



BIORISK MANAGEMENT POLICY FOR MEDICAL LABORATORIES

Purpose

This document is to describe the requirements and regulation of health and safety, which **shall** be applied at Medical laboratory, to assure the safety of **health care workers, equipment, material and environment**, and protect them against chemical and Microbiological hazards. In addition to protect the dealing with medical wastes.

Scope

This policy is intended to **address bio risk management requirements for** medical laboratories with guidelines to control **biosafety and biosecurity** risks as required by Accreditation Unit

Authorship

This publication has been written by the Technical Committee, and approved by the Accreditation Director.

Official language

The text may be translated into other languages as required. The English language version remains the definitive version.

Copyright

The copyright of this text is held by **JAS-AU**. The text may not be copied for resale.

Further information

For further information about this publication, kindly contact **JAS-AU**.

This document is also available at our website where you can check updates directly.

Contents

Subject	Page
1. Introduction	4
2. Definitions	4
3. Responsibilities	4
4. Policy	4
5. References	13
6. Annex 1: Relation of risk group to Biosafety levels, practices and equipment	14
7. Annex 2: Minimum facility requirements at the four biosafety levels	15

1. Introduction

This Policy aims at setting the main **requirements** for **Biorisk management (Biosafety and Biosecurity)** followed by **health care workers** working in Medical laboratories.

The purpose of this **biorisk management** policy is to protect the life, health and **biosafety and biosecurity** of all **health care workers** as well as to eliminate the possibility of damage to the property and equipment while carrying out an efficient work schedule.

2. Definitions

2.1 Laboratory Biorisk management: System or process to control safety and security risks associated with the handling or storage and disposal of biological **OR CHEMICAL** agents and toxins in laboratories and facilities

2.2 Laboratory Biosafety [1]: Containment principles, technologies, and practices implemented to prevent unintentional exposure to pathogens and toxins, or their unintentional release.

2.3 Laboratory Biosecurity [2]: Protection, control and accountability for valuable biological materials within laboratories, in order to prevent their unauthorized access, loss, theft, misuse, diversion, or intentional release.

3. Responsibilities

It is the responsibility of **laboratory management**, and supervisory personnel (**Biorisk management officer**) to know and to follow the provisions of this Policy.

4. Policy

Biorisk management:

1. Risk Assessment

- Risk assessment requires evaluation of both task-specific and environmental hazards. Records **shall** be made of the perceived level of risk, who could be affected, with what consequences, and to what degree of severity. 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 **tool** to record and document the review program.
- Biological agents are classified into four risk groups (Biosafety levels)
 - a) Risk Group I (low individual and **low** community risk)
 - b) Risk Group II (moderate individual risk, limited community risk)
 - c) Risk Group III (high individual risk, low community risk)
 - d) Risk Group IV (high individual risk, high community risk)

*Note: Details of risk groups are mentioned in Annex1, **and Annex 2**

- All Medical **shall** be designed **and** organized for Biosafety level 2 or above (Refer to Annex 1).
- Medical laboratories dealing with Risk Groups III and IV infectious agents will need to meet additional requirements to ensure safety (Refer to Annex2).

2. Biosafety manual

- A safety manual shall be readily available in work areas as required and shall be read and signed by all **health care workers**. The manual shall be specific for the laboratory's needs including, but not limited to, the following major categories:
 - Fire prevention;
 - Electrical safety;
 - Chemical safety;
 - Radiation;
 - Microbiological hazards; and
 - Hazardous waste disposal.
- **The Biosafety** manual shall include detailed instructions for workplace evacuation and the protocol for dealing with an incident. The **Biosafety** Manual shall be reviewed and updated periodically by **biorisk management officer and/or** laboratory management.

3. **Biorisk management orientation and training**

It is the responsibility of lab management and biorisk management officer to provide orientation and training with respect to biorisk management.

