohibition signage shall be displayed.

In addition to national, regional, and local regulations, reference should be made to [11].

### 18.2 Radiation protection advisors, officers, and supervisors

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 legislative requirements, and institute appropriate measures to enable compliance with the advice received, including any required laboratory design and equipment standards.

The laboratory shall appoint a Radiation Protection Officer (RPO) who shall report to the RPA. The RPO shall have particular responsibilities for the design of the operational radiation protection programme, its implementation, and maintenance.

The Radiation Protection Officer should report managerially to the Laboratory Director and professionally to the Radiation Protection Adviser.

The laboratory shall appoint Radiation Protection Supervisors (RPSs) to supervise day-to-day work with ionizing radiation to ensure the use of good radiation practice. The RPSs report to the laboratory RPO.

Local rules shall dictate the availability, roles and responsibilities of the RPA, RPO and RPSs.

The formation of a Radiation Safety Committee is strongly recommended where this is not already a statutory requirement.

NOTE 1 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.

NOTE 2 Other jurisdictions may refer to the position of RPA by another title.

### 18.3 Workplace monitoring

A programme of systematic monitoring shall be established to ensure that comprehensive and frequent monitoring of the workplace is undertaken. Monitoring records shall be maintained.

A protocol for routine cleaning and decontamination shall be designed and adopted.

The use of radionuclides shall be regularly reviewed, work practices frequently monitored and modified as dictated by the RPA and RPO. Remedial action or procedural changes shall be recorded and held for the period of time dictated by statute or locally agreed rules.

Radioactive waste shall be labelled and held in a secure and radiation-protected store 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. Storage and disposal shall be determined by legislation and local rules.

### 18.4 UV and laser light sources (including light from high-intensity sources)

Wherever 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 should be opened only by maintenance staff qualified to service such equipment.

### 18.5 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 should 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 should be posted to warn of the effects such devices can have on people wearing pacemakers. Personnel who have pacemakers fitted should be prohibited from the immediate location of high-powered microwave and radiowave devices.

Flammable substances shall not be placed in microwave equipment.

# 19 Fire precautions

## 19.1 Construction

Architectural specifications shall be based upon the type of laboratory hazard to be contained. Primary exit routes shall be designated.

Medical laboratories within inpatient facilities should be separated from medical areas by fire resistant construction. Where flammable gases are stored, spark-proof or spark-protected lights and switches should be installed. Electrical equipment should be specially designed for use within such areas.

## 19.2 Secondary exits

Secondary exits shall be provided to ensure safe evacuation of personnel from laboratories.

Designated fire exits should open into a fire-protected area.

## 19.3 Alarm systems

Automatic smoke or heat detection and alarm systems shall be provided for every laboratory area where flammable gases or liquids are used or stored.

Alarm systems should be regularly tested to ensure their function and to familiarize all personnel with their operation.

## 19.4 Fire risk reduction strategies

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.

Flammable gases and liquids shall be used only in well-ventilated areas.

Work involving release of flammable vapours shall be conducted only in a laboratory fume hood or cupboard.

Flammable liquids and gases shall be kept away from heat and sources of ignition, including electric motors and direct sunlight.

Piped-in gas supplies require the installation of emergency shut-off valves and pipework in accordance with national, regional or local regulations.

Spill kits shall be immediately available to contain small quantities of flammable spillage.

In case of a spill, fire department assistance shall be sought immediately. National, regional and local regulations shall apply.

## 19.5 Storage of flammable materials

Containers for flammable liquids and gases shall be kept as small as possible, compatible with laboratory needs.

Containers for flammable liquids shall be kept closed except when in use.

Flammable liquids and gases shall be stored only in approved cabinets or stores. Storage should comply with prevailing national standards.

Refrigerated flammable liquids shall be stored only in “explosion-safe” nonsparking 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.

### 19.6 Fire safety training programmes

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.

### 19.7 Firefighting equipment

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.

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

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.

## 20 Emergency evacuations

An action plan for emergency evacuation shall be developed (see Annex A for more information on development of action plans). As an alternative, the plan shall take into consideration chemical, fire and microbiological emergencies. This shall include measures to be taken to leave the unoccupied building in as safe a state as possible.

All personnel, including visitors, shall be made aware of the action plan, routes of exit, and assembly points for emergency evacuation.

All personnel shall participate at least once a year in a fire drill.

