Medical Laboratory Science Council of Nigeria

Guidelines On Biosafety an Biosecurity in Nigeria

Plot 1166, Muhammad N. Umar lane,
Durumi Phase II,
Garki, Abuja
Email – info@mlscn.gov.ng
Website – www.mlscn.gov.ng

This guide does not purport to be an interpretation of law and/or regulations and is for guidance purposes only.

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SECTION ONE

Chapter 1 - Introduction

Scope

The handling of pathogens or their toxins cannot be done without the knowledge and application of special procedures for safety. The release of human and animal pathogens and toxins from laboratories or other containment facilities poses a risk to public health, animal health, or both. These risks can be minimized through the application of appropriate biosafety and biosecurity principles and practices.

Biosafety is the application of knowledge, techniques and equipment to prevent personnel, laboratory and environmental exposure to potentially infectious agents or biohazards. Biosafety defines the containment conditions under which infectious agents can be safely manipulated.

Laboratory Biosecurity is a set of preventive measures designed to reduce the risk of intentional removal (theft), release, or misuse of valuable biological material in order to cause harm to others.

There has been an increase in emerging and re-emerging infectious diseases with consequent morbidities and mortalities; so also has there been increase in agitations and violence, including use of valuable (select) biological agents and toxins as weapons of destruction.

It is therefore instructive that MLSCN, as a regulatory agency, provides guidelines to obviate these concerns, based on national and international regulations and global best practices.

Medical Laboratory Science Council of Nigeria (MLSCN) has developed this standard to guide practitioners working in laboratories where human pathogens or toxins are handled or stored, such as public health laboratories, teaching and research laboratories, diagnostic laboratories in hospitals, and vaccine production plants, with the intent to regulate and standardized procedures for biosafety and biosecurity. MLSCN will ensure that all Laboratory facilities have the statutory requirements/permit in accordance with these regulations and that they follow these requirements, and that all reasonable precautions have been taken to protect the health and safety of the public against the risks associated with the materials in their possession.

Regulatory Authorities

Medical Laboratory Science Council of Nigeria (MLSCN) is the National authority on the regulation and standardization of Medical Laboratory services, practices and systems as provided under the Medical Laboratory Science Council Act (CAP M25, LFN, of 2004). Thus, under the law is warranted to make regulations on all matters that guarantee biosafety and biosecurity in the laboratories. This is without prejudice to the National Biosafety Management Agency (NBMA) Act 2015, whose scope is limited to regulations of genetically modified organisms and the regulation of the application of modern biotechnology as it applies to agricultural development and food security.

This regulation and guideline will be used to verify the ongoing compliance of regulated facilities.Compliance with the physical containment, operational practice, and performance and verification testing requirements, respectively described in this regulation will help prevent the inadvertent release of pathogens or toxins, which could potentially pose significant risks to the health of humans or animals, the environment, or the economy.

In some instances, facilities may need to be upgraded or renovated to meet some of the physical containment requirements outlined in this guideline. As per the current compliance and enforcement program, MLSCN will review non-compliance items on a case-by-case basis. Regulated parties are encouraged to discuss non-compliance items with relevant MLSCN department to determine a timeframe for compliance based on the level of risk and the risk mitigation strategies in place or to determine if alternative mitigation strategies can be implemented for these items.

Legislative and Regulatory Requirements for Human Pathogens and Toxins.

Under this guidance, facilities conducting controlled activities involving human pathogens or toxins shall have to comply with specific requirements in addition to the requirements described above. A summary of these requirements will be described hereunder and shall not however, be considered exhaustive, and persons conducting controlled activities with human pathogens or toxins are to refer to the specific sections of the guideline for a complete understanding of the requirements. It remains the responsibility of the facility (regulated party) to understand their obligations under guideline, in addition to the applicable requirements set out in this guideline and their conditions of permit or licence.

SECTION TWO

LABORATORY BIOSAFETY

Chapter 2 - How to Use the Biosafety Standard

This guideline prescribes the containment level, the physical containment requirements, operational practice requirements, and performance and verification testing requirements for facilities where pathogens, toxins,or other regulated infectious material are handled or stored. In this context, "handling or storing" pathogens or toxins includes possessing, handling, using, producing, storing, permitting access to, transferring, importing, exporting, releasing, disposing of, or abandoning such material.

Containment Levels and Containment Laboratory Facilities

Containment level refers to the minimum physical containment and operational practices required for containment facilities where infectious material or toxins can be safely handled. This guideline describes the containment levels ranging from the lowest level permitted to work with pathogens, toxins, and other regulated infectious material to the highest level of containment. A containment facility itself is a physical area that meets the requirements for a specified containment level. This can be a single room (e.g., a laboratory) or a series of co-located rooms (e.g., several non-adjoining but lockable laboratory work areas), or it can be comprised of several adjoining rooms of the same containment level comprised of dedicated laboratory work area and support areas, such as anterooms, change rooms, storage rooms, preparation areas, wash up rooms, centralized autoclave room). A containment facility may include one or more work areas of different types (i.e., laboratory work area, large scale production area, animal work areas), as long as they are of the same containment level.

