



National Biosafety and Biosecurity Policy and Guidelines

2022

Forward

The National Biosafety and Biosecurity policy and guidelines for Sierra Leone have been developed as a result of the need to promote a shared culture of responsibility, reduce dual use risks, mitigate biological proliferation and deliberate use threats, and ensure safe custody of biological agents. It's a synthesis of guidelines from the World Health Organization (WHO), the FAO, WOA, and IPPC as well as from national and local regulatory standards. The national and local regulatory standards and guidelines maybe reviewed from time to time, therefore, references shall apply to the most current versions.

Owing to the global increase in bio-risk resulting from disease outbreaks, emerging and re-emerging pathogens, and global bioterrorism threats, the development of this policy and guidelines is timely. Although continued biosciences research and biotechnological advances are important in guiding strategies and intervention for containment of emerging disease threats to human, animal and plant sectors as well as enhancing food security, these activities are associated with bio-risk. The bio-risks could be accidental, naturally occurring or even intentional, not only to laboratory and field workers but also to the community and the environment at large. In addition, personnel working with biological and non-biological hazardous materials are constantly exposed to these hazards. There is, therefore, an urgent need to ensure proper biosafety and biosecurity standards are in place and are adhered to, in order to protect personnel, the environment, and the community at large.

This policy and guidelines, therefore, will go a long way in guiding institutions to develop effective and efficient systems for the assessment and management of bio-risks, and ultimately help to protect themselves, colleagues, secure biological materials and also protect the environment. This document will be available for use within the human, animal, plant, environment sectors as well as other relevant sectors. The Government of Sierra Leone encourages all partners and stakeholders to support its dissemination and implementation in order to strengthen bio-risk management systems in the country. This document draws legal authority from the Public Health Ordinance 1960 (Revised version)

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Definition of terms

Biological risks:	Risks associated with pathogens, chemicals, or toxins
Bio-risk:	The probability or chance that a particular adverse event (in the context of this document: accidental infection or unauthorized access, loss, theft, misuse, diversion or intentional release), possibly leading to harm, will occur
Biosafety:	The containment principles, technologies and practices that are implemented to prevent unintentional exposure to pathogens and. toxins, or their accidental release
Biosecurity:	Institutional and. personal security measures designed to prevent the loss, theft, misuse, diversion or intentional release of pathogens and toxins
Competent:	State of having the necessary and sufficient ability, knowledge, judgement or skill to successfully execute one's role, responsibility or job
Operations:	The day-to-day activities of an ongoing safety program
Trained:	Having been taught a particular skill or type of behavior through practice and instruction over a period of time, and acquired the knowledge needed for a particular role, job or activity

Abbreviations

BSC	Biological Safety Cabinet
BSBS	Biosafety and Biosecurity
CWA	Cen Workshop Agreement
EIA	Environmental Impact Assessment
EPA	Environmental Protection Agency
FAO	Food and Agriculture Organization of the United Nations
HSE	Health Safety and Environment
IHR	International Health Regulations
IATA	International Air Transport Authority
IEC	International Electro -technical Commission
IPPC	International Plant Protection Convention
ISO	International Organization of Standardization
MDA	Ministries Departments and Agencies
MoHS	Ministry of Health and Sanitation
NaSCIA	National Security and Central Intelligence Act
NEMS	National Emergency Medical Services
NGO	Non-Governmental Organization
NPHA	National Pharmaceutical Association
NSRPA	Nuclear Safety and Radiation Protection Authority
OH	One Health
WOAH	World Organization for Animal Health
ONS	Organization of National Security
OSHA	Occupational Safety and Health Administration
PPE	Personal Protective Equipment
SOP	Standard Operating Procedure

TOR	Terms of Reference
TWG	Technical Working Group
US – CDC	United States Centers for Disease Control and Prevention
WHO	World Health Organization

Introduction

The proper handling of pathogens and microbial toxins is vital to counter the ever-evolving threat of infectious diseases, and, to improve the methods for pathogen prevention, detection and control, in order to facilitate the development of new vaccines and drugs. Any type of work with hazardous materials, however, poses additional risks, which should be considered and minimized to acceptable levels. Biological risks could be mitigated by introducing a comprehensive biosafety and biosecurity system.

