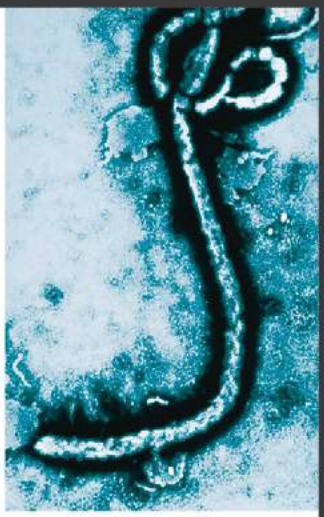

The Hashemite Kingdom of Jordan

JORDAN BIORISK MANAGEMENT GUIDELINES

Ministry of Health / Laboratory Directorate
In collaboration with EMPHNET

Ministry of Health

EMPHNET
The Eastern Mediterranean Public Health Network

JORDAN 2016

Jordan Ministry of Health / Laboratory Directorate

In collaboration with
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"EMPHENET"

JORDAN BIORISK MANAGEMENT GUIDELINES

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Acknowledgments

We would like to thank his Excellency the Minister of Health and the Eastern Mediterranean Public Health Network for facilitating the development of Jordan national biorisk management guidelines. Special thanks and appreciation to the National committee from different national institutes for their participation in revising and approving these guidelines.

Foreword

It is my great pleasure to introduce the first National Guidelines on Biorisk Management. This efficient tool highlights the reduction of risks while working with biological agents in all health institutes and research centers, particularly in laboratories handling infectious substances.

Biorisk is relatively a new concept for our region that includes two main components, Biosafety and Biosecurity. Although the concept of biosafety is known to many healthcare workers, Biosecurity is a new concept. Raising awareness of the policy makers and stakeholders will facilitate the implementation of this concept.

Implementation of biorisk management is a comprehensive issue which should be tackled as a whole package. Many health sectors are invited and responsible to adopt these guidelines in order to ensure the safety of health workers, patients and the environment.

Although the Directorate of Laboratory / Ministry of Health has conducted many training courses for laboratory technicians and recently nominated Biorisk Management coordinator, institutionalization of this concept should take place in both public and private sectors.

On this occasion, I would like to thank the team of Laboratory Directorate for their enormous efforts to adapt these guidelines, as well as the representatives from different health and academic institutions for their fruitful work to review and finalize the guidelines.

My thanks and gratitude is extended to the Eastern Mediterranean Public Health Network "EMPHNET" for their financial support to develop the guidelines.

Minister of Health

Dr. Ali Hyasat

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Preface

These guidelines were prepared as a draft by a committee depending on CWA15793 (European /Committee Workshop Agreement) manual prepared in 2008, updated 2011. Which used WHO Laboratory biosafety manual, third edition 2004,WHO/CDS/CSR/LYO/2004.11 and WHO Biorisk Management: Laboratory Biosecurity Guidance, 2006, WHO/CDS/EPR/2006.6 as the central guidance documents for biorisk management and the development of that manual.

This document tried to include all measures that can be applicable and practical to boost biorisk management activities in Jordan; taking into consideration the great variability in health institutes structures starting from research centers to small biological laboratories.
The related WHO documents, laboratory Quality Standards, states that in large laboratories a member of staff will be appointed in a full time capacity to over sea safety task, and in smaller laboratories, the safety officer may also have other responsibilities.

These guidelines were revised and approved by a different Jordanian stake-holders experts with the goal to build a consensus to amend, adopt and facilitate its implementation.
Annexes are added to facilitate implementation but not to restrict creative individual implementation.
The challenge is the development of a national policy to address this issue, with the goal to unify understanding, implementation, and consequently preparedness for inspection, certification or accreditation.

Biorisk management training activities should be included in Facilities yearly budget to address continuous education and implementation readiness. In addition, it is recommended to consider biorisk management standards implementation as a separate item in employee evaluation.
To manage and supervise biorisk management activities within the Kingdom, a Biorisk management unit was established within the laboratory directo-rate/MOH, functioning since 2011 supervised by biorisk management expert to give more enforcement to legislative situation and supervising activities and facilitating communication between different sectors.
As biorisk management would not stop at medical laboratory facilities, the implementation of these guidelines would improve biosafety and biosecurity and monitor the performance among different facilities that handle biological agents and toxins.

Introduction

Biorisk management is a fundamental issue in LQMS and it encompass two main concepts, biosafety and biosecurity. Although biosafety as a concept is known to many in the field worker, biosecurity is a new concept that needs awareness.

Implementation of BM is a comprehensive issue and not fractional. Identifying, understanding and managing biorisk management that would improve the organization's effectiveness and efficiency, and construct the base for responsibility towards workers, community and environment.

Comprehensive implementation of biorisk management to all activities within facilities would result in:-

1. Defining all going activities
2. Facilitate continual improvement and evaluation
3. Improve resources management
4. Guarantee readiness for successful emergency management

An effective management system approach should be built on the concept of continual improvement through a cycle of:

Plan: Planning, including identification of hazard and risk and establishing goals
Do: Implementing, including training and operational issues
Check: Checking, including monitoring and corrective action
Act: Reviewing, including process innovation and acting to make needed changes to management system.

Success of implementation and harvesting the value will not be in effect unless decision makers of facilities show commitment and implementation support.

Guidelines objectives:

1. Adopt biorisk management standards on national scale.

2. Facilitate biorisk management implementation in relevant organizations including health agriculture, research and industry different Facilities.

3. Support Lab Quality Management system in Facilities.

4. Consider guidelines standards in health licensing legislation.

Scope

This standard requires necessary control risks associated with the handling, storage and disposal of biological agents and toxins in laboratories and facilities.
The standard is performance-based and sets out requirements and places responsibility on organizations to demonstrate that appropriate and validated risk reduction procedures have been established and implemented.
The implementation of the guidelines will enable facilities to:

1. Achieve biorisk management awareness.
2. Control or minimize risk to acceptable levels in relation to the employees, community as well as the environment which could be directly or indirectly exposed to biological agents or toxins.
3. To support the accreditation purpose.
4. Seek training (if needed).
5. These guidelines could be directed to a life scientist working in different sectors such as health industries, institutes, academic laboratories, veterinary, and agricultural related fields.

Terms and definitions

*Please note these definitions are for the purpose of this document.

Accident: unintended event giving rise to harm.
Auditing: systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled.
Acceptable risk: A risk is deemed acceptable based upon evaluation of risk if it has been reduced to a level that your organization can tolerate, giving its occupation health and safety policy and its legal obligation.
Assurance: Systematic process of checking BM implementation through audits & inspections
Awareness: the state or condition of being aware; having knowledge and consciousness.
Biological agents: Any microorganism including those which have been genetically modified, cell cultures and endoparasites, which may be able to provoke any infection, allergy or toxicity in humans, animals or plants.
Biorisk management: System or process to control safety and security risks associated with the handling, storage and disposal of biological agents and toxins in laboratories and facilities.
Biosafety: laboratory biosafety describes the containment principles, technologies and practices that are implemented to prevent the unintentional exposure to biological agents and toxins, or their accidental release.

Biosecurity: laboratory biosecurity describes the protection, control and accountability for biological agents and toxins within laboratories, in order to prevent their loss, theft, misuse, diversion of, unauthorized access or intentional unauthorized release.
Certification: To award a certificate to (a person/ institute) attesting to the completion of a specific standard.
Competence: appropriate education, training, skills and experience.
Consequence: a result or effect, typically one that is unwelcome or unpleasant.
Corrective actions: Are steps that are taken to remove the cause or causes of an existing nonconformity or other undesirable situation.
Facility: General operational units, associated buildings and equipment used to manage biological agents and toxins.

NOTE: This may also include human and/or animal health facilities, academic facilities, environmental facilities and other units that may be dealing with biological agents.

Hazard: source with a potential for causing harm.
Improvement: Setting & achieving biorisk management goals based on internal and external feedback
Incident: event with a potential for causing harm.
Inventory: itemized record of stored supplies of biological agents or valuable biological materials.
Laboratory: A building, part of a building, or other place equipped to conduct scientific experiments tests, investigations, etc.
Likelihood: probability or chance of something to happen
Non-conformity: any deviation from relevant work standards, practices, procedures, and legal requirements of biorisk management system requirements.
Risk: The function of likelihood and consequences
Risk assessment: process of identifying, analyzing and evaluating the risk(s) arising from a hazard(s), taking into account the adequacy of any existing controls measurements.
Simulation: The imitation of the operation of a real-world process or system over time.
Stakeholder experts: are parties with an interest in subject matter experts
Threat: The likelihood for an adverse event to occur, as an expression of intention to inflict evil, injury, disruption or damage.
Toxin: Any substance, produced by a biological system, which small or moderate amounts produces an adverse effect in humans, animals or plants.

