UNITED ARAB EMIRATES
MINISTRY OF HEALTH & PREVENTION

UAE Biosafety Biosecurity Guideline

Introduction

A culture of safety encourages all clinical, veterinary, foods and research laboratories to promote an organizational culture of systematic assessment of all work procedures and processes to identify associated risks and implement plans to mitigate those risks. There is often an unknown biohazard risk associated with handling diagnostic specimens; thus, each section of the diagnostic laboratory shall develop procedures and processes to minimize work/occupational exposure risk whilst handling unknown and known biological agents with high potential infectious risk. Exposure risk is typically associated with design flaws or lack of or inadequacy of safety procedures and training.

Successful establishment of a culture of safety requires that laboratory safety become an integral and apparent priority to the organization, embraced first and fore most by top management and with the concomitant infrastructure support required to foster safe behaviors among its employees.

As required by the UAE national Bio Risk Strategy, law and regulations **(Refer to Appendix4)** and, other accrediting agencies, a laboratory management system needs to assume the responsibility for:

- Establishing and enforcing a policy for a culture of safety within the laboratory
- Identifying as many hazards as possible and specifying practices and procedures
- that will minimize or eliminate those hazards
- Ensuring that all personnel are instructed and engaged in performing risk assessments and demonstrating that they can identify laboratory hazards in their individual work environments;
- Ensuring that all personnel are trained and competent in the standard practices and techniques that minimize identified workplace hazards

- Educating technical and all health care providers about safe specimen handling and transport to ensure their safety.
- Educating technical and all health care providers about biohazard waste management.

Implementation of Bio Risk management guideline is an integrated Process which would improve the organization's biosafety and Biosecurity effectiveness and construct the base for responsibility towards workers, community and environment. The implementation of bio Risk guideline will enable facilities to:

- Achieve bio risk management awareness.
- Control and minimize risk to acceptable level in relation to employee, community as well as the environment.
- Facilitate continuous improvement and evaluation
- Improve resources and management
- Guarantee readiness for successful emergency management
- Supporting accreditation Purpose

Guideline Objectives and Scope

The guideline objectives are:

I. Adopt Bio Risk management standers on national scale.

II. To implement the bio risk management in relevant organizations including health, animals, agricultures, and research and different industrial facilities

III. To support Laboratories Quality Management System, and consider guideline standard in Laboratories licensing legislations

The guideline implement in all laboratories in different sectors such as health industries, health facilities, academic laboratories, veterinary, and agricultural related fields in UAE.

This standard requires necessary control risks associated with the handling, storage, disposal of biological agents, and toxins in laboratories or facilities.

Terms and Definitions

Accident: Unintended event giving rise to harm

Auditing: Systematic, independent, and documented process for evaluating the level of conformity and compliance with required standards

Acceptable risk: A risk is deemed acceptable based upon evaluation of risk if it has been reduced a level that your organization can tolerate, giving its occupation health and safety policy and its legal obligation.

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 parasites, which may be able to provoke any infection, allergy or toxicity in humans, animal or plants.

Bio Risk: The probability or chance that a particular adverse event, accident infection or unauthorized access, loss, theft, misuse, diversion or international release, possibly leading to harm, will occur.

Bio Risk 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.

Biosecurity: Laboratory biosecurity describes the protection, control and accountability for biological agents and toxins within laboratories, in order to prevent their loss, theft, misuse.

Certification: To award a certificate to (a person/ an institute) attesting to the completion of specific standard.

Competence: Appropriate education training skills and experience.

Consequence: A result or effect, typically one that is unwelcome or unpleasant.

Corrective action: 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 potential for causing harm.

Improvement: Setting & achieving bio risk management goals based on internal and external feedback.

Incident: event with a potential for causing harm.

Inventory: Itemized record of stored supplies.

Likelihood: probability or chance of something to happen.

Non- conformity: any deviation from relevant work standards, practices, procedures, and legal requirements of bio risk 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 in to account the adequacy of any existing control measurements.

Simulation: The imitation of the operation of real-world process or system overtime.

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 effect in humans, animals or plants

List of Abbreviation

BM: Bio risk Management

BM Officer: Bio Security officer

BSC: Biological Safety Cabinet

GLP: Good Laboratory Practices.

PPE: Personal Protective Equipment.

SOPS: Standard Operation Procedures)

UAE: United Arab Emiratis

WHO: World Health Organization

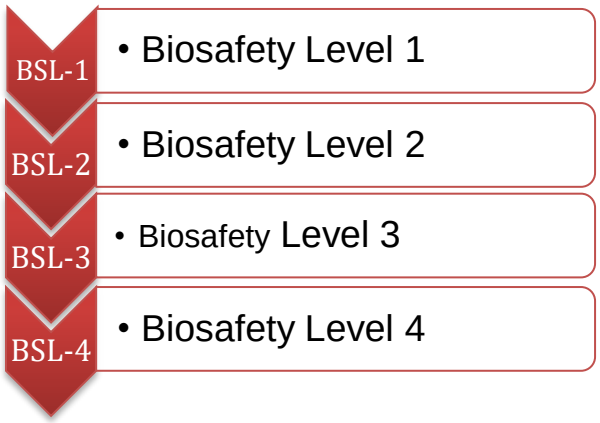
Biosafety Levels

A **Biosafety Level** is a set of bio containment precautions required to isolate dangerous biological agents in an enclosed laboratory facility. The levels of containment range from the lowest biosafety level 1 (BSL-1) to the highest at level 4 (BSL-4) based on the agents or organisms that are being researched or worked on in any given laboratory setting **(Refer to Appendix1).**

Risk Group for Laboratory Work:

- **Risk Group 1**: A micro-organism that is unlikely to cause human or animal disease.
- **Risk Group 2**: A pathogen that can cause human or animal disease but is unlikely to be a serious hazard to laboratory workers, the community, livestock or environment
- **Risk Group 3**: A pathogen that usually causes serious human or animal disease but does not ordinarily spread from one infected individual to another
- **Risk Group 4**: A pathogen that usually causes serious human or animal disease and that can be readily transmitted from on individual to another, directly or indirectly

Lowest Risk



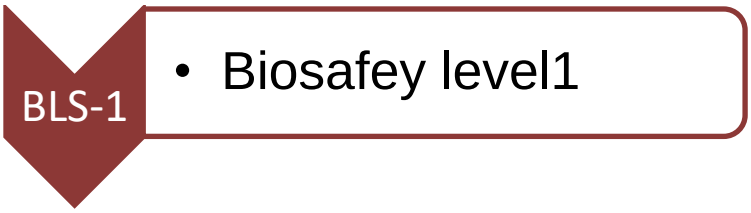
Highest Risk

These levels are very important because they statute the type of work practices that are allowed to take place in a lab setting. They also heavily influence the overall design of the facility, as well as the type of specialized safety equipment used within it