Biosafety is fundamental to protect and to prevent the workforce and the wider community against any accidental exposure to or from release of pathogenic agents and toxins. Biosecurity complements biosafety by establishing adequate security measures in institutions involved in the handling, storage and/or disposal of pathogens, chemicals and toxins. Biosecurity aims at the prevention of pathogens and toxins from being lost, accessed by an unauthorized person, stolen, misused, or intentionally released into the community so that biological materials with economic and/ or historical value are secured.

The success of the bio-risk management system will depend on the commitment by leadership of the institutions under the One Health platform to provide adequate resources, prioritization and communication of biosafety and biosecurity policy and guidelines; integrating of bio-risk management throughout the various institutions and identifying opportunities for improvement and prevention, determining root causes and preventing recurrence.

This policy and guidelines are generic and is intended to be applicable to all Institutions handling biological agents, chemicals and/or toxins, regardless of type and size. Compliance with national and local regulatory standards and requirements, are of primary importance. Where any part of this document is in conflict with any legal requirement, the conflicting part of the policy and guidelines may be eligible for exemption if the legal requirement meets or exceeds the intent of this document.

1.1 Scope

This policy and guidelines will be used by all institutions in Sierra Leone using the One Health Approach. The guidelines apply to all activities involving biological agents, chemical substances,

toxins, and all personnel working with these agents. Persons handling or storing infectious materials or toxins for in-vitro or in-vivo work are to comply with this policy and guidelines, as applicable. Compliance with the physical containment and operational practice requirements described herein will help prevent the inadvertent release of infectious materials or toxins, which could potentially pose significant risks to the health of humans and/or animals, the economy and/or the environment.

This detailed integrated national Biosafety and Biosecurity policy and guidelines is intended to guide government, private and research institutions to develop policies, programs and codes of practice. It is meant to be as comprehensive as possible, for use as a reference material and as a resource for development of appropriate manuals and standard operating procedures (SOPs) for different levels and types of institutions.

2. Bio-risk management system requirements

2.1. General requirements

2.1.1 Bio-risk management system

The institutions shall establish, document, implement and maintain a bio-risk management system in accordance with the requirements of this biosafety and biosecurity policy and guidelines.

2.1.2. Continual improvement

The institutions shall continually improve the effectiveness of the bio-risk management system through the use of the policy objectives, self-audit programme, audit results, analysis of data, risk assessment, corrective and preventive actions and management review.

2.2 Policy

2.2.1 Bio-risk management policy

The leadership of the institutions shall develop, authorize and sign a policy concerning the management of bio-risk (biosafety and biosecurity). It shall clearly state the overall bio-risk management objectives and a commitment to improving bio-risk management performance.

The policy shall be appropriate to the nature and scale of the risks associated with the institution and associated activities and commit to:

- a) Protecting staff, contractors, visitors, community and environment from biological agents and toxins that are stored or handled within the institution
- b) Reducing the risk of unintentional release of, or exposure to biological agents and toxins
- c) Reducing the risk to an acceptable level of unauthorized intentional release of hazardous biological materials, including the need to conduct risk assessments and implement the required control measures
- d) Complying with all legal requirements applicable to the biological agents and toxins that will be handled or possessed, and with the requirements of this document
- e) Ensuring that the need for effective bio-risk management shall take precedence over all non “health and safety” operational requirements

- f) Effectively informing all employees and relevant third parties and communicating individual obligations with regards to bio-risk management to those groups
- g) Ensuring that contractors that supply to or collect materials from their institution adhere to all the requirements for the safe handling and transportation of biological material
- h) Continually improving bio-risk management performance

NOTE: Bio-risk management should be stated clearly as part of the institution's health, safety and environment (HSE) policies. Depending on the relevance of bio-risk management to the institution, the bio-risk management policy should complement the general HSE policies. As appropriate, the bio-risk management policy may be integrated into the institution's HSE policies. The policy should require all projects/work areas to be assessed for risks and a full assessment conducted and documented before work is approved to commence.