List of abbreviations

BM: Biorisk Management
BM officer: Laboratory technical officer trained for doing assessment, mitigation, and performance activities (PDCA).
CWA15793: Committee Workshop Agreement, prepared in Europe 2008.
EMRO: Eastern Mediterranean Regional Office
GLP: Good Laboratory Practices
IHR: International Health Regulations.
LQMs: Lab Quality Management System
LQS: Laboratory Quality Standards and their Implementation, 2011.
PDCA: Plan Do Check Act(Risk management consecutive activities)
PPE: Personal Protective Equipment
SOPs: Standard Operation Procedures (set of written instructions that document a routine or repetitive activity followed by an organization).
WHO: World Health Organization.

Biorisk Management System Requirement:

General Requirements

Biorisk Management System

Facilities Decision maker shall:

1. Take ultimate responsibility for the organization's biorisk management system.
2. Ensure that roles, responsibilities and authorities related to biorisk management are defined and designated.
3. Assure maintenance and improvement of the system
4. Ensuring the availability of resources to run the system
5. In smaller organizations, one individual may hold more than one role described in this guidelines.

Personnel

Biorisk management national coordinator responsible for:
(Details described in Annex one)
1. Facilitate establishing and implementing of biorisk management in public health sector.
2. Facilitate establishing and implementing of biorisk management in private health sector in accordance with private laboratory legislations.
3. Facilitate communication with WHO/EMRO office regarding biorisk management updating.
4. Facilitate exchange of biorisk management expertise between different Facilities s.

A designated biorisk management officer responsible for:
(Details described in Annex two)

1. Establishing, implementing, and maintaining risk assessment system in accordance with this guidelines.
2. Specify control measures needed.
3. Design checking system
4. Obtain approval of decision maker for assessment, control, and checking system.

Continual improvement

Facilities shall continually improve the effectiveness of the biorisk management system through the use and update of the:
a. Policy
b. Objectives
c. Risk assessment
d. Corrective and preventive actions
e. Self-audit program
f. Audit results
g. Analysis of data
h. Management review.

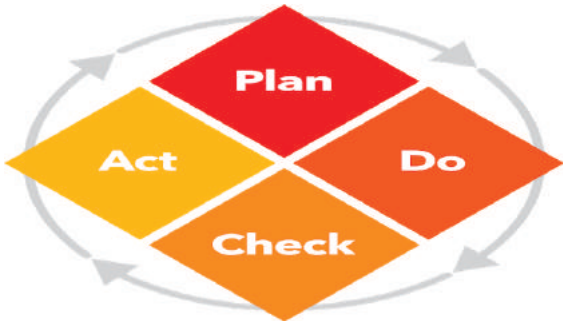
The organization shall develop a plan for continual improvement, implement it and follow-up.

Biorisk Management Policy

Facilities top management shall develop, authorize and sign a policy concerning the management of biorisk (biosafety and laboratory biosecurity).

The policy shall be appropriate to the nature and scale of the risk associated with the facility and associated activities, periodically reviewed and commit to:

a. Considering effective biorisk management as a priority.
b. Protecting staff, contractors, visitors, community and environment from biological agent and toxins that are stored or handled within the facility.
c. Reducing the risk of intentional and unintentional release of, or exposure to biological agents and toxins.
d. Complying with all legal requirements applicable to the biological agents at the national and international levels.



Planning For Hazard Identification, Risk Assessment And Control

Risk assessment timing and scope

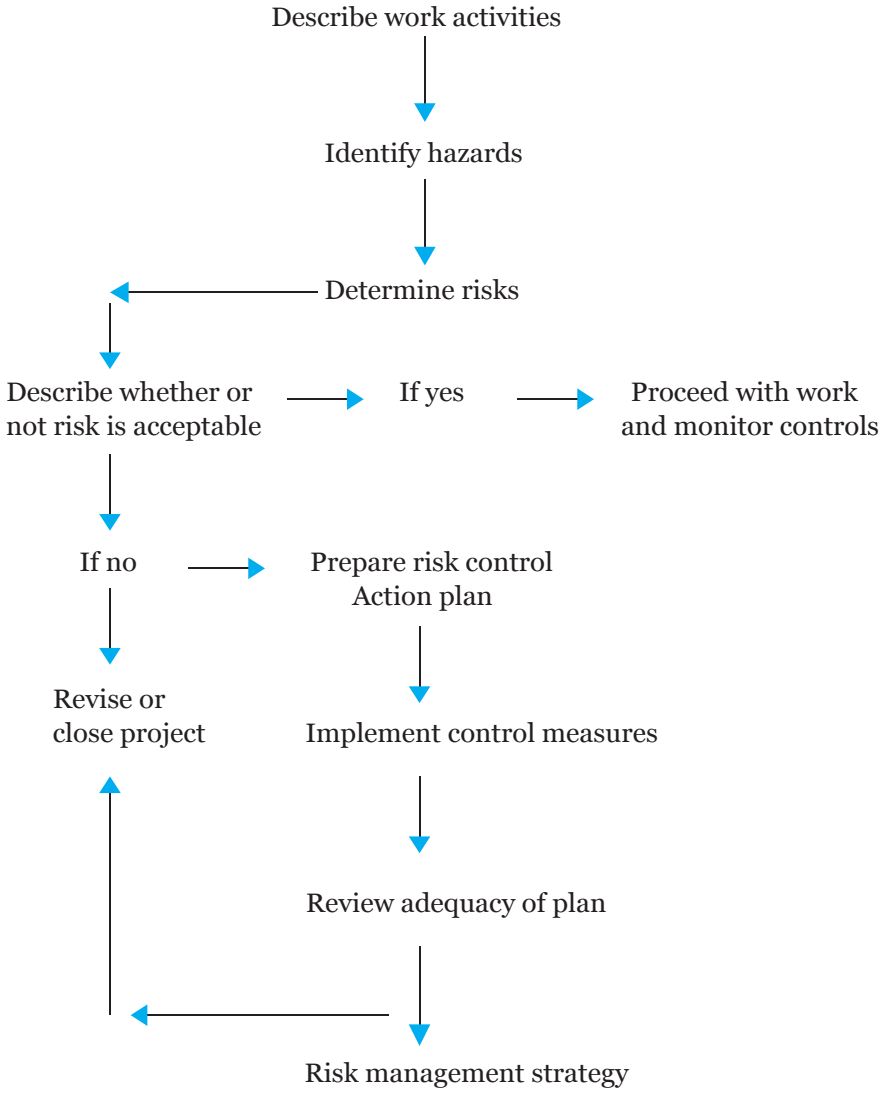
1. A proactive and reactive risk assessment is done with respect to each facility scope.
2. Assessment activity is unique to each individual facility
3. It must be done by a trained technical officer, with aid from internal or external experts if needed.

A new risk assessment or review of an existing one should be considered when:

• Commencement of new work or changes to the program of work including the introduction of new biological agents or alterations to work flow or volume.
• New construction / modifications to laboratories, design and equipment or its operation.
• Introduction of altered and unplanned staffing arrangements (including contractors, visitors and other non-core personnel).
• Significant alterations to Standard Operating Procedures (SOPs) or working practices (e.g. disinfection / waste management methodologies, PPE provision / usage entry / exit protocols, etc.).
• When unexpected events that may have relevance for the management of biorisk are observed.
• When actual or potential non-conformity with internal / external rules and regulations is identified (e.g. introduction of new legislation or major accident exposure).
• When considering emergency response and contingency planning requirements.
• As part of the existing management system review process (e.g. annually or at another appropriate and predetermined frequency).

Facilities decision maker shall ensure that a risk assessment system is established, implemented and maintained in accordance with this guidelines and that the performance of the risk management system is supervised by the BM officer.

The organization decision maker shall identify resource requirements.



Hazard Identification

An inventory of the hazards associated with proposed work shall be identified and documented by BM officer.

The first stage in the risk management process is to identify all hazards that are relevant for biorisk (in this case the principal hazard is most likely to be a biological agent or toxin, but others will include chemicals and asphyxiating gases such as nitrogen). It is useful to involve the whole work team in this process and to use inputs from organizational experts on safety and risk management.

The essence of a hazard is that it has the potential for causing harm, regardless of how likely or unlikely such an occurrence might be.