Risk Group for Laboratory Work:

Risk group	Biosafety level	Laboratory type	Laboratory Practices	Safety Equipment
1	BLS1	Basic teaching ,Research	Good microbiological techniques (GMT)	Open work bench
2	BLS2	Primary health and diagnostic services, research	GMT+ Proactive clothing , Bio hazardous sign	Level01+BSC for Potential aerosols
3	BLS3	Specials diagnostic services research	Level2+ special clothing, controlled access, directional airflow	BSC for all Activities
4	BLS4	Dangerous Pathogens Units	Level3+airlockentery ,shower exit, special waste disposal	Class III BSC, Or positive Pressure suits in conjunction with class II BSC, Double-ended autoclave, filtered air

WHO, laboratory biosafety manual (3rd edition)



BSL-1.is the lowest safety level and it's appropriate for laboratories works with agents posing minimal potential threat to laboratory workers and to the environment and are not associated with disease in healthy adult. This is the type of laboratory found in municipal water-testing laboratories, in high schools, and in some community colleges teaching introductory microbiology classes, where the agents are not considered hazardous.

Basic Laboratory Design, Facilities Design and special practices (Basic Laboratories (BSL-1) :

1. Laboratories are not usually isolated from the general building and there is a door that must be closed to keep visitors out of the lab while work with the agents is in progress.
2. There is a hand-washing sink available, preferably near the door.
3. It is a recommended practice to wear a lab coat and gloves while manipulating the agents.
4. Work is done on the open bench that can be easily cleaned and decontaminated
5. Hazard warning signs posted on the door indicating any hazards that may be present, including radioactive materials, laser lights, or toxic chemicals.
6. Having a prohibition on eating, drinking and smoking in the lab,.
7. Waste materials are segregated according to hazard type, and there is an appropriate chemical decontaminated tray for collecting contaminated implements.
8. requiring hand washing when they finish their work or when exiting the laboratory

BSL -2 would cover work with pathogenic or infectious agents posing a moderate hazard which can lead to human disease. ***Examples are the Hepatitis B and C, HIV, S*. aurous*, some retroviral vectors.***

In addition to standard microbiological practices of BSL 1, BSL 2 labs must also provide the next level of barriers, i.e., specialty safety equipment and facilities. Preferably, this is a Class II biosafety cabinet or equivalent containment device for work with agents and an autoclave or other suitable method for decontamination within the lab. A readily available eyewash station is needed. Self-closing lockable doors and biohazard warning signs are also required at all access points.

Unlike the BSL-1, there are a number of immunizations recommended before working with specific agents. Most notable is Hepatitis- B virus immunization which is recommended by the Occupational Safety and Health standard for persons, including lab staff, at high risk of exposure to blood and blood products. Therefore, because of potential to cause human disease, great care is used to prevent percutaneous injury (needle sticks, cuts and other breaches of the skin), ingestion and mucous membrane exposures.

Basic Laboratory Facilities Design and Special Practices (BSL- 2):

1. Laboratories should have doors with access control, which have vision panel, fire ratings and preferably self-closing, Also Specific policies and procedures regarding access to the BSL-2 laboratory should be developed and poste.
2. Hand Washing sinks, preferably near the exit door.

3. Walls, ceilings and floors should be smooth, easy to clean, impermeable to liquids and resistant to the chemicals and disinfectants normally used in the laboratory.
4. Floors should be slip-resistant.
5. Laboratory furniture should be strong equipment should be accessible for cleaning.
6. Bench tops should be impervious to water and resistant to disinfectants, acids, alkalis, organic solvents and moderate heat.
7. Chairs used should be covered with non-porous materials that can be easily cleaned and decontaminated.
8. Provision of mechanical ventilation systems that provide an inward flow of air without recirculation. If there is no mechanical ventilation, windows that open to the exterior should be fitted with Screens.
9. A reliable and adequate supply of electricity, and emergency
    a. Lighting to permit safe exit.
    b. A stand by generator is desirable for the support of essential equipment.
10. A reliable and adequate supply of gas.
11. Some work may be done on the open bench by persons wearing appropriate protective clothing or gear. All work that might create aerosols of infectious materials should be done in containment cabinet.
12. Waste materials need to be segregated into chemical, radioactive, bio-hazardous, or general waste streams. Infectious waste should be decontaminated (by treating with chemical disinfectants or by steam autoclaving).
13. Decontaminating work surfaces after completing the work with the infectious materials.
14. Reporting all spills and accidents.
15. Developing the lab's biological safety manual.
16. Training the laboratory personnel and making them aware about the potential hazards associated with the work.

BLS-3

- Biosafety level 3

BSL-3 laboratories would cover work with dangerous or exotic agents that may cause serious disease via aerosol transmission which dictates the next level of protective procedures and barriers. ***Examples are M. Tuberculosis, SARS, Yellow fever, St. Louis encephalitis and West Nile virus***

In addition to all the BSL- 2 practices and equipment, The BSL-3 must have even more stringent in access entry control and waste management.

Basic Laboratory Facilities design and special Practices (BSL- 3):

1. The laboratory must be separated from areas that are open within the building.
2. Laboratory access is restricted. Access to the laboratory is through two self-closing doors Laboratory doors must be self-closing and have locks in accordance with the institutional policies. A clothing change room (anteroom) may be included in the passageway between the two self-closing doors.
3. Laboratories must have a sink for hand washing. The sink must be hands-free or automatically operated, located near the exit door. If the laboratory is segregated into different laboratories, a sink should be also available for hand washing in each zone.
4. An eyewash station must be readily available in the laboratory.
5. The laboratory must be designed so that it can be easily cleaned and decontaminated, floors, walls, and ceiling surfaces should be sealed. Spaces around doors and ventilation openings should be capable of being sealed to facilitate space decontamination.
6. Decontamination of the entire laboratory should be considered when there has been gross contamination of the space, significant changes in laboratory usage, for major renovations, or maintenance shut downs. Selection of the appropriate

materials and methods used to decontaminate the laboratory must be based on the risk assessment.