4. **Biosafety program audits**

- The safety program shall be audited and reviewed periodically (by appropriately trained personnel)

5. **Biorisk management officer**

- An appropriately qualified and experienced Laboratory **Biorisk management** Officer shall be designated to assist the managers with safety issues. This person shall develop, maintain and monitor an effective laboratory safety program.

6. **Standard operating procedures (SOPs)**

- 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 periodically by the management representative responsible for the work place activity.

7. **Material safety data sheets (MSDS)**

- Technical bulletin for chemicals and agents handled in the laboratory providing detailed hazard and precautionary information.

- **MSDS shall be accessible to health care workers for all chemicals (MATERIALS) used in the laboratory.**
8. **Biorisk management check records**
- **Shall be available and maintained.** e.g. Records of decontamination.
 - **Laboratory incidents record including the incidents happened and measures taken shall be available and kept in safe place.**
 - **Internal Biorisk management audit shall be conducted periodically.**

9. **Waste management**

- Laboratory waste management shall have the following objectives:
 - a) Minimizing the hazards in handling, collecting, transporting, treating and disposing of waste.
 - b) Minimizing harmful effects to the environment.
- All samples, cultures and other biological materials no longer required shall be discarded in containers specifically designed, intended and marked for disposal of hazardous waste.
- Biological waste containers **shall** not be filled **2/3** beyond their designed capacity.
- Sharps, including needles, scalpels, metal and glass, shall be discarded directly in puncture-resistant containers **that have tight fitting covers.**
- Laboratory management shall ensure that hazardous waste is handled by appropriately trained personnel using appropriate personal protective equipment.
- Laboratory waste disposal shall be managed in accordance with local and national rules and regulations.
- Laboratory waste shall not be allowed to accumulate.
- Filled containers shall be removed from working 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 have not been contaminated with reagents or body fluids can be handled and processed as nonhazardous waste.
- Appropriate and safe disposal **shall** occur regularly in accordance with local and national rules and regulations.
- All discarded microbiology laboratory samples, cultures and contaminated wastes shall be made intrinsically biologically safe before being taken from the laboratory facility.
- **Biologically safe waste is a result from processing by autoclave, or other approved techniques.**

10. **Laboratory premises**

- No structural or engineering work shall be undertaken without the appropriate permission being given by the laboratory director or his/her nominated representative based on risk assessment.
- The laboratory **shall** be designed to ensure a clear separation of phlebotomy facilities where they are included in the laboratory area, sample reception, **laboratory management** and analytical areas.
- Each area **shall** have environmental controls and facilities, furnishings, work surfaces and floor finishes appropriate to the activity being performed there.
- These **shall** be maintained in good condition.
- Lab premises shall be clean, uncluttered and free from obstructions, with no structural defects in floor.
- Floors and stairs shall be slip-resistant.
- Work space shall be adequate for safe operation.
- Corridors and passages to the exits shall be clear of obstructions.
- Bench surfaces shall be resistant to solvents and corrosive chemicals.
- Dedicated hand washing sinks shall be fixed within all areas where biological materials are handled.
- There **shall** be an independent power support unit (UPS) provided in case of power breakdown that is checked and maintained.
- Access to laboratory areas **shall** be restricted only to authorized personnel.
- **“No smoking” signs shall be clearly displayed in all places of inside laboratory premises.**
- **Special part of the lab shall be allocated for sample collection and testing procedures of epidemic or pandemic infections. That part shall be completely separated from other parts of the lab and well equipped to achieve all biorisk management objectives.**

11. Storage facilities

- Storage facilities, shelves, etc. shall be arranged so that stores are secure against sliding, collapse or falls.
- Storage facilities shall be kept free from accumulations of rubbish, unwanted materials and objects that present hazards from tripping, fire, explosion and harborage of pests.
- Environmental conditions in storage areas shall be appropriately monitored and documented.