A hazard identification should use information including:
a) Group experience and knowledge.
b) External or specialized expertise not found in the facility.
c) Results of previous assessments.
d) Surveys of previous accidents/incidents.
e) Hazardous materials data.
f) Information on hazardous organisms.
g) Guidelines and codes of practice.
h) Facility drawings.
i) SOPs, manuals, etc.
j) Process maps.

Note: Unless hazards are identified effectively, it is not possible to assess the risk associated with the facility and associated activities.

Example of an inventory table

Product/ Hazard	Vendor	Required Initials	Date Ordered Initials	Date Received Initials	Quantity	Storage Area
	N/A					

Risk Assessment

Assessments can be qualitative, semi-quantitative or quantitative, and a method suitable to the situation should be identified and followed. Reference biological agents and toxins data sheets (e.g. from risk grouping descriptions, material safety data sheets etc.) should be used in risk assessment. Annex three has the "Basis for the classification of biohazardous agents by risk group" available for convenience.

BM officer risk assessment should:

a) Categorize risks.
b) Identify those which need to be eliminated or controlled.
c) Describe likelihood and consequence.
d) Define acceptability of risk levels.
e) Comply with legal regulatory requirements national and international.

Note:

1. Unless risk assessment is comprehensive, control measures will never be sufficient and exposure to risk consequences will stay.
2. Suggested lab assessment sheet (Annex four could be used as a templet)

Risk Management

Health institute decision makershall:

Ensure that suitable methodologies for assessing, recording, controlling, implementing and maintaining risks identified by observing:

a) Who is responsible and accountable for doing risk assessment (biorisk officer)
b) What resources are to be utilized (e.g. people, budget).
c) Timetable for implementation.
d) Details of the mechanism and frequency of review in compliance with the plan.

Biorisk control measures:

Describe the procedures and measures needed to prevent all biorisks identified, with the goal to reach acceptability of risk levels.

Using the results from your risk assessment:

1. Identify different risk mitigation measures as much as you can (safety & security)
2. Categorize risk mitigation measures as:
   - Elimination or substitution
   - Engineering control

- Administrative control
- Practice and procedures
- PPE

3. Prioritize them according to effectiveness and reliability at your facility.

Implementation And Operation

Facilities shall identify those operations and activities that are associated with possible biological risk and where control measures shall be applied.
The facilities shall plan these activities, including maintenance, and ensure that they are carried out under specified conditions.

Security Management

Ensure that no individual holds critical knowledge regarding the safe and secure operation of the facility that is not available to others in the event of their departure or unavailability.

Security officer

1. Someone with an in-depth knowledge of laboratory and facility security, who should communicate with other personnel (e.g., biorisk management officer)
2. Implement effective and proportionate laboratory biosecurity measures, based on the biological risk.
3. Providing input into risk assessment and management from a security perspective.

Note: BM officer can carry this task, unless somebody assigned specifically for it as could be in advanced health institutes.

Physical security

Facilities shall ensure that the controls for the physical security of cultures, specimens, samples and potentially contaminated materials or waste determined as part of the risk assessment process are implemented and maintained.

In planning and conducting security risk assessments the organization should consider:

a) Theft or diversion of biological agents and toxins or related equipment, documents or data.
b) Labor issues and disputes.
c) Emergencies (i.e., earthquake, flood, tornado, etc.)
d) Workplace violence.
e) Screening and isolation of suspect packages.
f) Acts of terrorism.

Information security

Facilities shall have a policy and procedure in place to identify sensitive information; a review and approval process shall be used to control access to such information.

Procedures addressing information security should consider:

a) Secure storage of all sensitive written records and data, including electronic records and electronic signatures.
b) Computer security including robust internet firewalls and encryption protocols.
c) Strict policies regarding PC's, laptop computers, storage media, cameras, etc. entering or leaving the facility.
d) Thorough destruction of paper files to be discarded and complete erasure of unwanted electronic files.

Personnel training and competence

Training

Facilities shall ensure that requirements and procedures for biorisk-related training of personnel are identified, established and maintained. Training should include raising personnel awareness of biorisk issues including the relevance of human factors in biorisk management.

Procedures should address:

- Definition of biorisk training needs.
- Provision of required biorisk training.
- Determination of effectiveness of biorisk training.
- Provision of refresher biorisk training.
- Restrictions on personnel to ensure they do not perform tasks for which they are not trained.
- Maintenance of adequate records.

Competence levels should be judged on:

- Appropriate education (Higher certification) upon recruitment.
- Training and experience. (Training certification).
- Trained personnel should conduct activities within the facility under close supervisionuntil competency has been demonstrated.
- Records verifying that staff members have attained and demonstrated those levels of competency.
- Restrictions on personnel who have not demonstrated competence.

Consultation and communication

For the sake of Biorisk management system competence, the facility should implement communication mechanisms to ensure that relevant information with the potential to affect employees, community and environment is defined and delivered to Biorisk management focal point.
This activity could be achieved through:

a) Documented employee involvement and consultation arrangements.
b) Local, national and international governmental organizations.
c) Relevant regulatory agencies.
d) Certifiers.
e) Emergency services and health care providers.
f) Contractors and suppliers
(e.g. cleaners, maintenance providers, security personnel).
g) Local community representatives
(e.g. through a community liaison committee).

Operational control

The facilities shall have a systemic process of checking BM implementation through audits and inspections.
Examples may include:
a. Daily inspection checklists (Annex fivecould be used as a templet)
b. Accidental /Incidental reports (Annex sixcould be used as a templet)
c. Time allocated revision

General safety

Facilities should adopt:

a) A preventive and proactive approach to managing sources of risk
b) Address the implications for biorisk in the event of an accident / incident resulting from such sources.
c) Measures should be identified and implemented to detect, mitigate and respond to emergencies.

Issues addressed should include but are not limited to:
a) General laboratory safety.
b) Fire safety.
c) Electrical safety.
d) Radiation safety.
e) Chemical safety.
f) Use of gasses (including risk of asphyxiation).

g) Hot work and cold work.
h) Equipment under pressure.
i) Laboratory animal care and use (vet.labs).
j) General housekeeping, including storage requirements and tidiness.

Biological agents and toxin inventory and information

The inventory process should be based on risk and include:
a) Identifying all biological agents and toxins held, including cultures, specimens and other sources (e.g. infected tissues/ samples or animals).
b) Restricting access to biological agents and toxins to authorized individuals with a demonstrable legitimate need.
c) Implementing effective physical security measures according to risk (e.g. locks, alarms, access controls, etc.)
d) Developing and maintaining a reliable sample identification system.
e) Segregating and storing biological agents and toxins according to risk.
f) Determining what materials should be controlled (e.g. seed stocks, working stocks, infected animals) and what level of information should be captured in the inventory for those materials.
g) Chain of custody.

Inventory information should include:
a) The name(s) of and contact information for the individuals(s) responsible for the material and details of other personnel with access to the materials or immediate area based on the level of the risk.
b) Restricted access to the detailed inventory records to those individuals whose work requires access to that information.
c) Identification numbers and other relevant identifiers.
d) Records of quantities / volumes of biological agents and toxins at an appropriate level and based on risk (i.e. for certain biological agents, location and responsible individual may be adequate while for others more detail may be necessary).
e) Records of materials consumed, destroyed or removed from the facility where appropriate.
f) Inventories shall be documented as a soft and/or hard copy

Requests for biological material and/or toxins
a) Originate from legitimate facilities and individuals.
b) Brought into the facility or sent elsewhere if authorized by those responsible for the facility.
c) Shipment tracking and verification of receipt are important considerations.

Work program, planning and capacity

Facilities work program, planning and capacity should include the following:

a) The nature of the activities authorized to be conducted in the facility and their definitions (e.g. diagnostics, research, small scale / large scale, etc.)
b) All activities associated with the work program should be specified and supported by formal SOPs and approved by health institute.
c) The organization shall establish criteria for work that requires prior approval.
d) It shall ensure there is sufficient resource capacity and capability to manage workflow, whether planned or unplanned.

Change management

The organization shall ensure that all changes associated with the design, operation and maintenance of the facility are subject to a defined and documented change management process.