7. Laboratory furniture must be capable of supporting anticipated loads and uses..
8. Bench tops must be impervious to water and resistant to heat, organic solvents, acids, alkalis, and other chemicals.
9. Chairs used in laboratory work must be covered with a non-porous material that can be easily cleaned and decontaminated with appropriate disinfectant.
10. All windows in the laboratory must be sealed.
11. BSCs must be installed so that fluctuations of the room air supply and exhaust do not interfere with proper operations. BSCs should be located away from doors, heavily traveled laboratory areas, and other possible airflow disruptions.
12. Vacuum lines must be protected with HEPA filters, or their equivalent. Filters must be replaced as needed. Liquid disinfectant traps may be required.
13. A ducted air ventilation system is required. This system must provide sustained directional airflow by drawing air into the laboratory from “clean” areas toward “potentially contaminated” areas. The laboratory shall be designed such that under failure conditions the airflow will not be reversed.
14. A method for decontaminating all laboratory wastes should be available in the facility, preferably within the laboratory (e.g., autoclave, chemical disinfection, or other validated decontamination method).
15. The BSL-3 facility design, operational parameters, and procedures must be verified and documented prior to operation. Facilities must be re-verified and documented at least annually

BLS- 4

• Biosafety Level 4

Agents requiring BSL-4 facilities and practices are extremely dangerous and pose a high risk of life-threatening disease. ***Examples are the Ebola virus, and any agent with unknown risks of pathogenicity and transmission.***

These facilities provide the maximum protection and containment. In addition to standard microbiological practices of BSL- 3, there are requirements such as complete clothing change before entry, a shower on exit and decontamination of all materials prior to leaving the facility.

There are two models for BSL-4 laboratories:

1. A Cabinet Laboratory—Manipulation of agents must be performed in a Class III BSC.
2. A Suit Laboratory—Personnel must wear a positive pressure supplied air protective suit.

Usually, BSL- 4 laboratories are in separate buildings or a totally isolated zone with dedicated supply and exhaust ventilation. Exhaust streams are filtered through High-Efficiency Particulate Air (HEPA) filters, depending on the agents used.

Basic Laboratory Facilities design and special Practices (BSL- 4):

1. The BSL-4 facility design parameters and operational procedures must be documented.
2. The facility must be tested to verify that the design and operational parameters have been met prior to operation.
3. Facilities must also be re-verified annually. Verification criteria should be modified as necessary by operational experience
4. The BSL-4 cabinet laboratory consists of either a separate building or a clearly demarcated and isolated zone within a building.

5. Laboratory doors must have locks in accordance with the institutional policies.
6. Rooms in the facility must be arranged to ensure sequential passage through an inner (dirty) changing area, a personal shower and an outer (clean) change room upon exiting the room(s) containing the Class III BSC(s).
7. Appropriate communication systems must be provided between the laboratory and the outside (e.g., voice, fax, and computer).
8. An automatically activated emergency power source must be provided at a minimum for the laboratory exhaust system, life support systems, alarms, lighting, entry and exit controls, and door gaskets. Monitoring and control systems for air supply, exhaust, life support, alarms, entry and exit controls, and security systems should be on an uninterrupted power supply (UPS).
9. A double-door autoclave, fumigation chamber, or ventilated airlock must be provided at the containment barrier for the passage of materials, supplies, or equipment.
10. A hands-free sink must be provided near the door of the cabinet room(s) and the inner change room. Also sink must be provided in the outer change room. All sinks in the room(s) containing the Class III BSC must be connected to the waste water decontamination system.
11. Walls, floors, and ceilings of the laboratory must be constructed to form a sealed internal shell to facilitate fumigation and prohibit animal and insect intrusion.
12. The internal surfaces of this shell must be resistant to chemicals used for cleaning and decontamination of the area. Floors must be monolithic, sealed and covered.
13. All penetrations in the internal shell of the laboratory and inner change room must be sealed. Openings around doors into the cabinet room and inner change room must be minimized and capable of being sealed to facilitate decontamination.
14. Drains in the laboratory floor (if present) must be connected directly to the liquid waste decontamination system.
15. Services and plumbing that penetrate the laboratory walls, floors, or ceiling must be installed to ensure that no backflow from the laboratory occurs. These penetrations must be fitted with two (in series) backflow prevention devices.

16. Atmospheric venting systems must be provided with two **HEPA filters** in series and be sealed up to the second filter.
17. Decontamination of the entire cabinet must be performed using a validated gaseous or vapor method when there have been significant changes in cabinet usage, before major renovations or maintenance shut downs, and in other situations, as determined by risk assessment. Selection of the appropriate materials and methods used for decontamination must be based on the risk assessment.
18. Laboratory furniture must be of simple construction, capable of supporting anticipated loading and uses.
19. Chairs and other furniture must be covered with a non-porous material that can be easily decontaminated.
20. Windows must be break-resistant and sealed.
21. If Class II BSCs are needed in the cabinet laboratory, they must be installed so that fluctuations of the room air supply and exhaust do not interfere with proper operations. Class II cabinets should be located away from doors, heavily traveled laboratory areas, and other possible airflow disruptions.
22. Central vacuum systems are not recommended. If, however, there is a central vacuum system, it must not serve areas outside the cabinet room. Two in-line HEPA filters must be placed near each use point. Filters must be installed to permit in-place decontamination and replacement.
23. An eyewash station must be readily available in the laboratory.
24. A dedicated non-recirculating ventilation system is provided. The supply and exhaust components of the ventilation system must be designed to maintain the laboratory at negative pressure to surrounding areas and provide differential pressure or directional airflow, as appropriate, between adjacent areas within the laboratory.
25. Redundant supply fans are recommended. Redundant exhaust fans are required. Supply and exhaust fans must be interlocked to prevent positive pressurization of the laboratory.

26. The ventilation system must be monitored and alarmed to indicate malfunction or deviation from design parameters.
27. A visual monitoring device must be installed near the clean change room so proper differential pressures within the laboratory may be verified prior to entry.
28. All HEPA filters should be located as near as practicable to the cabinet and laboratory in order to minimize the length of potentially contaminated ductwork.
29. All HEPA filters must be tested and certified annually. The HEPA filter housings should be designed to allow for in situ decontamination and validation of the filter prior to removal. The design of the HEPA filter housing must have gas-tight isolation dampers, decontamination ports, and ability to scan each filter assembly for leaks.