12. Flammable liquid storage

- Fire-risk area shall be clearly labeled.
- Light fittings inside shall be sealed to protect against ignition of vapors by sparking.
- Flammable liquids shall be stored in proper, ventilated containers that are made of non-flammable materials.
- Contents of all containers shall be correctly described on the labels.
- Appropriate fire extinguishers and/or fire blankets shall be placed outside but near to the flammable liquid store.

- “No smoking” signs shall be clearly displayed inside and outside the flammable liquid store.
- Only minimum amounts of flammable substances shall be stored in laboratory rooms.
- Flammable liquids shall be stored in properly constructed and labeled flammable storage cabinets.
- Personnel shall be trained to properly use and transport flammable liquids.

13. Fire prevention and fire protection

- There shall be a fire alarm system and local fire detection device in good working order and regularly tested.
- Fire alarm stations shall be accessible.
- All exits shall be marked by proper signs.
- All exits shall be **clear of any motion blocking decorations**, furniture or equipment and unlocked when the building is occupied and lead to an open space.
- All fire-fighting equipment and apparatus (fire extinguishers, fire blankets) shall be easily identified.
- The laboratory shall periodically, and in accordance with a predetermined schedule maintain Portable fire extinguishers.
- Portable fire extinguishers shall be maintained fully charged and in working order and kept in designated places at all times.
- If flammable liquids and gases are used in any room, the mechanical ventilation shall be sufficient to remove vapors before they reach a hazardous concentration.
- Personnel shall be trained to respond to fire emergencies.

14. Sanitation and staff facilities

- Lab premises shall be maintained in a clean, orderly and sanitary condition.
- Clean and adequate toilet (WC) and washing facilities shall be provided separately for staff.
- There shall be an accommodation (e.g. lockers) for street clothing for individual members of the staff.
- There shall be a staff room for rest.
- **Hand wash sinks:**
- **Hand wash sinks shall be designated close to exits.**
- **Hand wash sinks shall be equipped with liquid soap / appropriate disinfectant and disposable towels.**
- **Hand wash sinks shall not be used to dispose any hazardous waste.**

15. Physical conditions

15.1 Heating and ventilation

- Ambient temperature in laboratories **shall** be controlled as far as possible to a level compatible with laboratory worker comfort.
- Blinds **shall** be fitted to windows that are exposed to full sunlight.
- Local natural or mechanical ventilation is advised where unpleasant or nauseous odors could arise from certain manual processes.

- Ambient humidity and changes of air in laboratories **shall** be made compatible with laboratory worker comfort and safety.
- Air flow rates **shall** be monitored regularly to ensure adequate ventilation and **shall** be engineered to avoid dispersion of potentially infectious agents and toxic fumes **With negative air pressure**

15.2 Lighting

- General illumination shall be adequate.

15.3 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.

16. Services

- Each laboratory room shall be provided with enough sinks, water, electricity (cables, fuses, lights, pipes) and gas outlets properly maintained for safe working.
- Information technology services shall be available and secured.

17. Laboratory biosecurity

- A qualitative risk assessment shall be performed to define risks that a security system should protect against.
- Laboratory entrances shall have lockable doors.
- These door locks shall not prevent exit in an emergency.
- 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 shall be assessed and appropriate steps taken to prevent these acts from happening.

18. Compressed and liquefied gases

- Each portable gas container shall be legibly marked with its contents.
- Compressed-gas cylinders and their high-pressure and reduction valves shall be regularly inspected.
- A pressure-relief device shall be connected when a cylinder is in use.
- Protection caps shall be in place when cylinders are not in use or are being transported.
- All compressed gas cylinders shall be secured so that they cannot fall, especially in the event of natural disaster.
- Cylinders and liquid petroleum gas tanks shall be kept away from sources of heat.
- Personnel shall be trained to properly use and transport compressed and liquefied gases.

19. Electrical hazards

- The building **should** have earth wire with its technical specifications
- The flexible connecting cables of all equipment shall be as short as practicable, in good condition, and not frayed, damaged or spliced.
- Each electric socket **OR** outlet shall be used for only one appliance (no adapters **or** distributors to be used).