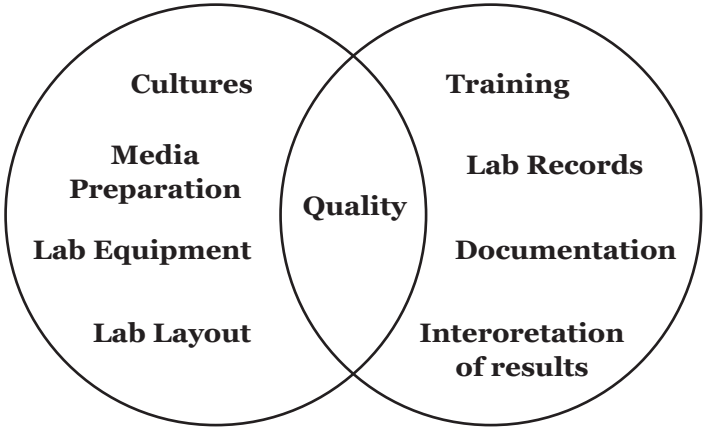
Examples of changes that should be subject to the change management process:

a) Modifications to buildings and equipment or their operation, which may or would have an effect on biorisk.
b) Introduction of altered staffing arrangements (such as temporary presence of on-site contractors or students, temporary reassignments of personnel).
c) Changes to the program of work, including alterations to work flow or volume which may or would have an effect on biorisk.
d) Alterations to SOPs, including significant changes in materials or reagents.
e) Modifications to entry / exit protocols.
f) Modifications to personnel policies and visitor protocols.
g) Modifications to disinfection and other waste management methodologies.
Changes associated with PPE provision and usage.

Work practices, decontamination and personnel protection

Work practices might include confined lab, facility and environment.Good Laboratory Practices should be adopted in each situation.

Good Laboratory Practices:



The organization shall ensure that all personnel handling biological agents and toxins are competent in Good Laboratory Practices.

Procedures should address risks associated with but not limited to the following:

a) Centrifugation.
b) Control of needles and sharps.
c) Correct use of vacuum pumps.
d) Culture, purification and storage techniques.
e) Minimization /containment of aerosols.
f) Pipetting
g) Sonication and other mechanical forms of cell / tissue disruption.
h) Animal handling
i) Use of biological safety cabinets.
j) Use of disinfectants, including spill control, routine decontamination, hand washing and showering.

Inactivation of biological agents and toxins

The organization shall ensure that all contaminated or potentially contaminated waste items have been identified and documented (including those that may result from an emergency), and that effective procedures are put in place to devise effective decontamination and other appropriate treatments.

Sources of contamination that should be considered include but not limited to:

a) Personnel clothing and PPE.
b) Glassware.
c) Equipment.
d) Cultures and associated materials.
e) Spill clean-up materials and equipment.
f) Possibly infectious microorganisms and toxins and contaminated materials.
g) Paper and plastic waste.
h) Needles, syringes and sharps.
i) Waste water, including that from sinks and showers.
j) Air.
k) Filters and air handling systems.
l) Discarded equipment used in the facility.
m) Animals exposed to laboratory biological agents or toxins.
n) Animal carcasses and bedding.
o) Facilities.

Note: All potential waste streams and other sources of contamination should be identified and documented.

Waste Management

The definition of medical waste can be referred to the Jordanian Medical Waste instruction.

Facilities shall establish and maintain an appropriate waste management policy for biological agents and toxins. Facilities should have a validated procedure for the inactivation of biological agents and toxins waste products. More information can be found in regards to the national medical waste management legislation, issued in the Gazette, refer to pages 4545 to 4568.

The following elements should be considered for a waste management policy:

a) Ensure program is in place to minimize the waste production.
b) Ensure effective waste audit trails are in place and documented.
c) Provide adequate facilities and procedures for the storage of waste (including short term storage).
d) Ensure methods are available for effective segregation and decontamination of mixed waste (e.g., infected animals that have received radioactive materials)
e) Ensure appropriate packaging material is used to contain the waste and to maintain its integrity during storage and transportation.

Personal Protective Equipment (PPE)

The organization shall ensure that PPE needs are identified and suitable equipment is specified, made available, used and maintained appropriately within the facility. The personnel in the facility should have easy access to PPE. Protective equipment should be used in conjunction with, but never as a substitute for, reasonable and appropriate administrative and engineering controls. PPE should be used in accordance with established standards and manufacturers specifications. PPE should be made available by the employer at no cost to the employee. Below PPE examples can be found:

Measures in place should include:

a) Ensuring adequate information is used in selecting PP
(e.g. risk assessments, review and analysis of tasks, employee feedback, etc.)
b) Ensuring all personnel who have to use PPE (including scientific staff, visitors and contractors) are identified and supplied with correct fitting equipment and clothing.
c) Explicitly addressing selection and use of PPE in SOPs, training and competency assessments.
d) Defining and conducting an appropriate program to ensure that routine checks and maintenance of PPE are defined and carried out.
e) Defining and addressing the need for and provision of replacement and spare PPE.
f) Identifying and controlling the hazards associated with PPE itself
(e.g. impaired dexterity or visibility).
g) Providing adequate PPE for use during both normal and emergency working conditions.
h) Ensuring procedures are in place for the cleaning and if appropriate the validated decontamination of used PPE including the safe storage prior to decontamination.

Worker health program

Health surveillance program shall be determined by a defined health hazard identification and risk assessment process. Personnel considered to have significant risk of exposure should be identified and their healthcare needs assessed. The immune status of the individual should be considered and periodic checks as appropriate to work conditions should be established.

For vaccination programs for personnel refer to Annex seven
Facilities shall ensure that a vaccination policy be defined and implemented, and that access to laboratories or work is controlled for individuals until they comply with the policy.
Measures should be implemented to identify non-responders to vaccination when needed (depending on the response rate of the vaccine) and a policy should be in place to address these individuals. Individuals considered unfit for work in the facility on health grounds should be identified and prevented from accessing areas where there are risks of exposure. Areas requiring vaccinations to enter should be posted.

Vaccination should in no way mean that other controls such as the use of Good Laboratory Practices or use of PPE can be relaxed.

Behavioral factors and control of workers;
Facilities shall establish and maintain a program to address risk associated with human behavior, including the management of how workers interact with the facility and its equipment.

Personnel Reliability

Measures should be set in place to address:
a) Human reliability and behavioral safety, including adherence to procedures.
b) Communication, consultation and feedback.
c) Conflict management and resolution.
d) Empowerment, including authority to stop work if potentially unsafe or unsecure conditions are identified.
e) Avoidance of “blame culture”, including willingness to report accidents, incidents or unsafe conditions/behaviors, and protection of workers who do so.
f) Ergonomics, including equipment and work practice design to take account of individual needs.
g) Respect for individual privacy and dignity.

Contractors, visitors and suppliers:

Security and safety consideration for non-core personnel (e.g. contractors, visitors, students, etc.)

Exclusion:

Facilities shall ensure that measures are set in place for the removal and exclusion of personnel (both temporary and, if appropriate, permanent) from the facility where deemed necessary through risk assessment.

Infrastructure and operational management

Facilities shall ensure that equipment and processes are designed and run in a safe and secure way with respect to biorisk management. The design process shall identify and incorporate all relevant legislative requirements, together with information from recognized standards, guidelines, industry good practices and facility-specific risk assessments.

Maintenance, control, calibration, certification, and validation

Facilities shall establish and maintain documented procedures to ensure equipment that may impact biorisk be identified, purchased, maintained, calibrated, certified or validated in a manner consistent with the intent and requirements of the biorisk management program.

Control of supplies

Facilities shall ensure suppliers are evaluated and selected based on their ability to provide products / services that meet the requirements of this standard. Criteria for selection, evaluation and re-evaluation shall be established. Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained.