Working with Human and Animal Pathogens and Toxins

Pathogens

A pathogen is a microorganism, nucleic acid, or protein capable of causing disease in humans or animals. This can include bacteria, viruses, fungi, parasites, prions, recombinant DNA, genetically modified microorganisms, viral vectors, and synthetic biology products. Thus, any isolate of a pathogen or any biological material that contains human or animal pathogens is referred to as "**infectious material**" and therefore a **“Biohazard.”**

Toxins

Biological toxins are poisonous substances that are a natural product of the metabolic activities of certain microorganisms, plants, and animal species. Unlike pathogens, toxins are non-infectious and unable to propagate when isolated from the parental organism. However, in this guideline, the word "toxin" refers only to microbial toxins. In general, toxins capable of producing human or animal disease are safely handled in a defined containment level facility 2, at a minimum. Additional physical containment or operational practice requirements may be necessary, based on risk assessment.

Prions

Prions are small, proteinaceous, infectious particles that are generally considered to be the cause of a number of fatal progressive neurodegenerative diseases in humans and animals, known as transmissible spongiform encephalopathies. The most likely route of transmission of infectious prions is through inoculation or ingestion. Prions are resistant to **decontamination** procedures and processes commonly effective against other pathogens. Activities involving infectious prions are generally assessed to be safely conducted at containment level 2 facilities with specific additional physical and operational requirements.

Valuable Biological Agents

Valuable biological agents (VBAs) are human pathogens and toxins that have been determined to pose an increased biosecurity risk due to their inherent dual-use potential for bioterrorism. A toxin present in a facility in a quantity below the trigger quantity will not be considered VBA; however, it remains a regulated toxin, and subject to the requirements as contained herein. For ease of reference, the MLSCN shall maintain an exhaustive list which shall be reviewed from time to time.

Layout:

The requirements for facilities where pathogens, toxins, and other regulated infectious materials are handled or stored are provided in this guideline. The requirements are risk- and evidence-based, and, where possible, more performance-based than explicitly prescriptive i.e the physical containment requirements (i.e., engineering controls and facility design) that are to be met prior to the handling or storing of infectious material or toxins. The guideline also provides the operational practice requirements (i.e., administrative controls and procedures) to be implemented in order to mitigate risks and protect personnel, the community, and the environment in relation to the handling of infectious material or toxins. It also provides the requirements for the performance and verification tests necessary to demonstrate compliance with the physical containment requirements outlined in this guideline and, in some cases, the operational practice requirements.

Chapter 3 - Physical Containment Requirements

Structure and Location

The site selection process for a containment facility generally includes a risk assessment. Consideration of the risks, including the impact of possible pathogen or toxin release, is important at the beginning of the design phase and before construction work begins. In areas prone to natural disasters, buildings and support systems for containment facilities may need to meet more stringent building codes.

Containment Barrier

The **containment barrier** refers to the physical structure(s) or obstruction(s) present that create a boundary between the "clean" and "dirty" areas of a **containment facility**. The containment barrier itself is created by the walls, doors, floors, and ceilings of a room that physically enclose the areas where **infectious material**, **toxins**, and/or infected animals are handled or stored. In containment facilities where **inward directional airflow** is provided, the containment barrier is also maintained through negative air pressure differentials and inward directional airflow. Points of access through the containment barrier are provided through doors and **anterooms**. Equipment such as **dunk tanks**, **pass-through chambers**, and double-door barrier autoclaves, are examples of penetrations of the containment barrier.

Access

Physical and security barriers (e.g., doors, locks, anterooms, interlocks) at points of entry into and exit from the containment facilities are critical to maintaining containment integrity and allowing only trained and authorized individuals, access to the Laboratory facility. In high containment Laboratories, the physical barriers help maintain inward directional airflow (IDA) and provide space so that contaminated or potentially contaminated personal protective equipment (PPE) remains inside the containment barrier.

Surface Finishes and Casework

Selecting the appropriate surface finishes and casework for containment Laboratories is necessary to facilitate the maintenance, cleaning, and decontamination of surfaces within the Laboratory. Surface finishes also help protect against the stresses associated with activities routinely performed within the containment Laboratory facilities, such as repeated decontamination and frequent high pressure washing.

Table 3.1: Summary of Biosafety Level Requirements

	BIOSAFETY LEVELS			
	1	2	3	4
Isolation 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 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 Cabinet	No	Desirable	Yes	Yes
Personnel Safety Monitoring Capability[d]	No	No	Desirable	Yes

[a]*Environmental and functional isolation from general traffic*
[b]*Dependent on location of exhaust*
[c]*Dependent on agent(s) used in the laboratory*
[d]*For example, windows, closed-circuit television, two-way communication*

Air Handling

The heating, ventilation, and air conditioning (HVAC) systems can be designed to create a defined containment barrier to minimize the spread of infectious aerosols or aerosolized toxins. These systems, particularly in high containment Laboratories,

incorporate secondary containment barriers such as inward directional airflow (IDA) and high efficiency particulate air (HEPA) filters for exhaust air.