Table1. Summary of biosafety level requirements as per WHO:

Requirements	Biosafety Levels			
	BSL-1	BSL-2	BSL-3	BSL-4
Isolation [a] of laboratory	NO	NO	YES	YES
Room sealable for decontamination	NO	NO	YES	YES
Ventilation:				
- inward airflow	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 laboratory room	NO	NO	Desirable	YES
-double-ended	NO	NO	Desirable	YES
Biological safety cabinets	NO	Desirable **(CLASI,CLASII)**	YES **(CLASII,CLASIII)**	YES **(CLASIII)**
Personnel safety monitoring capability [b]	NO	NO	Desirable	YES

A. Environmental and functional isolation from general traffic.
B. Dependent on location of exhaust (see Chapter 4 in biosafety manual 2004 third edition).
C. Dependent on agent(s) used in the laboratory.
D. For example, window, closed-circuit television, two-way communication.

Implementation and operation of bio risk management system

Top management of the Facility

Roles, responsibilities and authorities

1. Shall take ultimate responsibility for the facility's bio risk management system.
2. Shall ensure that roles, responsibilities and authorities related to bio risk management are defined, documented and communicated to those who manage, perform and verify work associated with the control of biological agents and toxins.
3. Shall demonstrate its commitment by ensuring the availability of resources to establish, implement, maintain and improve the bio risk management system.

Notes:

- Top management includes Officers (Director General, Chief Executive Officer, Chief Operating Officer, Chief Financial Officer, etc.) and Directors of the facility. Overall responsibility for management of bio risk rests with top management but tasks may be delegated through the facility provided that they are passed to competent individuals with adequate resources to perform the activities safely and securely. In smaller facility, one individual may hold more than one role. It is important to define roles and responsibilities and that there is clear communication within the facility in terms of the actions that need to be taken, and who has the required authority.
- In assigning roles and responsibilities, potential conflicts of interest should be considered.
- Resources include human resources and specialized skills, facility infrastructure, technology and financial resources.

Bio Risk Management Officer /Biosafety officer

A competent individual(s) shall be designated to provide advice and guidance on bio risk management issues. This individual shall report directly to the responsible senior manager and have delegated authority to stop work in the event that it is considered necessary to do so.

Functions of the bio risk management officer should include

I. Verifying, in conjunction with other relevant personnel, that all relevant bio risk considerations have been addressed.
II. Advising or participating in the reporting, investigation and follow-up of accidents / incidents, and where appropriate referring these to management / bio risk management committee.
III. Ensuring that relevant and up-to-date information and advice on bio risk management is made available to scientific and other personnel as necessary.
IV. Advising on bio risk management issues within the facility (e.g. management, occupational health department, security).
V. Contributing to the development and / or delivery of bio risk training activities.
VI. Ensuring that all relevant activities are performed in compliance with bio risk regulations and that required bio risk authorizations for work were in place**. (Refer to Appendix2)**

Bio Risk Management Policy

Facilities Top Management shall develop, authorize and sign a policy concerning the management of bio risk (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:

I. Considering effective bio risk management as a priority.
II. Protecting staff, contractors, visitors, community and environment from biological agent and toxins that are stored or handled within the facility.

III. Reducing the risk of intentional and unintentional release of, or exposure to biological agents and toxins.

IV. Complying with all legal requirements applicable to the biological agents at the national and international levels.

V. Facilities shall continually improve the effectiveness of the bio risk management system through the use and update of the:

- Policies
- Communication policy (for general public and stakeholders)
- Objectives
- Risk assessment
- Corrective and preventive actions
- Self-audit program
- Audit results
- Analysis of data
- Management review.
- Others (complains, observation …etc.)

VI. The facility shall develop a plan for continual improvement, implement it and follow it up.

Planning for Hazardous Identification, Risk Assessment and Control

Risk assessment scope:

I. A proactive and reactive risk assessment is done with respect to each facility scope.

II. Assessment activity is unique to each individual facility

III. It must be done by a trained technical officer, with aid from internal or external experts if needed.

IV. The facility top management shall identify resource requirements.

The facility top management shall:

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

I. Who is responsible and accountable for doing risk assessment (bio risk officer)
II. What resources are to be utilized (e.g. people, budget).
III. Timetable for implementation.
IV. Details of the mechanism and frequency of review in compliance with the plan.

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

1. 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.
2. New construction / modifications to laboratories, design and equipment or its operation.
3. Introduction of altered and unplanned staffing arrangements (including contractors, visitors and other non-core personnel).
4. Significant alterations to Standard Operating Procedures (SOPs) or working practices (e.g. disinfection / waste management methodologies, PPE provision / usage entry / exit protocols, etc.).
5. When unexpected events that may have relevance for the management of bio risk are observed.
6. When actual or potential non-conformity with internal / external rules and regulations is identified (e.g. introduction of new legislation or major accident exposure).
7. When considering emergency response and contingency planning requirements.
8. As part of the existing management system review process (e.g. annuall).

Note: There are many defined methodologies and approaches available for conducting hazard identification, risk **(Refer to Appendix 3)**

Risk management protocol

Risk investigation Risk identifcation	• Determine the potential source of errors, risks, or problems that may occur in the lab.
Risk prioritization	• The process of calculating the possibilities and consequences of risk events in order to establish ranking levels to provide a clear vision for management to mitigate the risk event. • Risk needs to be scored according to severity from negligible to catastrophic or scored according to likelihood from rare to almost certain
Risk categorize	• All risk shall be categorized as low risk which has minimal impact as a result of existence, or moderate risk which has a short term impacts, and high risk which cause a catastrophic result
Reporting Risk	• Fulfills with legal and regulatory requirements in the collecting and recording of risk information. Clarifies the purpose of evaluating and recording risk performance and the use of technology to maintain effective risk management. Establishes a complete risk recording system that is associated with other organizational performance management structures and processes
Mangment straegy	• Concerned leaders and managers shall develop action plans to respond to different types of risks covering time frame and responsibilities
Risk investgation	• To prevent reoccurrence of the same incident in the future and detect any opportunities for improvement
Management and monitoring	• To analyses the root of the problem, evaluated the performance, identify corrective action and increase efficiency. • All claims or complaint should be reviewed by lab managers and safety officer to redesign the risk areas and define the process to comply with it

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 bio risk (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 facility 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.