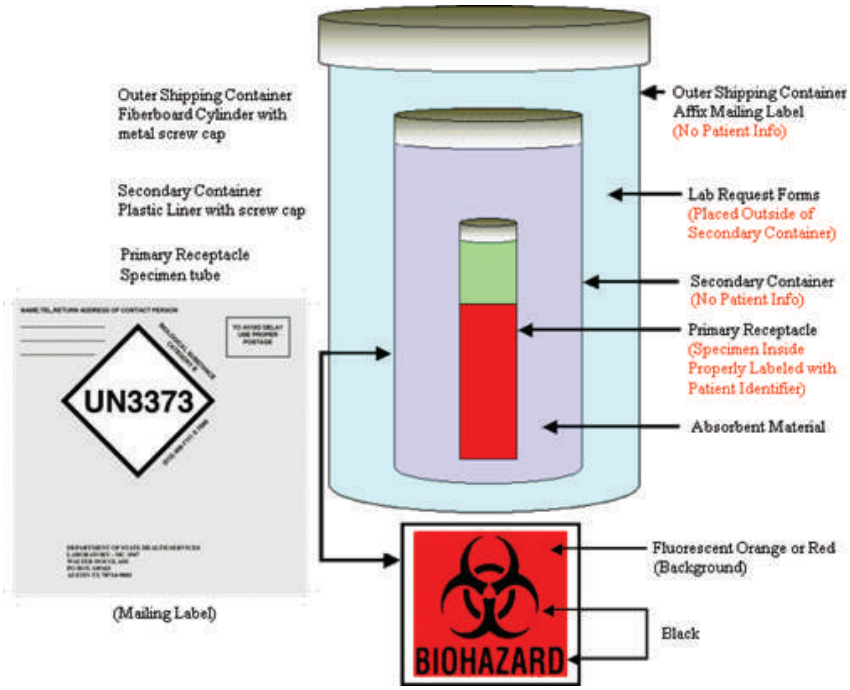
Transport of biological agents and toxins

National Transportation Bags

Facilities shall ensure that procedures for the safe and secure transport of cultures, specimens, samples and contaminated and potentially contaminated materials are established and maintained in accordance with national legal requirements for the transport of dangerous goods. National transportation bags can be used as an asset in transportation of samples. Annex eight has the National Transportation Legislation Act for reference.

In planning and conducting transport activities the organization should consider:

a) Ensuring transport requirements are identified and implemented, including legal requirements and national and international guidelines.
b) Ensuring adequate packaging systems, materials, labels, PPE and documentation are available and used as part of the transportation process. Please note: below International packaging example is shown, in the case that samples need to be transported externally.
c) Selecting a reliable, trustworthy carrier that is qualified to handle the package safely and securely.
d) Whether a request for biological agents and toxins or material that may contain viable biological agents and toxins is being made by an approved facility for a legitimate reason, and equivalent controls are applied to importation of material to the facility.
e) The need is identified for formal documented transfer forms signed by the responsible management representative authorizing movement of materials.
f) Document control that allows traceability of material movements.
g) Identifying and implementing adequate and proportionate emergency response and contingency plans associated with transportation, including adequate precautions for handling suspicious packages, quarantine areas and appropriate explosive stand-off.



International triple packaging

Emergency response and contingency

Facilities shall ensure that in the event of an emergency, adequate contingency measures shall be in place to ensure the safety and security of continued operations.

Emergency plans

Facilities shall ensure that biorisk are taken into account when preparing and implementing emergency plans.

The organization shall also ensure that control measures in place can be demonstrated as being reasonable and proportionate to the scale and nature of the emergency.

Emergency plans shall be effectively communicated to all employees and relevant third parties, and tested, with the intention that everyone is aware of their obligations.

Emergency exercises and simulations

Facilities shall ensure that structured and realistic emergency exercises and simulations, including security drills are conducted at regular intervals, based on risk, to test the plans, prepare personnel, and learn from any good practices or deficiencies identified.

NOTE: Exercises and simulations should be conducted in order to provide an assurance that plans are effective and to learn from any lessons that arise.

Checking and corrective action

Performance measurement and analysis of data

Facilities shall ensure that appropriate data are determined, collected and analyzed to assess the suitability and effectiveness of the biorisk management system and to evaluate where continual improvement of the system can be made.

NOTE: The analysis should include data generated as a result of monitoring, measurement, audits, analysis,and any other resources.

Records, document and data control

Facilities shall have a procedure to ensure that records, documents and data are established, controlled and maintained to provide evidence of conformity to the requirements of this standard and that they remain legible, readily identifiable and retrievable.

NOTE: Where appropriate, documents should be identified and controlled based upon the nature of the work and need for record keeping.

Controlled documents may include:

a) Risk assessments(safety and security), standard operating procedures (SOPs) and manuals.
b) Job hazard analyses and charts of authority.
c) Design records and commissioning/test plans, maintenance plans and records and all associated data.
d) Audit and inspection checklists.
e) Training records.
f) Containment equipment certifications.

Inventory monitoring and control

Facilities shall ensure that a review of the inventory is conducted at predetermined intervals based on risk and at a level and frequency whereby materials can be accounted for in an appropriate manner.

Facilities shall ensure that the measures are put in place to minimize the quantities of biological agents and toxins that make up the inventory.

NOTE: Facilities should demonstrate proactive measures towards the reduction of risk through elimination, substitution or minimization of volumes / quantities of biological agents and toxins used, and the number of manipulations conducted.

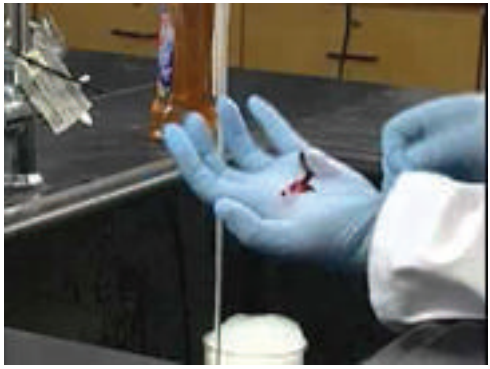
Accident and incident investigation, non-conformity, corrective and preventive actions

Accident/ incident investigation

Facilities shall establish and maintain documented procedures to define, record, analyze and learn from accidents and incidents involving biological agents and toxins.

As a minimum, the accident / incident investigation process should include:

a) Identifying those responsible for maintaining the accident/incident reporting system.
b) Defining what constitutes an accident / incident, and what triggers recording and reporting.
c) Specifying required documentation to support the system.
d) Identifying the reports that will be generated, their frequency and distribution.
e) Ensuring analysis of trends.
f) Identifying root causes using individuals trained in investigation techniques.
g) Providing feedback at regular intervals and action tracking mechanisms to ensure that lessons learned result in action to avoid the repeat of such events and / or minimize their potential impact.
h) Identifying where it may be appropriate or necessary, for security professionals may be required to coordinate with law enforcement.



An example of laboratory accident can be found above.

Corrective/ preventive action

Facilities shall ensure action is taken to eliminate the causes of non-conformities with the requirements of this guidelines in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered.

NOTE: A procedure should be established to define requirements for:
a) Reviewing the non-conformities.
b) Determining the cause of non-conformities.
c) Evaluating the need for action to ensure that non-conformities do not recur.
d) Determining and implementing action needed.
e) Recording results of action taken.
f) Reviewing corrective actions taken.

Inspection and audit

Facilities shall ensure that a program of inspection and audit is conducted which is appropriate to the risk associated with the facility at planned intervals.
Note: Recommendation preferred annually

Biorisk Management Review

Top management shall review the organization's biorisk management system at planned intervals, to ensure its continuing suitability, adequacy and effectiveness.

The review input should include information on:

a) Results of audits.
b) Compliance to SOPs and work instructions.
c) Status of risk assessment activities.
d) Status of preventive and corrective actions.
e) Follow-up actions from previous management reviews.
f) Changes that could affect the system.
g) Recommendations for improvement.
h) Results of accident / incident investigations.

The review output should include decisions and actions related to:

1. Improvement of the effectiveness of the biorisk management system.
2. Improvement related to the requirements and risk assessments.
3. Resource needs.

Bibliography

• CWA15793 (European/Committee Workshop Agreement) manual prepared in 2011 -2008.

• WHO Laboratory biosafety manual, third edition, 2004, WHO/CDS/CSR/LYO/2004.11

• WHO Biorisk Management: Laboratory Biosecurity Guidance, 2006,WHO/CDS/EPR/2006.6

• Ministry of Health Jordan- Lab directorate / Biorisk Management Unit / Documents (Checklists)

• Biorisk management advanced training program/ Biorisk mitigation control/page 4 / WHO

• Sandia National Laboratories

• OHSAS 18001 Health & Safety Standards

• Official Newspaper /Hashemite Kingdom of Jordan

Annex One: Biorisk Management Coordinator Job Description

الوصف الوظيفي / وزارة الصحة

المسمى الوظيفي :	منسق ادارة المخاطر الحيوية Biorisk management coordinator
مسؤول أمـــــام:	مدير مديرية المختبرات
مسؤول عـــــن :	تطبيق تعليمات إدارة المخاطر الحيوية في المنشأه الصحية او مختبرات وزارة الصحة .
المؤهلات العلمية:	درجة البكالوريوس في التقنية الطبية او ما يعادلها على الاقل وحاصل على تصريح مزاولة مهنة فني او اختصاصي مختبرات طبية الحيوية.
الخبرة العملية المتخصصة :	خبرة لا تقل عن ثلاث سنوات في مجال التحاليل المخبرية وشارك في دورة تدريبية لإعداد وتأهيل مدربين في مجال إدارة المخاطر الحيوية.
المهارات والقدرات والصفات للشخصية والمهنية :	١ : إجادة اللغة العربية كتابة وقراءة. ٢ : إجادة اللغة الانجليزية كتابة وقراءة. ٣ : القدرة على استخدام الحاسوب. ٤ : امتلاك مهارات شفوية وتحريرية في الاتصال. ٥ : القدرة على تنظيم العمل . ٦ : العمل بروح الفريق. ٧ : على دراية بالقوانين والتعليمات التي تحكم العمل. ٨ : مقدرة على اتخاذ القرارات التي تسهم في رفع الأداء وتطوير العمل . ٩ : المحافظة على خصوصية المهنة والتقيد بالقيم الأخلاقية والاجتماعية السائدة .