Facility Services

Facility services include all plumbing, electrical, and other services related to the operation of the containment Laboratory.

Essential Biosafety Equipment

Essential biosafety equipment is key to ensuring effective containment of pathogens, toxins, and other regulated infectious materials. This includes all primary containment devices (e.g., biological safety cabinets (BSCs), isolators, centrifuges with sealable cups, process equipment, fermenters, microisolator cages, ventilated cage racks, sealed biological waste containers).

Effluent Decontamination Systems

Effluent decontamination systems prevent the release of contaminated liquids into sanitary sewers, and ultimately, the environment. An effluent decontamination system is critical for decontaminating all liquid waste generated in containment laboratories.

Chapter 4 - Operational Practice Requirements

Biosafety Program Management

This chapter describes the operational practice requirements designed to mitigate risks associated with handling or storing pathogens, toxins, or other regulated infectious material, including infected animals. Operational practice requirements are achieved through specific administrative controls and by performing specific documented procedures. Although the requirements in this chapter are specified for each containment Laboratory, institutions or organizations may decide to combine certain biosafety program elements (e.g., Biosafety Manual, biological safety officer (BSO), biosecurity plan) for multiple containment laboratories as determined by an overarching risk assessment. The majority of requirements in this chapter are to be based on a risk assessment (RA) whether it is indicated in the text or not.

Medical Surveillance Program

The medical surveillance program aims to prevent and detect illnesses related to exposure of personnel to pathogens or toxins and to provide a response mechanism through which potential infections and intoxications can be quickly identified and treated before serious injury, disease, or transmission to the public occurs.

Training Program

Training and retraining is a core element of **biosafety** and **biosecurity**, and is essential to the success of the biosafety program. It is critical that Laboratory personnel be knowledgeable about the hazards associated with the **pathogens** and **toxins** present in the work environment and the practices and tools that can protect them from these hazards. The training program should encompass both didactic (i.e., theoretical) and practical.

Personal Protective Equipment

Personal protective equipment (PPE) includes protective equipment and clothing that are designed to minimize the **risk** of **exposure** to **pathogens** and **toxins**. PPE serves as a last line of defence to prevent exposure in the event of failure in the administrative or engineering controls. Selection of PPE is determined by a **risk assessment** (RA) and is specific to both the pathogen(s) and the work activities/practices to be performed.

Entry and Exit of Personnel, Animals, and Material

The operational practices for entry/exit are critical to maintaining containment integrity and ensuring that only trained and authorized individuals can access the **containment laboratory.** Laboratories can develop SOPs that outline essential elements for entry and exit procedures.

Work Practices

Adherence to safe work practices when handling infectious material or toxins helps protect personnel from exposure to pathogens and toxins, and helps prevent

their release. Good laboratory work practices are the foundation for all safe work practices involving biological materials. In containment laboratories where infectious materials and toxins are handled or stored, safe work practices include the proper use and maintenance of biocontainment systems, biosafety equipment (e.g., biological safety cabinets (BSCs), centrifuges), as well as aspects of general containment Laboratory maintenance (e.g., tidiness, clutter). Safe work practices should be documented in standard operating procedures (SOPs) so they can be easily understood and implemented by all personnel.

Decontamination and Waste Management

Effective decontamination of waste is critical in all containment Laboratories so that contaminated material is treated and safely disposed of. The principles of sterilization, disinfection, and decontamination are essential for reducing the risk of pathogen and toxin transmission within containment facilities or release to the environment or the community. Decontamination and waste management procedures documented in standard operating procedures (SOPs) can be easily understood and implemented by all personnel (Refer to MLSCN guideline on waste management & Decontamination)

Records and Documentation

A biosafety program will generate records for most activities. These records provide evidence that a specific activity was performed, document of the results achieved, and can also be used for the ongoing improvement of the biosafety program.

Summary of Biological Containment Levels/ Safe Work Practices

This takes into account multiple factors and how organism is used in the workplace. Details include physical requirements and operational practices.

Appropriate work practices described by the US Centers for Disease Control (CDC) and NIH are selected based on the assigned Risk Group of the specific microorganism. Work practices are divided into Biosafety Levels (BL) 1 through 4, which containment range from the lowest biosafety level 1 to the highest at level 4. These are called *BSL1* through *BSL4*, with one anomalous level *BSL3-ag* for agricultural hazards between BSL3 and BSL4. Higher numbers indicate a greater risk to the external environment.

Biosafety levels

A biosafety level is the level of the bio-containment precautions required to isolate dangerous biological agents in an enclosed facility. Each level requires specific practices, design criteria and barriers. The level of biosafety practices correspond to the risk group of the microorganisms.

Biosafety level 1

Biosafety Level 1 Suitable for work involving well-characterized agents not known to consistently cause disease in healthy adult humans and of minimal potential hazard to laboratory personnel and the environment. It includes several kinds of bacteria and viruses including canine hepatitis, non-pathogenic *Escherichia coli*, as well as some cell cultures and non-infectious bacteria.