## 21 Electrical equipment

Electrically operated equipment shall be designed and manufactured to comply with appropriate safety requirements. Recognized standards include the ISO/IEC 61010 series, *Safety requirements for electrical equipment for measurement, control, and laboratory use* (see Bibliography). To ensure safety, some items of equipment must be connected to back-up power supplies.

New, modified or repaired equipment shall not be put into use 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.

Users of electrical equipment shall be trained in its proper use, and shall handle it in such a way that electrical safety is not compromised.

NOTE Splash-proof or nonsparking (intrinsically safe) equipment may be required for some applications.

Users of electrical equipment shall routinely inspect the equipment for damage that could lead to electrical fault.

If conducting liquid is accidentally spilt on equipment, the latter shall be disconnected from the electrical supply and carefully dried. It shall not be reused until a competent person has approved it for use. Steps to decontaminate equipment shall be taken to reduce the risk of chemical or biological contamination exposure to the maintenance personnel (see also Clause 13, Annex A and Annex C).

Only competent persons shall be permitted to carry out work on electrical equipment and circuitry. Unauthorized work shall be forbidden.

## 22 Transport of samples

The laboratory director, or an appointee, e.g. the laboratory safety officer, shall be responsible for the provision of appropriate guidance and direction to all sites that submit samples to the laboratory.

All samples shall be transported to the laboratory in such a manner as to prevent contamination of workers, patients, or the environment.

Samples shall be transported in approved, inherently safe, leakproof containers.

Samples sent within a facility's premises shall comply with the facility's rules for safe transport. Samples sent outside the facility shall comply with prevailing regulations regarding the transport of infectious and other materials of biological origin.

Samples, cultures and other biological material transported between laboratories or other facilities shall be sent in a manner compliant with facility safety rules. Where applicable, international and national regulations pertaining to transport of dangerous materials for road, rail and ship shall apply.

Materials deemed by national or International Standards as dangerous goods intended for national or international air transport shall be packaged, labelled and documented in compliance with current national or international regulations or requirements.

## 23 Waste disposal

Laboratory waste disposal shall be managed in accordance with national, regional, or local regulations.

Laboratory waste management shall have the following objectives:

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

b) minimizing harmful effects to the environment.

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. Biological waste containers should not be filled beyond their designed capacity.

Sharps, including needles, scalpels, metal and glass, shall be discarded directly in puncture-resistant containers.

Laboratory management shall ensure that hazardous waste is handled by appropriately trained personnel using appropriate personal protective equipment.

Rubbish and laboratory waste shall not be allowed to accumulate. Filled containers shall be removed from work areas on a regular basis. They shall be held in a designated secure place, normally within the laboratory area, prior to decontamination or final disposal. Laboratory rubbish and routine paper waste that has not been contaminated with reagents or body fluids can be handled and processed as nonhazardous waste. Appropriate and safe disposal should occur at least daily.

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

Biological safety may result from processing by autoclave, or other approved technology, or by packaging in appropriate containers.

Transport of waste that has not been treated may be allowed, provided that the material is packaged and transported in a manner consistent with hazardous waste regulations to a facility for safe and appropriate disposal.

Laboratory waste that is known to be contamination-free can be handled and processed as nonhazardous waste.

# Annex A
(informative)

# Action-plan outline for implementation of this International Standard

## A.1 Introduction

This International Standard 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 International Standard, 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

### A.2.1 Step 1: Safety lead

Identify a Laboratory Safety Officer with sufficient experience to take the lead on safety issues. This individual should be given sufficient time to undertake the task. In a small laboratory, this time commitment may be minimal, but it may increase with laboratory complexity.

### A.2.2 Step 2: Identifying hazards

Working with the senior laboratory personnel, the Safety Officer should list the hazards that exist or could arise within the laboratory or result from its activities. It is important to include issues that are not those of direct laboratory origin, for example linked to the building structure or the external environment.

### A.2.3 Step 3: Risk assessment

The Safety Officer, in close conjunction with senior laboratory personnel, should assess the level of risk associated with each hazard, both inherently within the hazard itself and as a component of a group of associated hazards. Risk assessment requires evaluation of both task-specific and environmental hazards. Records should be made of the perceived level of risk, who could be affected, with what consequences, and to what degree of severity.

### A.2.4 Step 4: Prioritizing risk

As part of Step 3, possible ways to reduce the level of risk will be identified. Working with senior laboratory personnel, the Safety Officer should prioritize risks according to those requiring immediate, intermediate, or long-term risk reduction strategies. This should be based on the potential for harm, not on economic grounds, although this component cannot be ignored. 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.