2.3 Planning

2.3.1 Planning for hazard identification, risk assessment and risk control

2.3.1.1 Planning and resources

The institution(s) shall ensure that a risk assessment system is established, implemented and maintained in accordance with this policy and that the performance of the risk management system is reported to senior management for review and as a basis for improvement.

The institution(s) shall identify resource requirements and provide adequate resources, including the assignment of trained and competent personnel for management, performance of work, and verification of activities, including internal review.

The roles and responsibilities of personnel who perform and verify work affecting risk management should be defined and documented, particularly for people who need the institutional freedom and authority to do one or more of the following:

- a) Initiate action to prevent or reduce the adverse effects of risk
- b) Control further treatment of risks until the level of risk becomes acceptable
- c) Identify and record any problems relating to the management of risks
- d) Initiate, recommend or provide solutions through designated channels

- e) Communicate and consult internally and externally as appropriate

2.3.1.2 Risk assessment timing and scope

The institution(s) shall ensure the approach to risk assessment is defined with respect to its scope, nature and timing so that it is proactive rather than reactive

The following should trigger either a new risk assessment or review of an existing one:

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

There are many defined methodologies and approaches available for conducting hazard identification, risk assessment and control, and the approach taken will vary depending upon the nature of the situation and the level of detail required. One framework which institutions may consider adopting is outlined in Figure 1 below.