At biosafety level 1, the laboratory is not necessarily separated from the general traffic patterns in the building and work is generally conducted on open bench tops using standard microbiological practices. Precautions against the biohazardous materials in question are minimal.

Work practices at BSL1

- Limit access to the laboratory when experiments or work with cultures and specimens are in progress (at the discretion of the laboratory director).
- Do not eat, drink, store food, apply cosmetics, smoke, or chew gum in areas where microorganisms are stored or handled.
- Food for human consumption should be stored outside of work areas in cabinets or refrigerators designated and used for this purpose only.
- Do not mouth pipette - always use mechanical devices
- Do not touch your face, eyes, nose, or mouth while working with microbial agents.
- Avoid spills and the production of aerosols and droplets when manipulating organisms.
- Always wash hands after handling micro-organisms, upon removing gloves, and when leaving the laboratory.
- Ensure laboratories are equipped with hand-washing and eyewash facilities.
- Use lab coats when handling microorganisms.
- Wear gloves if the skin on the hands is broken or if a rash is present.
- Provide alternates to powdered latex gloves, which can irritate hands.
- Wear protective eyewear when applicable.
- Persons who wear contacts should also wear goggles or a face shield.
- Know potential modes of transmission of agents in your laboratory.
- Decontaminate work surfaces before and after use, and immediately after spills of microbial agents.
- Decontaminate all laboratory waste such as cultures, stocks, and other regulated waste.
- Institute policies for the safe handling of sharps.
- Do not use carpet or rugs in the laboratory.

Biosafety level 2

Biosafety Level 2 is suitable for work involving agents of moderate potential hazard to personnel and the environment. It includes various bacteria, parasites and viruses that cause only mild disease to humans but not contracted via aerosol in a laboratory setting. Primary exposure is through ingestion, injection, and mucous membranes. Genetically modified organisms have also been classified as level 2 organisms. Examples include Measles virus, *Salmonellae, Toxoplasma* species, *Hepatitis* B virus.

Work practices at BSL2

- Limit access to the laboratory
- Label area with biohazard symbol where RG-2 microorganisms are stored or handled.
- Use secondary containment for storage and transport of microbial agents.
- Wear protective laboratory coats while in the laboratory.
- Always remove protective laboratory coats before leaving work area and have procedures in place for decontamination within the laboratory before sending for laundry.
- Workers should not take garments home to launder.
- Wear gloves when handling infectious materials, contaminated surfaces or equipment.
- Dispose gloves when overtly contaminated or when the integrity of the glove is compromised.
- Do not wash or reuse disposable gloves.
- Do not touch clean surfaces (such as telephones and keyboards) with gloves.
- Do not wear gloves outside the laboratory.
- Wash hands after removing gloves.
- Use appropriate Class I or II Biological Safety Cabinets for procedures that could result in splashes, spills, or aerosol production. (Class II are preferred).
- Class 2 biological safety cabinets required for procedures generating aerosols; certified annually, HEPA-filtered air can be re-circulated.

- Ensure that the laboratory facilities are adequate.
- Receive appropriate training on the potential hazards associated with the specific work involved.
- Centrifuge must be covered with safety caps/ covers and must not be opened immediately after centrifugation.
- Have appropriate safety Signages
- Doors should be self-closing
- Coat hooks for laboratory coats near exit laboratory located away from public areas, general areas,
- There must be patient care areas
- Floors, walls and furniture must be impervious for disinfection
- An autoclave must be in or near laboratory
- Inward directional airflow recommended

- PPE: Gloves, laboratory coat, and eye protection as required
- Emergency plan (i.e. spills)
- Vacuum lines protected by HEPA filters or Equivalent
- Contaminated glassware cannot leave facility

- Cleaning staff aware of hazards
- Medical surveillance program as required:
  Develop and maintain a written biosafety manual establishing policies and procedures specific to the laboratory and work conducted.

- The biosafety manual should describe:
  - Hazards of the work conducted
  - Waste and spill decontamination procedures
  - Emergency procedures
  - Specific safety precautions

- Use of biological safety cabinets, other safety equipment or other engineering controls
- Other appropriate safety information

Biosafety level 3

This level is applicable to medical laboratory facilities in which work is performed with indigenous or exotic agents (Risk group 3) which may cause serious or potentially lethal disease after inhalation. It includes various bacteria and viruses that can cause severe to fatal disease in humans but for which treatments exist. Examples: *Mycobacterium tuberculosis,* St. Louis encephalitis virus, *Coxiella burnetii.*