### A.2.5 Step 5: Reducing risk

There can never be a total absence of risk in the medical laboratory. The aim should be to decrease risk as much as possible, taking account of all factors involved. Action Plans should 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. The actions planned and implemented are the responsibility of the senior laboratory personnel, advised and assisted by the Safety Officer. Decisions made

and actions proposed should be carefully recorded, together with supporting information as to why the action was taken.

### A.2.6 Step 6: Reviewing risk strategies

As part of risk-reduction strategies, there should be careful monitoring of action-plan implementation. 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 Safety Officer.

## 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 nonanalytical 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 International Standard 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 through B.4 assist with compliance 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 compliance 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.<br>— Handwashing sinks are used for disposal of blood/body fluids. If yes, explain. | | | | |
| 2 In instances where handwashing facilities are *not* readily available, antiseptic hand cleanser and clean towels or towelettes are available. Indicate method used. | | | | |
| 3 Handwashing is required in the following instances:<br>— if hands become contaminated with blood or body fluids;<br>— when gloves are removed; and<br>— between patient contacts.<br>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? If no, see 4 a).<br>4 a) Needles shall be recapped in the procedures listed.<br>4 b) Method for recapping is:<br>— with one-handed scoop (passive recapping);<br>— a recapping device is used; or<br>— other (describe your method). | | | | |
| 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.<br>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.<br>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. | | | | |

**Table B.1** (*continued*)

| The following work-practice/engineering controls are in place in this department | Y | N | NA | Comments/Explanations |
|---|---|---|---|---|
| 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.<br>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.<br>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.<br>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.<br>13 a) Bulk body fluids (urine, vomitus, faeces, etc.) are disposed of properly through a sanitary sewer system.<br>13 b) Containers of body fluid (pleurevacs, blood bags, suction liners, etc.) are placed in biohazard waste containers for incineration or other approved disposal.<br>13 c) Laboratory samples are disposed of in biohazard bags (autoclavable, if appropriate) in leakproof containers with tight-fitting covers.<br>13 d) Laboratory samples are autoclaved before disposal when applicable.<br>13 e) If autoclaves are used for treatment of waste, they are monitored with biological indicators on a regular basis. Please define how often.<br>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.<br>15 a) Biological safety cabinets are inspected on an annual basis. | | | | |
| 16 Written laboratory biological/infection control safety policies are readily available to employees.<br>16 a) The Laboratory or Hospital Exposure Control of Infection Plan is readily available to employees.<br>16 b) A copy of an appropriate 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 | NA | Comments/Explanations |
|---|---|---|---|---|
| 1 Disposable gloves, in appropriate sizes, are available to all at risk of exposure, for either discretionary use or as required.<br>1 a) Are gloves worn:<br>— during contact with blood or body fluids, mucous membranes or the non-intact skin of patients?<br>— when handling items or surfaces soiled with blood or body fluids?<br>— 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?<br>4 a) If face protection is needed/required, the type(s) of face protection available are as follows (indicate all that apply):<br>— mask with glasses with solid side-shields<br>— mask and goggles<br>— mask with splash shield<br>— chin-length face shield<br>List other face protection available if not listed. | | | | |
| 5 Is protective body clothing required?<br>5 a) Type(s) of protective body clothing available (indicate all that apply):<br>— clinic jackets<br>— gowns<br>— laboratory coats<br>— aprons<br>List any other protective body clothing that is available. | | | | |
| 6 Is footwear and headgear required?<br>6 a) Type(s) of footwear and headgear available are as follows (check all that apply):<br>— surgical caps/hoods<br>— shoe covers<br>— short<br>— knee-high<br>List other footwear and headgear available. | | | | |
| 7 Is reusable protective clothing being reprocessed by either of the following?:<br>— hospital laundry services<br>— outside laundry services<br>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. | | | | |