20. Personal protection

- **Personal Protective Equipment (PPE)** shall be provided for all staff for normal work, e.g. gowns, coveralls, aprons, gloves.
- **Open shoes are not allowed.**
- **Hair/beard shall be secured if its length may interfere with laboratory work.**
- **Eating, drinking or smoking in the laboratory are not allowed.**
- **Sniffing culture plates is not allowed.**
- **Food or beverages shall not be stored in any refrigerator that contains specimens or reagents.**
- Additional protective clothing shall be provided for work with hazardous chemicals and radioactive and carcinogenic substances, e.g. rubber aprons and gloves for chemical spillages; heat-resistant gloves for unloading autoclaves and ovens.
- Safety goggles and/or shields shall be provided when needed.
- Eye-wash tools shall be present.
- Emergency showers (drench facilities) shall be present.
- Radiation protection shall be in accordance with national and international standards, including provision of dosimeters.
- If respiratory protection is needed because of potential exposure to an infectious and harmful agent by aerosol or droplet, suitable respirators (N95 or higher) **shall** be used with adequate personnel training.

21. Health and safety of staff

There shall be an occupational health service which includes:

- First-aid boxes provided at strategic locations.
- Immunization program relevant to the work of the laboratory.
- Skin tests and/or radiological facilities that are available for staff who work with **tuberculosis** materials or other materials requiring such measures.
- Proper records maintained of illnesses and accidents.
- Warning and accident prevention signs to minimize work hazards.
- Personnel trained to follow appropriate biosafety practices at different biosafety levels.
- Laboratory staff encouragement to report all **accidents, incidents and adverse health effects related to working in the laboratory.**
- Instructions given to non-laboratory **health care** workers, e.g. domestic and clerical staff on the potential hazards of the laboratory and the material it handles.
- Awareness of all members of the staff **on the** procedures for dealing with breakage and spillage of cultures and infectious materials.
- Appropriate disinfectants are being used correctly.
- **All work surfaces shall be cleaned and decontaminated before and at the end of each work shift.**

22. Laboratory equipment

- Procedures shall be available for decontaminating equipment prior to maintenance.
- Biological safety cabinets and fume cupboards shall be regularly tested and serviced.
- Autoclaves and other pressure vessels shall be regularly inspected.
- Centrifuge buckets and rotors shall be regularly inspected and decontaminated.
- HEPA filters shall be regularly changed.
- Pipettes shall be used instead of hypodermic needles.
- Cracked and chipped glassware shall be always discarded and not reused.
- There shall be safe receptacles for broken glass.
- **Only mechanical pipetting devices shall be used for pipetting.**
- **Mouth pipetting is not allowed.**
- **Needle recapping shall be prohibited.**
- Sharps disposal containers shall be available and properly used.
- The performance of sterilizers shall be checked by the appropriate chemical, physical and biological indicators.

23. Specimen Reception and Transportation

- Specimens shall be received in a safe condition.
- Records shall be kept of incoming **specimen** materials.
- Specimens shall be unpacked in biological safety cabinets with care and attention to possible breakage and leakage (According to lab's biosafety level).
- Gloves and other protective clothing shall be worn for unpacking specimens.
- Personnel shall be trained to ship infectious substances according to current national and/or international rules and regulations.
- Discarded infectious materials shall be removed daily or more often and disposed of safely.

24. Chemicals and radioactive substances

- Incompatible chemicals shall be effectively separated when stored or handled.
- All chemicals shall be correctly labeled with names and warnings.
- Chemical hazard warning charts shall be prominently displayed.
- Spill kits shall be provided.
- Staff shall be trained to deal with spills.
- Flammable substances shall be correctly and safely stored in minimal amounts **in approved** cabinets.
- Bottle carriers shall be provided if needed.
- Radiation protection officer or appropriate reference manual shall be available for consultation.
- Staff shall be appropriately trained to safely work with radioactive materials.
- Proper records of stocks and use of radioactive substances shall be maintained.