Work practices at BSL 3

- Conduct all work, in an appropriate Class II or III Biological Safety Cabinet.
- Do not conduct any work with open vessels on the open bench.
- Perform those operations that cannot be conducted in a BSC using the appropriate personal protective equipment (face mask or full-face respirator as appropriate) and engineering controls (centrifuge safety cups).
- Decontaminate laboratory waste within the laboratory prior to removal.
- Do not permit animals and plants unrelated to the work being conducted in the work area.
- Access to the laboratory must be through two sets of self-closing doors and a clothes change room in the passageway.
- Hand-washing sink must be foot, elbow, or automatically-operated.
- Laboratory windows must be closed and sealed.
- Ventilation of the laboratory must be designed to protect the laboratory worker with 100% in-and out- with no re-circulation.
- Ventilation should be designed such that the direction of airflow is from clean to contaminated areas.
- The Institutional Biosafety Committee and the Biological Safety Officer should evaluate the adequacy of the ventilation design from time to time.
- High Efficiency Particulate Air (HEPA) Filters must be used on Biological Safety Cabinets.
- Vacuum lines are to be protected with liquid disinfection traps and HEPA filters.
- Continuous flow centrifuges or other equipment that may produce aerosols are to be contained in devices that exhaust air through HEPA filters before discharging into the laboratory.
- Facility must be tested and certified annually
- Specialized training
  • Other PPE as required (head covers, foot covers, dedicated front laboratory coat, respirators)
  • No personal effects

Biosafety level 4

Biosafety Level 4 is suitable for work with dangerous and exotic agents that pose a high individual risk of aerosol transmitted laboratory infections and life-threatening disease. Agents cause severe to fatal disease in humans and vaccines or other treatments are *not* available Examples: Ebola Zaire virus, Rift Valley Fever virus.

Work practices at BSL4

- When dealing with biological hazards at this level the use of a Hazmat suit and a self-contained oxygen supply is mandatory.
- The entrance and exit of a BSL 4 will contain multiple showers, a vacuum room, an ultraviolet light room, and other safety precautions designed to destroy all traces of the biohazard.
- Multiple airlocks are employed and are electronically secured to prevent both doors opening at the same time.
- All air and water service going to and coming from a BSL4 laboratory will undergo decontamination procedures to eliminate the possibility of an accidental release.
- Agents with a close or identical antigenic relationship to BSL4 agents are handled at this level until sufficient data is obtained either to confirm continued work at this level, or to work with them at a lower level.
- Members of the laboratory staff have specific and thorough training in handling extremely hazardous infectious agents.
- They are supervised by qualified scientists who are trained and experienced in working with these agents.
- Access to the laboratory is strictly controlled by the laboratory director.
- The facility is either in a separate building or in a controlled area within a building.
- The facility is completely isolated from all other areas of the building.
- A specific facility operations manual is prepared or adopted.
- Building protocols often use negatively pressurized facilities to inhibit release of aerosol pathogens.
- Within work areas of the facility, all activities are confined to Class III biological safety cabinet.
- Class II biological safety cabinets used with one-piece positive pressure personnel suits ventilated by a life support system.

SECTION THREE

LABORATORY BIOSECURITY

Chapter 5- Introduction to Biosecurity and Risk Assessment

Laboratory Biosecurity is a set of preventive measures designed to reduce the risk of intentional removal (theft), release, or misuse of valuable biological material in order to cause harm to others.
Securing biological materials in the laboratory can be challenging. Viruses and Bacteria can multiply, making them difficult to count and keep track of in the laboratory. One needs only steal a small amount and more can always be grown from that seed stock. Detection of theft is almost impossible and more so, Laboratories do not often think of themselves as needing to be secure – this often requires a cultural change toward security.

For most laboratory workers, the idea that their biological materials could be desired for intentional misuse is foreign; in academic settings, openness is valued; in a clinical setting, security does not typically consider biological materials.

Need to Secure "Select Agents"

Select Agents are microbes and toxins that could be used as Biological Weapon agents. The aim of biosecurity is to mitigate Biological Weapon threat at the source by preventing terrorists or proliferant states from acquiring select agents from government, commercial, or academic facilities.

Biosecurity Risk Assessment

Risk Assessment is an evaluation of the probability and consequences of undesirable events caused by an adversary that could affect the defined assets. The goal is to determine which events the security system must be designed to protect against. A proper Risk Assessment is mandatory to determine security needs. This will include Asset assessment, Threat assessment and Vulnerability assessment.

Vulnerability Assessment- This is a systematic evaluation process in which qualitative and quantitative techniques are applied to arrive at an effectiveness level for a security system to protect biologic laboratories and operations from specifically defined acts that can oppose or harm a person's interest.

Five Step Risk Assessment-

i. Identify and prioritize assets as follows:
   -Identify agents, materials, equipment, personnel
   -Evaluate potential misuse or weaponization
   -Evaluate consequence of misuse
   -Prioritize assets based on consequence of misuse

ii. Assess potential threats and vulnerabilities
   -Identify types of **outsiders**
   -Identify types of **insiders**

-Evaluate **motive, means, opportunity** for potential adversaries

iii. Analyze the risk of specific security scenarios
-Develop list of possible security scenarios
-Evaluate probability of each scenario materializing and its consequences
-Prioritize or rank scenarios by risk for management to review

iv. Design and develop an overall risk management program

v. Re-evaluate institution's risk posture and protective objectives

Chapter 6- Biosecurity Risk Mitigation

Biosecurity Risk Mitigation is the process whereby risks identified and characterized during a Risk Assessment are reduced through active intervention, be it physical or procedural. Biosecurity Risk Mitigation should be based on a Risk Assessment including analyzing hypothetical scenarios with a defined agent, adversary, and a particular way that adversary will attempt to steal and/or misuse the biological material.