الوصف العام للوظيفة	العمل على تطبيق السلامة الحيوية والأمان الحيوي في مختبرات وزارة الصحة وتنسيق الجهود على المستوى الوطني والتواصل مع المؤسسات الدولية في هذا المجال .
المهام والمسؤوليـــــات	١- وضع سياسة التعامل مع المخاطر الحيوية في مختبرات وزارة الصحة. ٢- عمل برامج تدريبية لضباط ارتباط المخاطر الحيوية في مختبرات وزارة الصحة. ٣- الإشراف على تنفيذ متطلبات التعامل مع المخاطر الحيوية في مختبرات وزارة الصحة. ٤- كتابة تقارير شهرية وسنوية حول مدى تطبيق التعامل مع الـ الحيوية ومتطلبات تحسينها. ٥- إنشاء وتوحيد السجلات والتعليمات الخاصة بمتابعة المخاطر الحيوية على مستوى مختبرات الوزارة. ٦- متابعة المراقبة الصحية للعاملين في مختبرات وزارة الصحة وتوفير المطاعيم ومستلزمات التطبيق السليم للمخاطر الحيوية. ٧- التنسيق مع ضباط ارتباط إدارة المخاطر الحيوية في المؤسسات الصحية في المملكة. ٨- التواصل مع منظمة الصحة العالمية والمنظمات الدولية ذات العلاقة لتطوير المعايير الدولية وما يستجد في مجال إدارة المخاطر الحيوية. ٩- التواصل والتنسيق مع وحدة إدارة الأزمات وقسم ضبط العدوى في الوزارة فيما يخص إدارة السلامة الحيوية والأمان الحيوي. ١٠-العمل على نشر الوعي في التعامل مع المخاطر الحيوية بين الكوادر العاملة في المختبرات في المملكة.

يمكن تعديل هذا النموذج بناءا على احتياجات مختلف المؤسسات وطبيعة العمل فيها

Annex Two: Biorisk Management Officer Job Description

الوصف الوظيفي / وزارة الصحة

المسمى الوظيفي :	ضابط إرتباط المخاطر الحيوية في المختبرات Lab Biorisk management Officer
مسؤول أمـــــــام:	مدير المؤسسة الصحية
مسؤول عـــــــن :	تطبيق تعليمات إدارة المخاطر الحيوية في مختبر المؤسسة الصحية.
المؤهلات العلمية:	درجة البكالوريوس أو دبلوم في التحاليل الطبية وحاصل على مزاولة مهنة.
الخبرة العملية المتخصصة :	خبرة لا تقل عن ثلاث سنوات في مجال التحاليل المخبرية وشارك في دورة تدريبية في مجال إدارة المخاطر الحيوية.
المهارات والقدرات والصفات للشخصية والمهنية	١ : الإلمام باللغة العربية كتابة وقراءة. ٢ : الإلمام باللغة الانجليزية كتابة وقراءة. ٣ : القدرة على استخدام الحاسوب. ٤ : امتلاك مهارات شفوية وتحريرية في الاتصال. ٥ : القدرة على تنظيم العمل . ٦ : العمل بروح الفريق. ٧ : على دراية بالقوانين والتعليمات التي تحكم العمل. ٨ : مقدرة على اتخاذ القرارات التي تسهم في رفع الأداء وتطوير العمل ٩ : المحافظة على خصوصية المهنة والتقيد بالقيم الأخلاقية والاجتماعية السائدة .

الوصف العام للوظيفة	العمل على تطبيق متطلبات السلامة الحيوية والأمن الحيوي في المؤسسة الصحية.

المهام والمسؤوليـــــــات	١ : تقييم مكامن الخطورة فيما يخص العاملين والمراجعين وبيئة العمل في وحدات العمل المخبري. ٢ : وضع إرشادات السلامة العامة في المختبر. ٣ : تدريب الكوادر الفنية على تطبيق تعليمات السلامة العامة والأمن الحيوي. ٤ : توجيه حديثي التعيين في مجال السلامة العامة والأمن الحيوي قبل ممارسة العمل المخبري. ٥ : متابعة التزام الكوادر الفنية بتنفيذ إجراءات وإرشادات إدارة المخاطر الحيوية . ٦ : متابعة تأمين وسائل الوقاية الشخصية والأدوات اللازمة للمحافظة على سلامة العاملين في المختبر. ٧ : توفير المطاعيم الوقائية للعاملين في المختبر وتوثيقها في سجلات خاصة . ٨ : وضع سياسة عمليات التعقيم والتطهير والتخلص من النفايات المخبرية الصلبة والسائلة ومتابعة تطبيقها . ٩ : توثيق الإجراءات المتعلقة بمعالجة المخاطر الحيوية والاحتفاظ بسجل خاص للحوادث الطارئة في المختبر . ١٠ : توفير لوازم الإسعافات الأولية . ١١ : المشاركة في وضع خطة طوارئ ومتابعة التدرب عليها وتنفيذها.

يمكن تعديل هذا النموذج بناءا على احتياجات مختلف المؤسسات وطبيعة العمل فيها

Annex Three: Basis For The Classification Of Biohazardous Agents By Risk Group

Appendix A - Table 1. Basis for the Classification of Biohazardous Agents by Risk Group (RG)

Risk Group 1 (RG1)	Agents that are not associated with disease in healthy adult humans
Risk Group 2 (RG2)	Agents that are associated with human disease which is rarely serious and for which preventive or therapeutic interventions are *often* available
Risk Group 3 (RG3)	Agents that are associated with serious or lethal human disease for which preventive or therapeutic interventions *may be* available (high individual risk but low community risk)
Risk Group 4 (RG4)	Agents that are likely to cause serious or lethal human disease for which preventive or therapeutic interventions are *not usually* available (high individual risk and high community risk)

Appendix A-II. Risk Group 2 (RG2) Agents

RG2 agents are associated with human disease which is rarely serious and for which preventive or therapeutic interventions are often available.

1. Bacterial Agents Including Chlamydia

--Acinetobacter baumannii (formerly Acinetobacter calcoaceticus)
--Actinobacillus
--Campylobacter coli, C. fetus, C. jejuni
--Chlamydia psittaci, C. trachomatis, C. pneumonia
--Escherichia coli - all enteropathogenic, enterotoxigenic, enteroinvasive and strains bearing K1 antigen, including E. coli O157:H7
--H. influenza
--Helicobacter pylori
--Klebsiella - all species except K. oxytoca (RG1)
--Legionella including L. pneumophila
--Listeria
--Moraxella
--Mycoplasma, except M. mycoides and M. agalactiae which are restricted animal pathogens
--Neisseria gonorrhoeae, N. meningitides
--Pseudomonas aeruginosa
--Salmonella including S. arizonae, S. choleraesuis, S. enteritidis, S. gallinarum-pullorum, S. meleagridis, S. paratyphi, A, B, C, S. typhi, S. typhimurium
--Shigella including S. boydii, S. dysenteriae, type 1, S. flexneri, S. sonnei

--Staphylococcus aureus
--Streptococcus including S. pneumoniae, S. pyogenes
--Treponema pallidum,
--Vibrio cholerae, V. parahaemolyticus, V. vulnificus