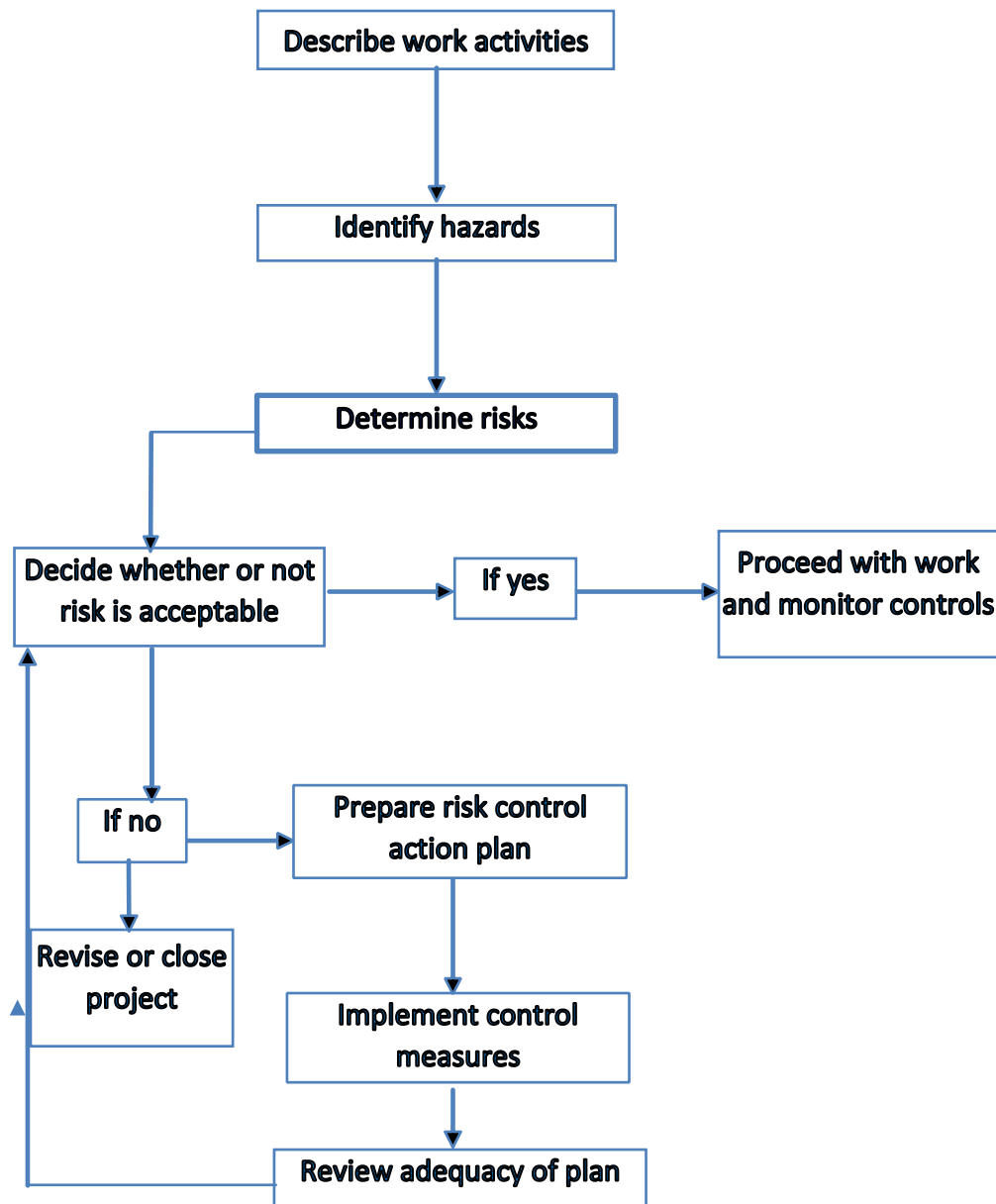


Figure1. Risk Assessment Strategy

The 1WHO Risk Assessment provides a detailed explanation to guide the systematic process of carrying out a risk assessment. There are several national organizations with specific risk assessment procedures depending on the nature of work they carry out.

The Ministry of Environment (MOE), and, the Environment Protection Agency, Sierra Leone (EPA-SL) which is empowered under the 2EPA Act of 2008 to amongst other things, protect the

1 Risk assessment. Geneva: World Health Organization; 2020 (Laboratory biosafety manual, fourth edition and associated monographs). Licence: CC BY-NC-SA 3.0 IGO

2Epa.gov.sl

environment and The Pharmacy Board of Sierra Leone have developed regulations and standard operating procedures to deal with the storage, transportation, treatment and disposal of hazardous wastes, including clinical, pharmaceutical and industrial waste as well as pesticides. All of the procedures in these documents require the use of a risk assessment form.

These documents include:

- 3Toxic and hazardous substances regulation, 2016
- 4Hazardous chemicals and pesticides control and management Bill, 2016
- 5SOPs on the disposal of unwanted pharmaceuticals (EPA-SL, 6Pharmacy Board, 7ONS), hazardous wastes (EPA-SL), clinical wastes and chemical wastes

Sierra Leone is also a party to several multilateral agreements that oblige her to observe certain procedures in undertaking risk assessments. These include:

- 8The World Animal Health Organization (WOAH)
- 9International Health Regulations (IHR), 2005
- 10Cartagena Protocol 2011 that specifies risk assessment when working with genetically modified organisms
- 11Bamako convention which prohibits the importation into Africa of any hazardous including radioactive waste
- 12Basel Convention on the Transboundary movement of hazardous wastes and their disposal

3 Toxic and hazardous waste substances regulation, 2016 (under development)

4 Hazardous chemicals and pesticides control and management Bill, 2016

5 SOPs on the disposal of unwanted pharmaceuticals (EPA-SL, Pharmacy Board, ONS), hazardous wastes (EPA-SL), clinical wastes and chemical wastes

6 www.pharmacyboard.gov.sl

7 National Security and Central Intelligence Act (Nascia), 2002

8 Oie.int/en/home/

9 Who.int/publications/i/item/9789241580496

10 Cbd.int/doc/legal/catagena-protocol-en.pdf

11 <https://www.informea.org/en/treaties/bamako/text>

12 <http://www.basel.int/TheConvention/Overview/TextoftheConvention/tabid/1275/Default.aspx>

All the above multilateral agreements give detailed procedures that shall be followed where relevant when carrying out risk assessments.