There are five pillars of Biosecurity Risk Mitigation- Physical Security, Personnel Management, Material Control and Accountability, Transport Security and Information Security.

A. Physical Security

Physical Security is the assurance of safety from physical intrusion. An important concept in Physical Security is the concept of Graded Protection. This is based on the idea that different areas of a facility will have different levels of security based on risk. Graded Protection is manifested in concentric rings of increasing security, spanning from outside to inside the facility.

Graded Protection will include:

Property Protection Areas (**Low risk assets**)
- Grounds
- Public access offices
- Warehouses

Limited Areas (**Moderate risk assets**)
- Laboratories
- Sensitive or administration offices
- Hallways surrounding Exclusion Areas

Exclusion Areas (**High risk assets**)
- High containment laboratories
- Computer network hubs

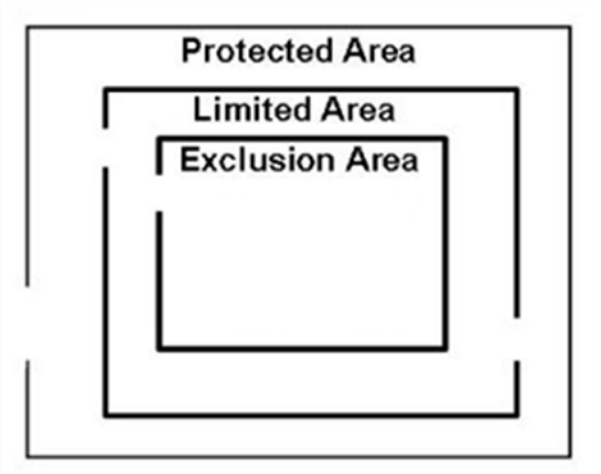

Fig 1.Concentric Layers of Security

Three principles of Physical Security include Detection, Delay and Response.

i. Detection: Intrusion Detection is the process of determining whether an unauthorized action has occurred or is occurring. Detection includes sensing the action, communicating the alarm, and assessing the alarm. Intrusion Detection can be as complicated as closed-circuit television system, infrared, motion sensors and guards patrolling throughout the facility, or, it could be as simple as good training of laboratory staff and a procedure to call someone in case a suspicious person is noticed in the laboratory.

ii. Delay: Delay is simply the act of slowing down an intruder's progress in your facility long enough so that the adversary may be detected, assessed and responded to.

There are many ways of delaying an intruder

- Guards
- Perimeter Fencing
- Solid doors with locks
- Bars on windows
- Magnetic locks on doors

iii. Response: Response is the act of alerting, transporting, and staging a security force to interrupt and neutralize an adversary. Based on your Risk Assessment and scenario analysis, Response can range from implementing a guard force in your facility to establishing a line of communication with your local police force.

Access Control

Access Control is the mechanism to determine and control authorized entry into secured areas. Access Control also provides capability to delay or deny unauthorized personnel. No person should bypass or be allowed to bypass access controls.

Access can be granted based on **Something you have** (Key, Card (Credential), **Something you know (**Personal Identification Number (PIN), Password) and/or **Something you are (**Biometric feature (i.e., fingerprints).

B. Personnel Management

Personnel Management, in the context of biosecurity, is the assurance that the people that are given access to sensitive biological materials should have that access.
The Objectives of a Personnel Management Program are to:
Understand that human factors can significantly impact the success of biorisk management.

- To reduce the risk of theft and fraud
- To reduce the risk of scientific misconduct
- To support the procedural and administrative access control requirements
- Etc

Some factors that can influence Human Performance will include- Job setting and values, Individual personalities and values and Organization's expectations and assessments.

Personnel Training – Security Awareness
Promoting security awareness in employees is one of the most important ways breaches in security can be recognized. Laboratory workers should be aware of who should be and should not be in their work areas, e.g. a person with the wrong type of badge. There should also be a proper assessment of the **risk** of **insider** versus **outsider** threat.
An **insider** is a person who has authorized access to a facility, its units (such as laboratories), and its assets while an **outsider** is a person who does not have authorized access.

C. Material Control & Accountability

Material Control and Accountability (MC&A) is the assurance that there is an awareness of what exists in the laboratory, where it is, and who is responsible for it.
The Objective of MC&A is to:

- Ensure the complete and timely knowledge of: What materials exist, where the materials are and who is accountable for them.

The objective is NOT to detect whether something is missing but to create an environment that discourages theft and misuse by establishing oversight, which is also important from a security perspective.
Key Issues in MC&A are-

- What materials are subject to MC&A measures?
- What operating procedures are associated with the materials?
  - Where can they be stored and used?
  - How are they identified?
  - How is inventory maintained?
- What records need to be kept for those materials? What timeliness requirements are necessary for those records?
- What does accountability mean?
- What documentation and reporting requirements?