Hazard identification should use information including:

- Group experience and knowledge.
- External or specialized expertise not found in the facility.
- Results of previous assessments.
- Surveys of previous accidents/incidents.
- Hazardous materials data.
- Information on hazardous organisms.
- Guidelines and codes of practice.
- Facility drawings.
- SOPs, manuals, etc.
- 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	Quantity	Storage Area

Risk Assessment

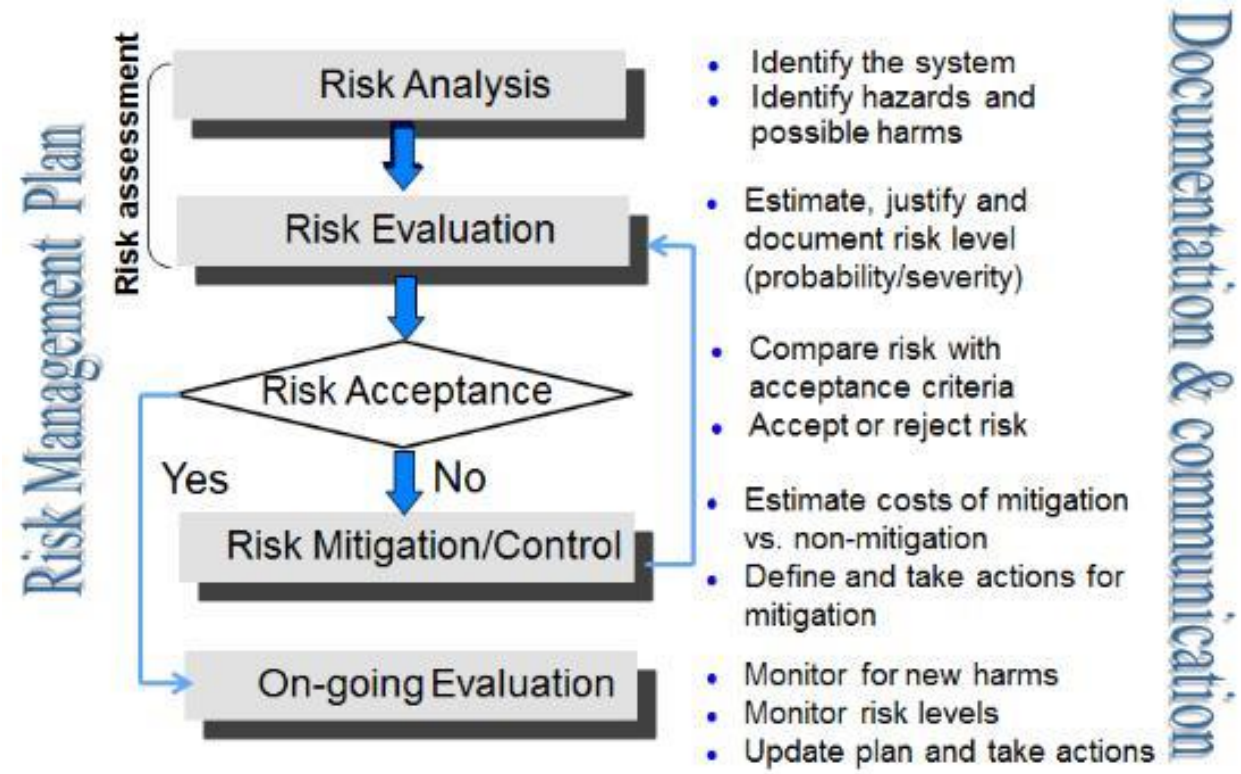
Assessments can be qualitative, semi-quantitative or quantitative, and a method suitable to the situation should be identified and followed. Reference biological agents and toxins data sheets (e.g. from risk grouping descriptions, material safety data sheets etc.) should be used in risk assessment. Annex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

BM officer risk assessment should:

1. Categorize risks.
2. Identify those which need to be eliminated or controlled.
3. Describe likelihood and consequence.
4. Define acceptability of risk levels.
5. Comply with legal regulatory requirements national and international.

Note: Unless risk assessment is comprehensive, control measures will never be sufficient and exposure to risk consequences will still be there.

Risk Management plan



Bio risk control measures:

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

Using the results from your risk assessment:

I. Identify different risk mitigation measures as much as you can (safety & security)

II. Categorize risk mitigation measures as:

- Elimination or substitution
- Engineering control
- Administrative control
- Practice and procedures
- PPE

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

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

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

Note: BM officer can carry this task, unless somebody assigned specifically for it .

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 facility should consider:

- Theft or diversion of biological agents and toxins or related equipment, documents or data.
- Labor issues and disputes.
- Emergencies (i.e., earthquake, flood, tornado, etc.)
- Workplace violence.
- Screening and isolation of suspect packages.
- 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:

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

Personnel training and competence

Facilities shall ensure that requirements and procedures for bio risk-related training of personnel are identified, established and maintained. Training should include raising personnel awareness of bio risk issues.

Procedures should address:

- Definition of bio risk training needs.
- Provision of required bio risk training.
- Determination of effectiveness of bio risk training.
- Provision of refresher bio risk training.
- 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 supervision until 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 Bio risk 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 Bio risk management focal point.

This activity could be achieved through documented all of:

- Employee participation.
- Communication of Local, national, international governmental facilities and relevant regulatory agencies (certifiers).

Operational control

The facilities shall have a systemic process of checking BM implementation through management reviews, audits and inspections.

Examples may include:

- Daily inspection checklists
- Internal reports (staff observation)
- External or internal audits or inspection report
- Accidental /Incidental reports

General safety

Facilities should adopt:

I. preventive and proactive approach to managing sources of risk
II. Address the implications for bio risk in the event of an accident / incident resulting from such sources.
III. Measures should be identified and implemented to detect, mitigate and respond to emergencies.

Issues addressed should include but are not limited to:

- General laboratory safety.

- Fire safety.
- Electrical safety.
- Radiation safety.
- Chemical safety.
- Use of gasses (including risk of asphyxiation).
- Equipment under pressure.
- Laboratory animal care and use (vet. labs).
- General housekeeping, including storage requirements and tidiness.

Biological agents and toxin inventory and information

The inventory process should be based on risk and that include:

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

I. Inventory information should include:

- 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.
- Restricted access to the detailed inventory records to those individuals whose work requires access to that information.

- Identification numbers and other relevant identifiers.
- Records of quantities / volumes of biological agents and toxins at an appropriate level and based on risk
- Records of materials consumed, destroyed or removed from the facility where appropriate.
- Inventories shall be documented as a soft and/or hard copy

II. Requests for biological material and/or toxins

- Originate from legitimate facilities and individuals.
- Brought into the facility or sent elsewhere if authorized by those responsible for the facility.
- Shipment tracking and verification of receipt are important considerations.

Work program, planning and capacity

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

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

Change management

The facility 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.