**Many labels that give warnings and instructions for safety precautions are internationally recognized and can be found at the following websites

http://www.ehs.cornell.edu/lrs/lab_dot_labels/lab_dot_labels.cfm

<http://ehs.unc.edu/labels/bio.shtml>

<http://www.safetylabel.com/safetylabelstandards/iso-ansi-symbols.php>

4. References

- [1] Laboratory Biosafety manual, WHO, third edition, 2004.
- [2] **Biorisk management Laboratory biosecurity guidance (WHO, 2004)**
- [3] **National Biorisk Management Guidelines, 2016.**
- [4] **Laboratory General Checklist – CAP accreditation, 2007.**

[5] Mississippi State University Manual (MSU), 2008.

[6] http://www.ehs.cornell.edu/lrs/lab_dot_labels/lab_dot_labels.cfm.

[7] <http://ehs.unc.edu/labels/bio.shtml>.

[8] <http://www.safetylabel.com/safetylabelstandards/iso-ansi-symbols.php>

[9] Clinical Laboratory Safety GP17-A2; Approved Guideline—Second Edition. Volume 24 Number 13

[10] تعليمات إدارة النفايات الطبية- تعليمات رقم ٢٠٠/١

[11] الجريدة الرسمية للمملكة الأردنية الهاشمية العدد ٤٥١١ الموافق ١٦ تشرين الأول ٢٠٠١

[12] Safe Management of Wastes from Health-care Activities. WHO Second edition, 2013.

[13] Review of Health Impacts from Microbiological Hazards in Health-Care Wastes, WHO, 2004.

[14] CWA 15793:2008

Annex 1

Relation of risk group to Biosafety levels, practices and equipment

Risk Group	Biosafety Level	Laboratory Type	Laboratory Practices	Safety Equipment
1	Basic Biosafety Level 1	Basic teaching Research	Standard Microbiological Practices (SMP)	None; open bench work
2	Basic Biosafety Level 2	Diagnostic Research	SMP plus protective clothing, biohazard sign	Open bench plus BSC for potential aerosols
3	Containment Biosafety Level 3	Special Diagnostic Research	Level 2 plus special clothing, controlled access, directional airflow	BSC and/or other primary devices for all activities
4	Maximum Containment Biosafety Level 4	Dangerous Pathogens	Level 3 plus airlock entry, shower exit, special waste disposal	Class III BSC or positive pressure suits in conjunction with Class II BSCs, double-ended autoclave, filtered air

Annex2

Minimum facility requirements at the four biosafety levels.

BIOSAFETY LEVELS				
	1	2	3	4
Isolation ^a of laboratory	No	No	Yes	Yes
Room sealable for decontamination	No	No	Yes	Yes
Ventilation				
- Inward air flow	No	Desirable	Yes	Yes
- Controlled ventilating system	No	Desirable	Yes	Yes
- HEPA-filtered air exhaust	No	No	Yes/No ^b	Yes
Double-door entry	No	No	Yes	Yes
Airlock	No	No	No	Yes
Airlock with shower	No	No	No	Yes
Anteroom	No	No	Yes	-----
Anteroom with shower	No	No	Yes/No ^c	No
Effluent treatment	No	No	Yes/No ^c	Yes
Autoclave				
- on site	No	Desirable	Yes	Yes
- in lab room	No	No	Desirable	Yes
- doubled-doored	No	No	Desirable	Yes
Biological safety cabinets	No	Desirable	Yes	Yes
Personnel safety monitoring ^d	No	No	Desirable	Yes

^a Environmental and functional isolation from general traffic

^b dependent upon location of exhaust

^c dependent upon agent(s) used in the laboratory

^d Examples: window, closed-circuit TV, two-way communication