There are also several national regulations that require carrying out a risk assessment process. The 13 Factories Act, for example, mandates the Ministry of Labor and Social Security, while the Act mandates the Ministry of Trade and Industry, to regulate the registration of factories, inspection, health and cleanliness in establishments, keeping of records, notification of occupational accidents, diseases, offences and penalties.

2.3.1.3 Hazard identification

The hazards associated with the proposed work shall be identified and documented. The first stage in the risk management process is to identify all hazards that are relevant for bio-risk. It is useful to involve the whole work team in this process and to use inputs from institutional experts on safety and risk management.

A hazard may be a physical situation, e.g., a fire or explosion; an activity e.g., pipetting; or a material – 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. The essence of a hazard identification is that the hazard has the potential for causing harm, regardless of how likely or unlikely such an occurrence might be.

Biological hazards should be identified and assessed in relation to their potential damage to humans, animals, and the environment. Where hazardous materials are classified into hazard or risk groups based on international and/or foreign country classification schemes, local diverging needs and constraints should be considered

A hazard identification exercise should use information including:

- a) Group experience and knowledge
- b) External or specialized expertise not found in the institution
- c) Results of previous assessments

¹³https://www.ilo.org/dyn/natlex/natlex4.detail?p_lang=en&p_isn=15241&p_country=SLE&p_classification=14

- d) Surveys of previous accidents/incidents
- e) Hazardous materials data
- f) Information on hazardous organisms
- g) Guidelines and codes of practice
- h) Facility drawings
- i) Existing SOPs, manuals, etc.
- j) Process maps

Defined methodologies and approaches are available for conducting hazard identification exercises in Table 2.1 of the 14WHO Laboratory Biosafety Manual, 4th edition. Unless hazards are identified effectively, it is not possible to assess the risk associated with the institution and associated activities. Hazard identification should be appropriate in nature, structure and recorded to a level whereby others can review the process.

2.3.1.4 Risk assessment

The institution shall ensure that suitable methodologies for assessing and recording risks are identified, implemented and maintained. The risk assessment should categorize risks to identify those that need to be eliminated or controlled. Descriptions of likelihood and consequence, together with the acceptability of risk levels, should be defined and used in the assessment. Such a classification can be achieved, for example, through the use of a risk matrix identifying likelihood and consequence categories, ordered to illustrate those falling into high, moderate and low zones. Other approaches, however, may also be relevant and appropriate. The 15WHO Risk Assessment publication has a risk assessment matrix that uses color coding to categorize risks based on the likelihood of exposure and/or release, and consequences, ranging from very low (green) to very high (red).

¹⁴Laboratory biosafety manual, fourth edition. Geneva: World Health Organization; 2020 (Laboratory biosafety manual, fourth edition and associated monographs). Licence: [CC BY-NC-SA 3.0 IGO](#).

¹⁵Risk assessment. Geneva: World Health Organization; 2020 (Laboratory biosafety manual, fourth edition and associated monographs). Licence: CC BY-NC-SA 3.0 IGO]

Assessments can be qualitative, semi-quantitative or quantitative, and a method suitable to the situation should be identified and followed. In conducting the assessment, due consideration should be made of the inherent risk from the biological agents and toxins, e.g., from risk grouping descriptions, material safety data sheets, among others. After definition and implementation of control measures, the risks should be reviewed to decide if the remaining risk is acceptable or whether additional controls need to be identified and implemented.

2.3.1.5 Risk management

The institution shall ensure suitable methodologies for the allocation of actions resulting from risk assessments, including time lines, responsible persons and associated reporting and approval mechanisms are identified, implemented and maintained.

NOTE: The risk management approach should have a control plan to include:

- a) Who is responsible and accountable for implementation of the plan?
- b) What resources are to be utilized, e.g., people, budget
- c) Timetable for implementation
- d) Details of the mechanism and frequency of review of compliance with the plan

Risk management strategies should include the hierarchies of control. These are elimination of the work, substitution with an alternative organism/activity, isolation of the hazard, the use of engineering controls, administrative controls, or the reliance on personal protective equipment (PPE).