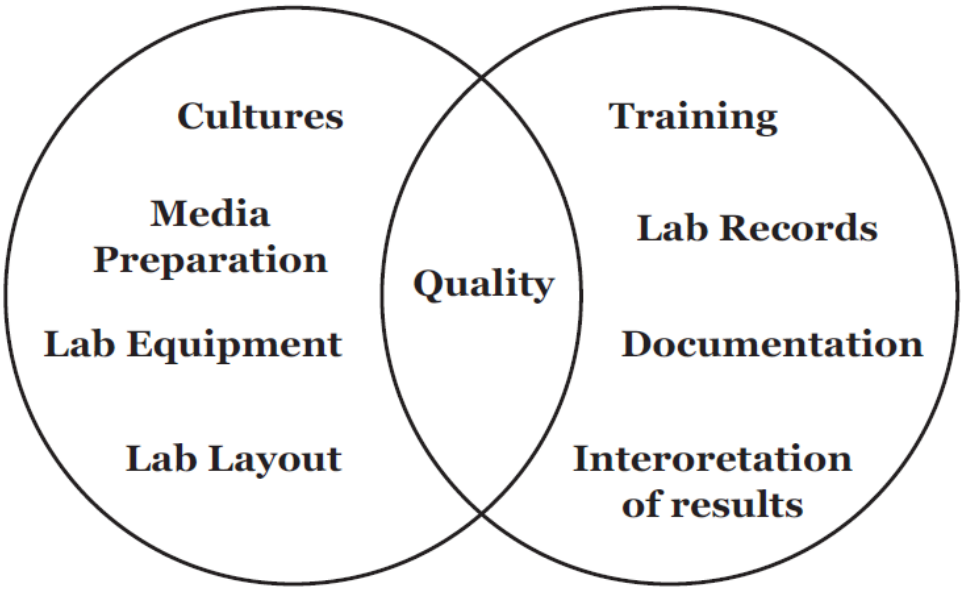
Examples of changes that should be subject to the change management process:

- Modifications to buildings and equipment or their operation, which may or would have an effect on bio risk.
- Introduction of altered staffing arrangements (such as temporary presence of on-site contractors or students, temporary reassignments of personnel).
- Changes to the program of work, including alterations to work flow or volume which may or would have an effect on bio risk.
- Alterations to SOPs, including significant changes in materials or reagents.
- Modifications to entry / exit protocols.
- 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 facility 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:

-
- Centrifugation.
- Control of needles and sharps.
- Correct use of vacuum pumps.
- Culture, purification and storage techniques.
- Minimization /containment of aerosols..
- Animal handling
- Use of biological safety cabinets.

- Use of disinfectants, including spill control, routine decontamination, hand washing and showering

Inactivation of biological agents and toxins

The facility 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:

- Personnel clothing and PPE.
- Equipment.
- Cultures and associated materials.
- Spill clean-up materials and equipment.
- Possibly infectious microorganisms, toxins and contaminated materials.
- Needles, syringes and sharps.
- Waste water, including that from sinks and showers.
- Filters and air handling systems.
- Animals exposed to laboratory biological agents or toxins.

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

Waste Management

Facilities shall establish and maintain an appropriate waste management policy for biological agents and toxins following the UAE federal and local legislations.

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

- Ensure program is in place to minimize the waste production.
- Ensure effective waste audit trails are in place and documented.

- Provide adequate facilities and procedures for the storage of waste (including short term storage).
- Ensure methods are available for effective segregation and decontamination of mixed waste.
- Ensure appropriate packaging material is used to contain the waste and to maintain its integrity during storage and transportation.

Personal Protective Equipment (PPE)

The facility 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.

Measures in place should include:

- Ensuring adequate information is used in selecting PPE (e.g. risk assessments, review and analysis of tasks, employee feedback, etc.)
- Ensuring all personnel who have to use PPE (including scientific staff, visitors and contractors) are identified and supplied with correct fitting equipment and clothing.
- Defining and conducting an appropriate program to ensure that routine checks and maintenance of PPE are defined and carried out.
- Defining and addressing the need for and provision of replacement and spare PPE.
- Providing adequate PPE for use during both normal and emergency working conditions.

- 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.
- 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 GLP or use 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:

- Human reliability and behavioral safety, including adherence to procedures.
- Communication, consultation and feedback.
- Conflict management and resolution.
- Empowerment, including authority to stop work if potentially unsafe or unsecure condition is identified.
- Avoidance of “blame culture”, including willingness to report accidents, incidents or unsafe conditions/behaviors, and protection of workers who do so.
- Ergonomics, including equipment and work practice design to take account of individual needs.
- Respect for individual privacy and dignity.

Contractors, visitors and suppliers:

Security and safety consideration for non-core personnel (e.g. contractors, visitors, students, etc.) are implemented to ensure they are applied where necessary.

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 bio risk 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 bio risk be identified, purchased, maintained, calibrated, certified or validated in a manner consistent with the intent and requirements of the bio risk 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:

Transportation of Materials

Facilities shall ensure that procedures for the safe and secure transport of cultures, specimens, samples and contaminated or potentially contaminated materials are established and maintained according to the WHO “guidance on regulation for the transport of infectious substance 2015-2016 **(Refer to Appendix 5**).

In planning and conducting transport activities the facility should consider:

- Ensuring transport requirements are identified and implemented, including legal requirements and national and international guidelines.
- Ensuring adequate packaging systems, materials, labels, PPE and documentation are available and used as part of the transportation process.
- Selecting a reliable, trustworthy carrier that is qualified to handle the package safely and securely.
- 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.

- The need is identified for formal documented transfer forms signed by the responsible management representative authorizing movement of materials.
- Document control that allows traceability of material movements.
- 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.

Storage of Category A and Category B substances awaiting transport by Triple packaging requires to follow the standard operating procedures of the laboratory.

The storage should be based on risk and include:

- Identifying all biological agents and toxins held, including cultures, specimens and other sources (e.g. infected tissues/ samples or animals).
- Segregating and storing biological agents and toxins according to risk.
- Restricting access to biological agents and toxins to authorized individuals with a demonstrable legitimate need.
- Implementing effective physical security measures according to risk (e.g. locks, alarms, access controls, etc.)
- Developing and maintaining a reliable sample identification system.
- Maintaining the chain of custody.

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 Bio Risk is taken into account when preparing and implementing emergency plans.

- The facility 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 bio risk 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:

- Risk assessments (safety and security), standard operating procedures (SOPs) and manuals.
- Job hazard analyses and charts of authority.
- Design records and commissioning/test plans, maintenance plans and records and all associated data.
- Audit and inspection checklists.
- Training records.
- 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

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 (e.g. annually).