2. Parasitic Agents

--Ancylostoma human hookworms including A. duodenale, A. ceylanicum
--Ascaris including Ascaris lumbricoides suum
--Cryptosporidium including C. parvum
--Cysticercus cellulosae (hydatid cyst, larva of T. solium)
--Echinococcus including E. granulosis, E. multilocularis, E. vogeli
--Entamoeba histolytica
--Enterobius
--Fasciola including F. gigantica, F. hepatica
--Giardia including G. lamblia
--Hymenolepis including H. diminuta, H. nana
--Leishmania including L. braziliensis, L. donovani, L. ethiopia, L. major, L. mexicana, L. peruviana, L. tropica
--Loa loa filaria worms
--Microsporidium
--Naegleria fowleri
--Plasmodium including simian species, P. cynomolgi, P. falciparum, P. malariae, P. ovale, P. vivax
--Schistosoma including S. haematobium, S. intercalatum, S. japonicum, S. mansoni, S. mekongi
--Strongyloides including S. stercoralis
--Taenia solium
--Toxocara including T. canis
--Toxoplasma including T. gondii
--Trichinella spiralis
--Trypanosoma including T. brucei brucei, T. brucei gambiense, T. brucei rhodesiense, T. cruz

3. Viruses

--Coronaviruses
--Flaviviruses - Group B Arboviruses
--Dengue virus serotypes 3 ,2 ,1, and 4
--Yellow fever virus vaccine strain 17D
Hepatitis A,
Hepatitis B,
Hepatitis C,
Hepatitis D,
Hepatitis E viruses
Herpesviruses - except Herpesvirus simiae (Monkey B virus)
--Cytomegalovirus
--Epstein Barr virus
--Herpes simplex types 1 and 2
--Herpes zoster
--Human herpesvirus types 6 and 7
--Influenza viruses types A, B, and C
--Tick-borne orthomyxoviruses
--Measles virus
--Mumps virus
--Parainfluenza viruses types 3 ,2 ,1, and 4
--Respiratory syncytial virus
--Rubella virus

Annex Four: Risk Assessment Tool Example

Organization/Institution In formation and Address **(Please provide address wherel aboratory is located)**		
Organization Name:		
Biorisk Officer (first & last name):		
Department:	**Building:**	**Phone Number:**
Laboratory Address		**City**
Country		

A. Laboratory & Laboratory Design	**Yes**	**No**	**N/A**
1. Signs are posted to notify workers and others entering the laboratory of potential hazards and who is responsible for the laboratory?			
2. Biohazard labels are posted on equipment used for manipulation, storage or transport of infectious material.			
3. Bench-tops are waterproof and resistant to acids, alkali, organic solvents and heat.			
4. Are chairsand other laboratory equipment made so that they can beeasily decontaminated with the appropriate disinfectant ?			
5. Adequate storage space is available and appropriately used			
6. Facilities and equipment are maintained and inspected regularly			
7. Are doors available to limit access control to laboratory areas?			
8. Is a sink available for hand washing?			
B. Safety Equipment	**Yes**	**No**	**N/A**
1. Are biosafety cabinets available for the manipulationof infectious materials. Type of BSC (circle all that apply): *Class I; Class II, Type A1 (A); Class II, Type A2 (A/B3)* *Class II, Type B1; Class II, Type B2, Class III; None of the above*			
2. Were biosafety cabinets certified in the past 12 months			
3. An eyewash station is readily available?			
4. Is eyewash flushed and tested regularly?			
5. Suitable clothing and PPE are identified and made available according to the assessed risks; *a. Lab coat:* *d. N95 masks:* *b. Gloves :* *e. Goggles:* *c. Surgical masks:* *f. Face shield*			

6. Staff are supplied with correctly fitting (e.g. size, material) equipment and clothing and properly trained to ensure appropriate usage, disposal and maintenance			
7. Fire extinguishers and alarm are available and maintained			
C. Agents and Special Practices	**Yes**	**No**	**N/A**
1. Is a list of biological agents that may be manipulated available Provide the list (see appendix).			
2. Please indicate the average number of diagnostic samples processed daily			
3. Is laboratory specific biosafety manual available			
4. Procedures are established and maintained for sending and receiving any infectious and potentially contaminated materials in accordance with applicable regulations and laws			
5. Gloves are worn when handling infectious material or contaminated equipment			
6. Gloves are removed prior to touching common areas such as door handles, computers, etc.			
7. All people exiting the laboratory wash their hands after handling potentially contaminated materials, infectious agents, and after removing gloves.			
8. Food and drinks are prohibited in the laboratory areas			
9. Mechanical pipetting devices are available for use			
10. All laboratory procedures are performed carefully to minimize splashes or aerosols			
11. Face protection is provided when working outside the biosafety cabinet with infectious material			
D. Decontamination And Waste Management	**Yes**	**No**	**N/A**
1. Are decontaminationprocedures in place and enforcedfor the following: **a. Worksurfaces;** **b. Spillsinvolvingpotentially hazardousmaterial;and** **c. Wastegeneratedthat may containpotentiallyhazardousmaterial?** Specify what decontamination procedures are used:			
2. Wastes segregated in proper containers			
3. Chemical waste containers are labeled, dated and kept closed			
4. Sharps containers used and disposed of properly			
5. No trash on floor			

6. Waste disposal procedures are posted in laboratory			
7. Infectious waste containers are used			
8. Containers not overfilled			
9. Biohazard waste containers are labeled and closed			
10. Culture stocks and other regulated waste properly decontaminated before disposal			
11. Materials decontaminated outside the laboratory transported in closed, durable, leak proof containers according to local rules and regulations			
12. Please indicate the weekly volume of waste generated:			
E. Hazard Communication and Training	**Yes**	**No**	**N/A**
1. All personsentering the laboratory are advised of entry/exitrequirements			
2. The laboratory supervisor ensuresthat all personnelworking with Risk Group 2 agents have the appropriate knowledge and can demonstrate proficiency in standard and special laboratory practices			
3.Does the laboratory have anoccupational health and medical surveillance program which includes offering appropriate immunizations for the agents handled?			
4. Personnel read, review and follow the instructions on practices and procedures in the biosafety manual, including safety or operations manual			
5. Are laboratory personnel trained prior toassuming their duties and onan annual basis or when policies change on the hazards associated with the material they are manipulating and the precaution stoprevent exposures, and exposure evaluation procedures?			
F. Security	**Yes**	**No**	**N/A**
1. Access is limited and restricted to authorized personnel			
2. A policy and procedure is in place to identify sensitive information and to control access to such information			
3. A personnel reliability policy is defined and implemented and the access to the facilities or work is controlled accordingly			
4. Controls are in place for the physical security of infectious materials of all kinds commensurate with the assessed risk			

G. Accident / Incident Investigation	Yes	No	N/A
1. Procedures are established and maintained to investigate, record, analyze and learn from accidents, incidents and illnesses in order to prevent further occurrences by identifying and addressing the root cause(s)			
2. Have there been any accidents or lab acquire illnesses in the last 12 months? If yes, please indicate the number of accidents: _____			

Arethereany additional safety features about your facilities that you would like to provide?

Appendix: Please indicate all infectious materials your lab has manipulated in the past 12 months.

Risk Group 2 (RG2) Agents *RG2 agents are associated with human disease which is rarely serious and for which preventive or therapeutic interventions are often available.*			
1. Bacterial Agents	Yes	No	N/A
Acinetobacter baumannii (formerly Acinetobacter calcoaceticus)			
Campylobacter coli, C. fetus, C. jejuni			
Chlamydia psittaci, C. trachomatis, C. pneumonia			
Escherichia coli - all enteropathogenic, enterotoxigenic, enteroinvasive and strains bearing K1 antigen, including E. coli O157:H7			
H. influenza			
Helicobacter pylori			
Klebsiella - all species except K. oxytoca (RG1)			
Legionella including L. pneumophila			
Listeria			
Moraxella			
Mycoplasma, except M. mycoides and M. agalactiae which are restricted animal pathogens			
Neisseria gonorrhoeae, N. meningitides Pseudomonas aeruginosa			
Salmonella including S. arizonae, S. choleraesuis, S. enteritidis, S. gallinarum-pullorum, S. meleagridis, S. paratyphi, A, B, C, S. typhi, S. typhimurium			
Shigella including S. boydii, S. dysenteriae, type 1, S. flexneri, S. sonnei Staphylococcus aureus			
Streptococcus including S. pneumoniae, S. pyogenes			
Treponema pallidum,			
Vibrio cholerae, V. parahaemolyticus, V. vulnificus			