2.3.2. Conformity and compliance

The institution shall ensure that all relevant requirements are identified and fulfilled within the bio-risk management system. Legal requirements include: national and local regulatory requirements with which the institution shall comply. The institution should adopt measures to identify legal and other requirements for the institution in relation to the biological agents and toxins that will be held and used, but also other regulations including: worker protection and rights, environmental impact, and general health & safety against other hazards like fire, electrical. There is a need to monitor for new and upcoming requirements, as well as those

already in existence, including regional and international requirements. This information should be kept up to date and the requirements incorporated into the bio-risk management system of the institution.

2.3.3 Objectives, targets and programme

2.3.3.1 Bio-risk control objectives and targets

The institution shall establish, implement and maintain documented bio-risk control objectives and targets for an effective control of bio-risk at relevant functions and levels in the institution.

2.3.3.2 Monitoring controls

Management shall establish the controls and put in place documented procedures for monitoring the effectiveness of the controls being applied to reduce or eliminate the hazards identified in the risk assessment process.

The controls can be monitored by regular audits, by utilizing corrective action reporting processes where problems have been identified, by investigation of incidents and accidents and improving controls and their implementation and by ensuring that adequate resources are provided to maintain the effectiveness of the controls.

2.4. Implementation and operation

2.4.1 Roles, responsibilities and authorities

2.4.1.1 Coordination Committee¹⁶

The national bio-risk management system shall be guided by the coordination committee under the One Health (OH) platform with ultimate responsibilities. The coordination committee is responsible for ensuring that functions, duties, and authorities related to bio-risk management are established, and communicated to the technical committee that oversee, conduct, and verify work related to biological agent and toxin control. The coordination committee shall show its dedication by ensuring that resources are available to set up, execute, sustain, and develop the

¹⁶Coordination Committee shall be drawn from the following institutions and include Chief Medical Officer (Ministry of Health and Sanitation), Chief Agriculture Officer (Ministry of Agriculture and Forestry), Executive Chairperson (Environment Protection Agency Sierra Leone/Ministry of the Environment), National Security Coordinator (Office of the National Security) and National Disaster Management Agency (NDMA).

bio-risk management system. The coordination committee shall also be responsible for development of policies and guidelines as stipulated in the WHO Laboratory Biosafety Manual¹⁷

NOTE: The Chair of the coordination committee shall be rotational annually

2.4.1.2 Technical Committee

The technical committee shall be in charge of overseeing the bio-risk management system for an institution. The Directors of Ministries Divisions and Agencies within the One Health (OH) Platform shall make up this committee.

This committee's responsibilities will include:

- a) Allocating sufficient resources to ensure adequate staff, equipment, and other resources are available for the facility's safe and secure operation
- b) Reporting on the performance of the bio-risk management system and any areas that need improvement to the leadership
- c) Ensuring that the bio-risk management policy and guidelines is promoted through the One Health Platform
- d) Instituting review, audit, and reporting mechanisms to ensure that the policy and guidelines' provisions are successfully enforced and maintained
- e) Recommending and ensuring that a biosafety risk assessment is carried out prior to the start of any operation involving infectious and potentially infectious agents, products, or microbial toxins
- f) Ensuring that workers who deal with infectious and potentially infectious agents, as well as materials and microbial toxins, are properly trained in:
 - i. Biosafety and biosecurity fundamentals exemplary to institution procedures
 - ii. Biosafety and biosecurity protocols unique to the agent or toxin
 - iii. Job-specific training, for example, how to use a biological safety cabinet (BSC), how to treat waste, how to handle equipment, among others, following guidance

¹⁷Laboratory biosafety manual, fourth edition. Geneva: World Health Organization; 2020 (Laboratory biosafety manual, fourth edition and associated monographs). Licence: CC BY-NC-SA 3.0 IGO.