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:

- Identifying those responsible for maintaining the accident/incident reporting system.
- Defining what constitutes an accident / incident, and what triggers recording and reporting.
- Specifying required documentation to support the system.
- Identifying the reports that will be generated, their frequency and distribution.
- Ensuring analysis of trends.
- Identifying root causes using individuals trained in investigation techniques.
- 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.
- Identifying where it may be appropriate or necessary, for security professionals may be required to coordinate with law enforcement.

Corrective/ preventive action

Facilities shall ensure action is taken to eliminate the causes of non-conformities with the requirements of this guideline 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:

- Reviewing the non-conformities.
- Determining the cause of non-conformities.
- Evaluating the need for action to ensure that non-conformities do not recur.
- Determining and implementing action needed.
- Recording results of action taken.
- Reviewing corrective actions taken.

Bio risk Management Review

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

The review input should include information on:

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

The review output should include decisions and actions related to:

- Improvement of the effectiveness of the bio risk management system.
- Improvement related to the requirements and risk assessments.
- Resource needs.

Appendix (1) Basis for the classification of bio hazardous Agents by risk group:

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)

Risk Group 2 (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. gallinar um-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
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

Appendix (2): Biosafety /Biosecurity Officer job description

Designation (Job Title)	Biosafety /Biosecurity Officer
Minimum Qualifications	• Advanced degree in microbiology, biochemistry, genetics, molecular biology or other life science and one years of broad experience as a Biological Safety Officer and /or Institutional Biological Safety Committee member including at least one year of supervisory experience. • Knowledge of principles of Biological Safety and Environmental Health. • Strong interpersonal and communication skills, and the ability to work both effectively and cooperatively with a wide range of people in a diverse community. • Knowledge and understanding of UAE Federal regulations environment and Biosecurity. • Proficient computer skills, including the ability to evaluate and utilize software applications to maximize efficiency. • High level of attention to details, thoroughness in making initial assessments, and attention to the conduct of subsequent monitoring activities and record keeping. • Demonstrated skill in problem solving operations and procedures, developing and implementing new strategies and procedures.
Job Description	• Ensure compliance with UAE federal laws , strategy , regulations, policies regarding, Biosafety /Biosecurity in Biomedical Laboratories. • Maintain current knowledge of applicable laws, regulations, policies, and procedures. • Establish and implement strategic goals and objectives for the Biosafety/ Biosecurity programs on laboratory department. • Prepare and provide official communications with the top management /federal lab management to ensure all required security assessments are performed. • Coordinate with the internal organization Biosafety or Biosecurity / Infection control Committee to establish and implement strategic goals and objectives for the Biosafety\biosecurity Programs. • Coordinate with the Facilities Management, Risk Management Services, and other support departments to ensure all required checks and evaluations are performed

	• Serve as committee member and work regularly with the Institutional Biological Safety Committee to review and interpret regulatory requirements and establish and enforce clinical safety practices • Develop, recommend, implement, review and revise lab policies and procedures regarding Biosafety/Biosecurity principles and practices. • Develop and implement internal procedures, assess control measures, and provide written guidelines to ensure that standards are observed relative to regulatory requirements and established professional practices. • Provide oversight and direction to one or more technicians and specialists responsible for reviewing and evaluating protocols and conducting audits and risk assessments for laboratories. • Perform ongoing management evaluations of each technical activity or project within the scope of the Biological Safety Programs to meet regulatory requirements; improve operational efficiency, and direct their proper integration into the overall departmental mission and programs. • Consult with Principal Investigators regarding mitigation of biological hazards, methods for maintaining compliance with the international Guidelines for Research Involving Recombinant especially for select agents and toxins regulations, and Biosafety in Microbiological. • Develop and maintain metrics to track level of service and efficacy with respect to the performance of regulatory compliance functions. • Direct and implement compliance program components including monitoring, recordkeeping, reporting, program evaluation and other compliance audits. • Develop and deliver training programs related to biosafety /Biosecurity • Oversee, process/review/evaluate, and track adverse events; and coordinate efforts with other partnering units to ensure appropriate reporting.(Compliance/Reporting) • Prepare all required annual requirements, emergency response drill review, security and safety policies and manual reviews.

Employee signature ……	**Direct line manager signature** ……

Appendix (3): Risk assessment tools Example of Risk Assessment tools:

Risk Assessment Tool for Laboratory Procedures Name of Procedure: _Date: Score:List chemicals used (included volume and weight): _____ Based on all the chemicals you will use in this procedure complete the following table (use the chemical's Safety Data Sheet to assign risk factors**Risk Factor**	**Risk**					
Chemical Volumes Used: Low = 2L	Low 0	1	2	Med 3	4	High 5
Hazard Recognition:						
Flammability Hazard						
Corrosive Hazard						
Toxic Hazard						
Cryogenic Hazard						
(use only the highest value for calculation) -->						
Process Conditions: Low=Sub-ambient (P<1 atm; T<10C) Medium=Ambient (P=1 atm; T>10 & <40C) High=Extreme						
Explosive Hazard:						
Radiation Hazard:						
Inhalation Toxicity:						
Reactivity						
Other(specify):						
Handling Procedure: Written=0; Routine=3; Under Development=5						
Personnel Preparedness & Training:						

Fully Trained=0; Routine=3; Untrained=5							,
Ventilation Needed: Hood Used=0; General Lab=3; Not Used=5							
Equipment Require : **Chemical hood , fire extinguisher,** **Emergancy shower/eyewash ,Spill kit** **Available= 0 not avalible =5**							
Equipment Maintenance: Regularly Maintained=0; Not Performed=5							

Recommended Actions Based on Score

Low	<20	Procedure can be performed With routine precautions.
Moderate	20 – 25	Procedure can be performed with attention given to specific hazards. Supervision and a Standard Operating Procedure (SOP) is recommended
High	26 – 35	Procedure may be performed if necessary. High level attention must be given to all hazards. High level, continuous supervision is mandatory. A Standard Operating Procedure (SOP) is required.
Extreme	>35	Procedure must be revised to lower the risk.

If score is greater than 25: • Develop a SOP for this process (including identifying risk reduction actions).