**Table B.2** (*continued*)

| The following fluid-resistant PPE is available to employees of this department free of charge | Y | N | NA | Comments/Explanations |
|---|---|---|---|---|
| 8 Is resuscitation equipment required?<br>8 a) Types of resuscitation equipment available are:<br>— mouthpieces<br>— resuscitation bag<br>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 | NA | 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.<br>2 a) Broken glass: Staff have been instructed never to pick up by hand any broken glassware that might be contaminated.<br>2 b) A brush, dust pan, forceps and/or tongs are available for picking up broken glassware.<br>2 c) Are the following procedures routinely used for spill clean-up?<br>— soak up spills with absorbent material (paper towels)<br>— decontaminate the area with an appropriate disinfectant<br>— 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.<br>4 a) Staff have been instructed to handle contaminated laundry as little as possible.<br>4 b) Staff have been instructed to place laundry directly in the standard laundry bag.<br>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:<br>— containers used to store or transport contaminated materials, including pneumatic tube carriers;<br>— containers used to store or transport regulated medical waste;<br>— refrigerators or freezers that hold potentially infectious materials. | | | | |

**Table B.3** (*continued*)

| Item | Y | N | NA | Comments/Explanations |
|---|---|---|---|---|
| 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 | NA | 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 | NA | 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 | Comments |
|---|---|---|---|
| 1 Are you familiar with the location and contents of the following items?: | | | |
| — Chemical Safety Plan | | | |
| — Chemical Safety Poster | | | |
| — Material 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:<br>— potential hazards of the chemicals?<br>— selecting the least hazardous chemicals for the procedure?<br>— ensuring that all chemical containers are properly labelled? | | | |
| **Distribution** | **Y** | **N** | **Comments** |
| 2 To reduce accidents during transport, do you:<br>— use a transport vessel or secondary container?<br>— use the least-trafficked routes?<br>— use correct PPE, when indicated? | | | |
| **Storage** | **Y** | **N** | **Comments** |
| 3 Do you<br>— understand and follow chemical storage colour coding recommendations on the container labels?<br>— store chemicals according to hazard class?<br>— avoid storing chemicals in an open area or in corridors, passages and stairs? | | | |
| 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?:<br>— weighing/preparing stock solutions;<br>— handling of concentrated acids/bases;<br>— pressurization activities;<br>— rinsing with solvents;<br>— heating/cooling chemicals;<br>— use of reactive chemicals;<br>— handling of particularly hazardous substances. | | | |
| 9 If yes, list what safety precautions you take. | | | |

**Table B.7** (*continued*)

| Particularly hazardous substances | Y | N | Comments |
|---|---|---|---|
| 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?:<br>— a designated work area has been established;<br>— containment devices are available and used;<br>— appropriate and safe waste-removal procedures are in place;<br>— appropriate authorities have been notified;<br>— appropriate and explicit signs are displayed;<br>— appropriate steps to prohibit entry of unauthorized persons into the vicinity of the hazardous substance. | | | |
| **High-risk protocols** | **Y** | **N** | **Comments** |
| 12 Are you aware that these activities require prior approval?:<br>— work with severely/extremely toxic inhalation hazards, both inside and outside of containment devices;<br>— work with highly reactive/unstable compounds. | | | |

**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?:<br>— chemical fume hood;<br>— 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 keep supplies and equipment at least 10 cm away from the hood face? | | | |
| 8 Do you maintain the sash height as low as possible? | | | |
| **Respiratory protection** | **Y** | **N** | **Comments** |
| 9 Do any procedures in the laboratory require the use of respiratory protection? | | | |
| 10 Are you currently participating in the Hospital/Laboratory Protection Programme? | | | |

**Table B.8** (*continued*)

| 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?:<br>— answering the phone;<br>— opening laboratory doors;<br>— leaving the laboratory environment. | | | |
| **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 within 30 m (100 ft) 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?:<br>— skin/eye irritation;<br>— respiratory distress or felt unwell in other ways while working with chemicals;<br>— 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? | | | |
| **Chemical spill response** | **Y** | **N** | **Comments** |
| 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?:<br>— if you experience signs or symptoms of exposure to chemicals;<br>— if you are present during a chemical spill, leak, explosion, or accidental release;<br>— if you are exposed to a chemical above its regulated level. | | | |

# Annex C
(informative)

# Decontamination, cleaning and disinfection following a spillage

## C.1 General

This annex is intended to assist in developing specific protocols for the decontamination, cleaning and disinfection of medical laboratory equipment or furnishings where accidents or spills have resulted in biological, chemical or radioactive contamination. This annex can also assist in developing suitable protocols for preparing and making equipment biologically safe before service or repair. 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 may require modification of these procedures.

## C.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 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 0,5 h to allow blood/body fluid droplets to settle before decontamination begins.

## C.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.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.6 Cleaning of the spill site

When the area where 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).

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