- What information should we keep track of?

Some examples of information to keep track of include:
Agent- Which agents? Are they viable organisms? Are they whole organisms or just DNA?
Quantity- Any amount of a replicating organism can be significant. For toxins, must define a threshold amount.
Form – Are they Repository Stocks or Working Samples; Agent in host or Contamination?
Detail - Materials as Items. Each vial as a separate inventory record?
Scope- Are they laboratory Strains, Wild-type or Clinical Samples?
All material should have an associated "accountable person" who is ultimately responsible for the material.

D. **Transport Security**

Transport Security is the assurance that the same rigorous processes that protect biological materials in the laboratory follow those materials when they are transported outside laboratory areas.

Transport Security aims to reduce the risk of illicit acquisition of *high-risk* biological agents as well as relies on chain of custody principles and end-user agreements.
High risk agents are routinely shipped worldwide for diagnostic and research activities and this is both local and international concern.
Transport is the movement of biological material outside of a restricted area (eg Research laboratories, Public health laboratories and diagnostic laboratories).
Transport can occur across international borders, within a country or within a facility
Internal Transport, which is the movement of materials to and from restricted areas within a facility, may involve Personnel from laboratory, Shipping areas, Receiving areas and Disposal areas (e.g. autoclave and incinerator rooms). In order to move materials safely and securely, there should be pre-approval process and established Chain of custody (CoC).
External Transport, which is the movement of materials from one facility to another may involve commercial carriers and occurs within a wide array of international and state regulations and standards.

Chain of Custody (CoC), aims to protect sample by documenting all individuals who have control of sample as well as securing receipt of material at appropriate location.
Chain of custody documentation includes:

- Description of material being moved
- Contact information for a responsible person
- Time/date signatures of every person who assumes control

To keep high-risk samples secure during transport, the followings should be considered.

- Require a responsible authority to pre-approve all transport
- Advise eligible receiving party of transport
- Document transport in lab records
- Ensure only trustworthy people handle the samples
- Physically secure samples in transit with special packaging and/or locks
- Control movements and document in delivery records
- Use timely shipping methods
- Maintain a Chain of Custody

- Request notification of receipt

It must be emphasized that a proper Risk Assessment can help determine transport security needs.

E. Information Security

This is the fifth "pillar" of BioSecurity Risk Mitigation.
Information Security is the assurance that the sensitive and valuable information stored in a laboratory is protected from theft or diversion. Information Security may not be the most obvious area of biosecurity, but a failure here could have very severe consequences in terms of securing pathogens and toxins.
Document control and computer security is necessary to reduce risks in a facility. However, these can also be intrusive. Any policies implemented should be based on a robust risk assessment.
The Objective of Information Security is to:

- Protect information that is too sensitive for public distribution. Therefore,
  - Label information as restricted
  - Limit distribution
  - Restrict methods of communication
  - Implement network and desktop security
  - Restrict Biosecurity-related sensitive information such as Risk assessment and Security system design.
  - Implement Access authorizations

Identification, Control, and Marking are very important in Information Security

- **Identification** designates sensitivity level of the information. A review and approval process aids in the identification of sensitivities and are Critical prior to public release of information.
- **Control** assigns Individual responsible for control of sensitive information through Physical security and Communication security. In some countries, in order to refuse public access upon request, information must be exempt from the Freedom of Information Act
- **Marking** is also Sensitivity level designation which should include Top and bottom of each page / cover sheet. Marking and control methods should be well understood by those working with information.

Communication and Network Security
Communication Security includes:

- Mail, email, or fax security is required
- Limited discussions in open areas
- Information should only be reproduced when needed and each copy must be controlled as the original.

Network Security

- Firewalls
- User authentication

- Virus protection
- Layered network access
- Desktop security
- Remote and wireless access controls
    - Encryption
    - Authentication

Security Considerations for Network Systems

Administrators have full control

- The ultimate insider

Protect the system using procedures

- Two person control
- Configuration management
- Password control

Restrict operator privileges

Provide physical protection for equipment

Backup equipment and procedures must be provided to maintain security

Emergency power and uninterruptible power supply required for computers

Security Awareness

Security Awareness is general awareness of the proper security posture in the laboratory; where the risks are and what should be done. Most Laboratory facilities are not accustomed to worrying too much about security, so appropriate security awareness may require a very difficult cultural shift.

Security Awareness will be easier to achieve if personnel in the laboratory trust that a biosecurity risk assessment is accurate and robust.

If the people in the facility are aware of the true biosecurity risks they face, they will be more likely to:

a. Report if someone strange is walking around
b. Keep an eye on sample storage areas and assign security responsibilities to each other
c. Keep sensitive information safe
d. Provide suggestions for improving security
e. Take training more seriously
f. Etc…

SECTION THREE

Chapter 7- Emergency Response

Emergency Response

In order to promote personnel safety and the containment of pathogens and toxins, plans need to be in place for situations where biosafety or biosecurity issues may arise as the result of an emergency. Emergency situations may include incidents or accidents, medical emergencies, fire, chemical or biological spills, power failure, failure of primary containment devices (e.g., biological safety cabinet (BSC)), loss of containment (e.g., heating, ventilation, and air conditioning (HVAC)), theft of Select Agents and natural disasters.