Appendix (4): Lows and regulation issue in UAE related to Biosafety and biosecurity:

Federal Regulation
- Federal Law No. (5) of 1984 regarding the practice of non-physicians and pharmacists for some medical professions
- Federal Law No. (20) of 1995 regarding medicines and preparations derived from natural sources
- Federal Law No. (24) of 1999 regarding Protection and development of the environment and its amendments and its executive decree
- Federal Law No. (15) of 2009 on tobacco control
- Federal Law No. (14) of 2014 Concerning the Control of Communicable Diseases -
- Federal Law No. (4) for the year 2015 concerning private health facilities (updated)
- Federal Law No. 10 of 2015 on Food Safety
- Federal Law No. (4) of 2016 on Medical Liability
- Federal Law No. (5) for the year 2016 on regulating the transplantation of human organs and tissues.
- Federal Law No. (8) of 2016 on Combating Narcotics and Psychotropic Substances (Updated)
- Federal Law No. 12 of 2018 on Integrated Waste Management.
- Federal Law No. (5) of (2019) in regulating the practice of the profession of human medicine
- Federal Law No. (7) of (2019) regarding medical assistance for reproduction

- Federal Law No. (8) of 2019 regarding medical products, the profession of pharmacy, and pharmaceutical facilities

- Decisions of the Council of Ministers

    - Decision of the Council of Ministers No. (7) for the year 2008 on the system of medical examination of expatriates of the state of work or residence amended by the Cabinet Decision No. 5 of 2016 amending certain provisions of Council of Ministers Decision No. (7) for the year 2008 regarding the system of medical examination of expatriates of the state for work or residence.

    - Decision of the Council of Ministers No. (29) for the year 2010 on the system of prevention of the community of HIV and the protection of the rights of PLWH.
    - Decision of the Council of Ministers No. (24) for the year 2013 concerning the executive regulation of Federal Law No. (15) for the year 2009 concerning tobacco control.
    - Decision of the Council of Ministers on the executive regulations of Federal Law No. 10 of 2015 on food safety

- Decision of the Council of Ministers on the executive regulations of Federal Law No. 10 of 2015 on food safety.
    - Decision of the Council of Ministers No. (39) for the year 2015 regarding strategic medical stocks.
    - Council of Ministers Decision No. (33) of 2014 on the Control of Communicable Diseases.
    - The Council of Ministers' Resolution No. (20) for the year 2017 adopted standard standards for the licensing of health professionals in the state.
- • Decision of the Council of Ministers No. (21) for the year 2018 on regulating the marketing of products related to infant and young child feeding
- Cabinet Resolution No. (40) for 2019 in the matter of the executive regulations of Federal Decree-Law No. (4) for 2016 regarding medical liability.

- **<u>Ministerial decisions</u>**

    - Ministerial Decree No. (932) for the year 2012 regarding the sanitary and technical conditions to be available in private pharmacies.
    - Ministerial Decree No. (60) for the year 2013 regarding the sanitary and technical conditions to be met in private medical warehouses.
    - Ministerial Decision No. 14 of 2016 on the Control of Imported Food for Non-Commercial Purposes

- Ministerial Decision No. (872) for the year 2016 regarding strategic medical stocks.
- Ministerial Decision No. (888) for the year 2016 regarding the rules and regulations for the prescription and disbursement of narcotic drugs and control and semi-control.
- Ministerial Decision No. (1110) for the year 2016 regarding scientific offices.

- Ministerial Decree No. 433 of 2017 on the National System of Fast Food Warning
- Ministerial Resolution No. (550) for the year 2017 regarding the criteria for the diagnosis of death.
  - Ministerial Decision No. (1412) for the year 2017 on the adoption of the Guide to the Practice of marketing and circulation of medical products
- Ministerial Decree No. 1448 of 2017 on the adoption of the Code of Ethics and Professional Conduct for Health Professions.
  - Ministerial Resolution No. (172) for the year 2018 regarding the adoption of the Manual on Handling of Biological Waste - Second Edition.
- Ministerial Decision No. 239 of 2018 on the National Food Accreditation and Registration System.

- **Local regulation ,policies , Guideline**
- **Abu- Dhabi Health Authority**
  -

- Brochures
  - Health Professionals Handbook (2017).
- Policies
  - Quality and Patient Safety Policy (2017).
  - Health Department's Emergency and Crisis Management Policy (2017).
- Evidence
  - Department of Health / Abu Dhabi Department of Antimicrobial Monitoring Programs (2017).
  - Abu Dhabi Health Department / Abu Dhabi Malaria Prevention Guide for Travelers from the Emirate of Abu Dhabi to Malaria-Endemic Areas (2018)

- **Dubai health Authority**
  -

- Policies
- Laboratory Accreditation Policy (2016)

- Infectious Diseases Policy for the Emirate of Dubai.

- Guidelines
  - Guidelines for the control of dental disease infection (2012).
  - Pharmacy Licensing Guidelines and Pharmaceutical Practices at Community Pharmacies in Dubai (2013).
  - Platelet-rich plasma action (2014).
  - Clinical Care Point Guidelines (2016).

- Guidelines for vaccinations

Appendix (5): Transport of Infectious Substances

Category A – Infectious Substances

An infectious substance which is transported in a form that, when exposure to it occurs, is capable of causing permanent disability, life threatening or fatal diseases in otherwise healthy humans or animals.

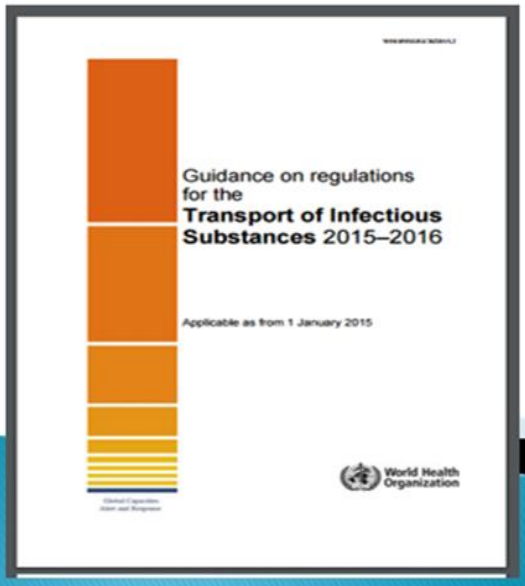
Category B – Biological Substances

An infectious substance which does not meet the criteria for inclusion in Category A and has not been determined by a medical professional to have a minimal likelihood that pathogens are present.

Exempt human/animal samples

Medical assessment has determined a minimal likelihood that pathogens are present

http://apps.who.int/iris/bitstream/10665/149288/1/WHO_HSE_GCR_2015.2_eng.pdf?ua=1



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