2. Viral Agents	Yes	No	N/A
Coronaviruses			
Flaviviruses - Group B Arboviruses			
Dengue virus serotypes 3 ,2 ,1, and 4			
Yellow fever virus vaccine strain 17D			
HIV			
Hepatitis A			
Hepatitis B			
Hepatitis C			
Hepatitis D			
Hepatitis E viruses			
Herpesviruses - except Herpesvirus simiae (Monkey B virus)			
Cytomegalovirus			
Epstein Barr virus			
Herpes simplex types 1 and 2			
Herpes zoster			
Human herpesvirus types 6 and 7			
Influenza viruses types A, B, and C			
Tick-borne orthomyxo viruses			
Measles virus			
Mumps virus			
Parainfluenza viruses types 3 ,2 ,1, and 4			
Respiratory syncytial virus			
Rubella virus			
3. Parasitic agents	Yes	No	N/A
Ancylostoma human hookworms including A. duodenale,			
Ascaris including Ascaris lumbricoides suum			
Cryptosporidium including C. parvum			
Echinococcus including E. granulosis, E. multilocularis, E. vogeli			
Entamoeba histolytica			
Enterobius			
Giardia including G. lamblia			
Hymenolepis including H. diminuta, H. nana			
Leishmania including L. braziliensis, L. donovani, L. ethiopia, L. major, L. mexicana, L. peruviana, L. tropica			
Toxoplasma including T. gondii			

Annex Five:daily Inspection Checklists Example

Laboratory name:

Month/ year:

Date	Waste management					Temp.control Chart			Bench Disinf. Decon..	PPE use
	Seg.	Label.	Safe Transp.	Autoclave		Fridge	Incubator	Water Bath		
				Indicat	Doc.					
	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No
	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No
	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No
	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No
	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No
	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No
	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No
	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No
	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No
	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No
	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No
	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No
	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No
	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No

Comments:

Signature:

Date:

Annex Six: Accidental / Incidental Reports Example

LABORATORY DIRECTORATE
Central Public Health Laboratory
Accident & Incident Report

Date and Time of Event:
Date and Time Event was Reported *(who was event reported to?)*:
Person Involved *(full name & address, position in lab)*:
Details of Event:
Provide a description of the event *(near-miss, accident or incident; what was being done at time of event)*
Provide a description of any harm, injuries or damage *(e.g. cut to left index finger, splash to eye or skin)*
Was first aid provided? *(If yes, please provide details. Who administered first aid?)*
What happened to the individual afterwards? *(E.g. went to hospital, went home, resumed work)*
Describe any conditions attributing to the event *(e.g. inappropriate personal protective clothing, equipment failure, wet floor)*
Please provide name of anyone who witnessed the incident.
Are you aware of any prior similar related problems? *(If so, please explain)*
What steps have been taken to prevent recurrence?

Declaration of Person Involved:

Date: **Signature:**

Response: **Corrective action:**

Annex Seven: Vaccination Programs

Vaccines	Recommendations in brief
Hepatitis B	If you don't have documented evidence of a complete hepB vaccine series, or if you don't have an up-to-date blood test that shows you are immune to hepatitis B (i.e., no serologic evidence of immunity or prior vaccination) then you should • Get the 3-dose series (dose #1 now, #2 in 1 month, #3 approximately 5 months after #2). • Get anti-HBs serologic tested 1–2 months after dose #3.
Flu (Influenza)	Get 1 dose of influenza vaccine annually.
MMR (Measles, Mumps, & Rubella)	If you were born in 1957 or later and have not had the MMR vaccine, or if you don't have an up-to-date blood test that shows you are immune to measles or mumps (i.e., no serologic evidence of immunity or prior vaccination), get 2 doses of MMR (1 dose now and the 2nd dose at least 28 days later). If you were born in 1957 or later and have not had the MMR vaccine, or if you don't have an up-to-date blood test that shows you are immune to rubella, only 1 dose of MMR is recommended. However, you may end up receiving 2 doses, because the rubella component is in the combination vaccine with measles and mumps. For HCWs born before 1957, see the MMR ACIP vaccine recommendations.
Varicella (Chickenpox)	If you have not had chickenpox (varicella), if you haven't had varicella vaccine, or if you don't have an up-to-date blood test that shows you are immune to varicella (i.e., no serologic evidence of immunity or prior vaccination) get 2 doses of varicella vaccine, 4 weeks apart.
Tdap (Tetanus, Diphtheria, Pertussis)	Get a one-time dose of Tdap as soon as possible if you have not received Tdap previously (regardless of when previous dose of Td was received). Get Td boosters every 10 years thereafter. Pregnant HCWs need to get a dose of Tdap during each pregnancy.
Meningococcal	Those who are routinely exposed to isolates of N. meningitidis should get one dose.

Annex Eight: National Transportation Legislation Act

تعليمات رقم (١) لسنة ٢٠٠٩
تعليمات شروط تغليف ونقل عينات المواد البيولوجية او العزولات الجرثومية صادرة بمقتضى المادتين (١٥, ٢٢) من نظام ترخيص المختبرات الطبية الخاصة رقم ٣٠ لسنة ٢٠٠٣

المادة (١)

تسمى هذه التعليمات (تعليمات شروط تغليف و نقل عينات مواد البيولوجية او العزولات الجرثومية رقم (١) لسنة (٢٠٠٩) ويعمل بها من تاريخ نشرها في الجريدة الرسمية .

المادة (٢)

يكون للكلمات و العبارات التالية حيثما وردت في هذه التعليمات المعاني المخصصة لها ادناه ما لم تدل القرينة على غير ذلك:-

- المادة البيولوجية او العزولات الجرثومية : هي المادة التي تحتوي او من المتوقع ان تحتوي على كائنات حية ممرضة يمكن ان تسبب مرضاً للانسان او الحيوان .
- العينة : عينة المادة البيولوجية او العزولات الجرثومية .
- النقل الداخلي : هو نقل العينة من العيادات او اقسام المستشفى او اي وحدة صحية الى المختبر الطبي او من مختبر طبي الى آخر داخل حدود المملكة الاردنية الهاشمية .

المادة (٣)

يشترط لتغليف ووسم العينة عند النقل الداخلي اتباع الطرق التالية :-

أ- وضع العينة في وعاء اولي(Primary Container) مقاوم للماء و مقاوم للكسر و غير منفذ .

ب- تغليف الوعاء الاولي الذي يحتوي العينة بلاصق (Tape) او بارا فيلم (Parafilm) .

ج- لف الوعاء الاولي بمادة قابلة للامتصاص (Absorbent Paper) ثم تغليفها بلاصق .

د- توفير حاوية ذات جيبين (Double-pocket Biohazard Bag) موسومة بعلامة الخطر البيولوجي.

ه- و ضع الوعاء الذي يحتوي على العينة في احدى جيبي الحاوية ووضع نموذج طلب الفحص المخبري واية نماذج ورقية اخرى في الجيب الآخر .

و- يجب ان يحتوي النموذج المرفق بالعينة على اسم و عنوان الجهة المرسلة , عنوان الجهة المرسلة اليها العينة , تايخ و ساعة ارسال العينة و درجة حرارة الحفظ اثناء النقل و اسم الشخص المكلف بنقل العينة .

ز- وضع لاصق على الحاوية يبين عنوان الجهة المرسل لها العينة و كذلك شروط حفظها .

المادة (٤)

يشترط في حاله النقل الداخلي للعينة إتباع الطرق التالية :-

أ- وضع الحاوية التي تحتوي العينة في صندوق نقل غير منفذ وغير قابل للكسر وموسوم بعلامة الخطر البيولوجي.

ب- توفير حقائب ثلج للمحافظة على طبيعة العينة خلال مرحلة النقل .

ج- أن تكون سيارة نقل العينات مزودة بمواد مطهرة وقفازات ومواد ماصة وعبوة غير منفذة لجمع النفايات الطبية .

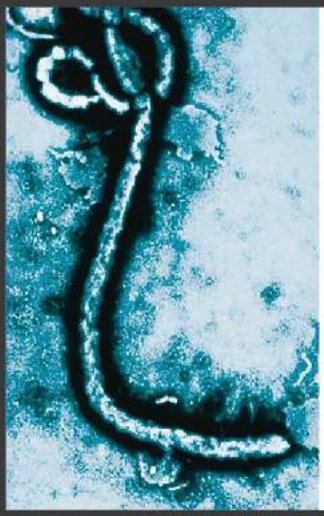
د- أن يكون الشخص المكلف بنقل العينة " السائق أو الفني.....الخ " على دراية بالمخاطر التي قد تترتب في حال تعرض العينة للكسر ومدرب على معالجة المشكلة.

المادة (٥)

يجب الالتزام بالتعليمات الفنية الصادرة عن الاتحاد الدولي للنقل الجوي (International Air Transport Association) والمنظمة الدولية للطيران المدني (International Civil Aviation Organization) عند النقل الخارجي للعينة .

وزير الصحة

الدكتور صلاح المواجدة



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