Protocols for incident reporting and investigation are an integral component of an emergency response plan (ERP) as incidents may be indicative of deficiencies in biosafety and/or biosecurity systems. Therefore, each Laboratory facility must have an ERP and policy as well as Biosafety Committee that oversees such plan.

- Develop plan before emergency
- Involve all appropriate parties in planning
- Inform community-based responders
- Conduct drills & after-incident reviews

Report chain may be to Management, Public Relation, Security, Biosafety and Public Health/law enforcement.

- Unaccompanied visitors
- Missing agents
- Potential break-ins

Biosafety vs. Biosecurity

In Biosafety, the objective is to reduce or eliminate accidental exposure to or release of potentially hazardous agents, while in Biosecurity, the objective is to protect against theft or diversion of select agents. Simply put: Biosafety protects people from dangerous pathogens while Biosecurity Protect pathogens from dangerous people.

Conflicts between Biosafety and Biosecurity may arise due to and should be resolved to accommodate both sets of objectives.
Example (i):
Emergency Response: In an emergency, there is

- Rapid egress of laboratorians,
- Emergency ingress of responders

There is need to ensure security of assets
Life safety measures must not allow an adversary access to biological materials by activating emergency alarm systems.

Example (ii):
Signage Requirements

- Biohazard signage aims to reduce risks in laboratory
  - BSL, agent, medical requirements, PPE required, contact name/ number
- Listing agent may compromise security

Modify signage to not disclose specific agent(s)

Chapter 8 - Performance and Verification Testing Requirements

Conducting minimal performance and verification tests is necessary to demonstrate compliance with the physical containment requirements. Reports demonstrating the successful completion of these tests are to be submitted to the MLSCN in support of applications for a license for controlled activities with human pathogens and toxins. In addition, test reports will be monitored by MLSCN for ongoing compliance verification, including during on-site inspections and audits.

Performance and Verification Tests for All Containment Levels

A table of Performance and verification tests will be provided by MLSCN.

Performance and Verification Tests to be conducted on Commissioning of Containment Laboratory

In addition to the performance and **verification** tests to be performed as outlined above, there are other performance and verification tests to be performed by any **containment laboratory** at the indicated **containment levels** upon **commissioning** of the containment facility. Test reports documenting successful completion of these tests will be requested by MLSCN.

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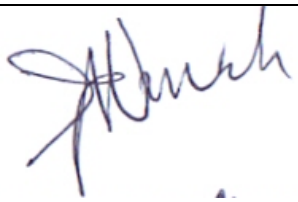
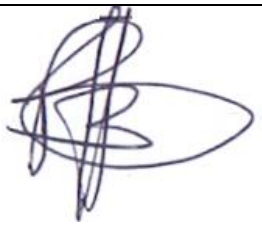
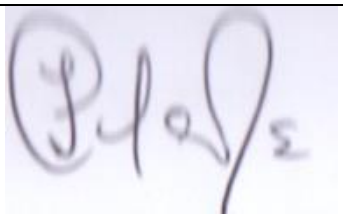
Contributors

S/N	Participant Name	Organization	Signature
1	ERHABOR, Tosan	Medical Laboratory Science Council of Nigeria	
2	AZEEZ, M. M.	Medical Laboratory Science Council of Nigeria	
3	UDO, Stella N.	Medical Laboratory Science Council of Nigeria	
4	NWOKAH, Easter G.	Rivers State University, Port Harcourt	
5	BARDE, Joshua B.	NEQAL Laboratory/ Medical Laboratory Science Council of Nigeria	
6	ADEOYE, Felix (Col.)	HIFASS	
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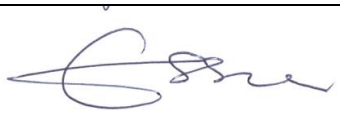
8	AIKPITANYI- IDUITUA, G. A.	Medical Laboratory Science Council of Nigeria	
9	RUBAINU, Manason G.	Peak Medical Laboratories Ltd.	
10	ESSIEN, Victor	Medical Laboratory Science Council of Nigeria	
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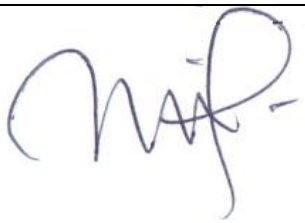
12	IFEANYI, CASMIR I. C. (Dr.)	University of Abuja	
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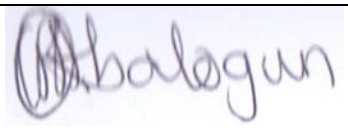
14	BALAGUN. Oyebimpe	Institute of Human Virology, Nigerian	
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16	AKINWALE, Abayomi Air Cdre (Rtd.)	USDOD Nigeria	

17	Tubi Abiola	NTBLCP