from existing documents including the WHO manual on Biological Safety Cabinets and Other Primary Containment Devices¹⁸

- iv. The training may be formal or informal, but it must be certified and/or approved by the OH coordination committee. The OH Platform shall determine the procedures, quality, and length of training, as well as ensuring a continuous work safety training and retraining program.
- v. The head of each institution shall appoint a focal person and inform the committee.
- vi. Take appropriate measures to address professional health and safety exposures

2.4.1.3 Bio-risk management committee

A bio-risk management committee shall be constituted to act as an independent review group for bio-risk issues, following guidance stipulated in the Biosafety Programme Management of The WHO Laboratory Biosafety Manual¹⁹. Members of the committee shall be nominated by the respective MDAs. Reporting to the technical committee, the committee shall:

- a) Have documented terms of reference
- b) Include a representative cross-section of expertise, appropriate to the nature and scale of the activities undertaken
- c) Ensure issues addressed are formally recorded, actions allocated, tracked and closed out effectively
- d) Be chaired by a member of the bio-risk management committee, depending on the bio-risk at hand
- e) Meet at a defined and appropriate frequency, and when otherwise required

2.4.1.4 Bio-risk management advisor(s)

A competent individual(s) shall be designated to provide advice and guidance on bio-risk management issues. This individual(s) shall report directly to the chair of the bio-risk management committee and have delegated authority to stop work in the event that it is

¹⁸Laboratory biosafety manual, fourth edition. Geneva: World Health Organization; 2020 (Laboratory biosafety manual, fourth edition and associated monographs). Licence: CC BY-NC-SA 3.0 IGO

¹⁹ Laboratory biosafety manual, fourth edition. Geneva: World Health Organization; 2020 (Laboratory biosafety manual, fourth edition and associated monographs). Licence: CC BY-NC-SA 3.0 IGO

considered necessary to do so. This role shall be independent of those responsible for implementing the programme of work as define in the WHO manual²⁰.

2.4.1.5 Bio-risk Technical Working Group (BSBS TWG)

The individuals in the bio-risk TWG within the institution shall be designated with responsibilities relevant to bio-risk management.

Functions shall include:

- a) Ensuring that all work is conducted in accordance with established biosafety and biosecurity policy and guidelines
- b) Supervising workers, ensuring only competent and authorized personnel can access and work in the institution
- c) Planning and conducting work activities, and ensuring adequate staffing levels, time, space and equipment are available
- d) Ensuring required authorizations such as TOR and SOP for work are in place
- e) Ensuring biosafety and biosecurity risk assessments have been performed, reviewed and approved, and that the required control measures are in place
- f) Ensuring that all employees have been informed of risk assessments and/or provisions for any recommended precautionary medical practices, e.g., vaccinations or serum collections and any other activity assigned by top management
- g) Ensuring that the Biosafety and Biosecurity policy and guidelines for transportation of infectious agents, which include traceability of movement²¹, proper documentation, and appropriate packaging procedure, are in place. It observes that all domestic and international transportation of infectious and potentially infectious agents' materials and microbial toxins adheres to local regulations (EPA-SL²², Phytosanitary²³, Zoo-sanitary²⁴,

²⁰ Laboratory biosafety manual, fourth edition. Geneva: World Health Organization; 2020 (Laboratory biosafety manual, fourth edition and associated monographs). Licence: CC BY-NC-SA 3.0 IGO

²¹ Basel Convention on Transboundary Movement of Hazardous Waste and Their Disposal

²² Section 58, subsections (2), (3) & (6) of the EPA-SL Act, 2008

²³ International Plant Protection Convention

²⁴ Sections 3 – 19, The Animal Diseases Act 1961, Statutory Instrument 38 – 4, revised Animal Health Bill, 2020.

ONS²⁵ and Pharmacy Board²⁶) as well as International Air Transport Association (IATA) requirements

- h) Establishes and institutes administrative controls for appropriate waste decontamination, disposal and management policy using existing guidance including: WHO Decontamination and Waste Management, Environmental SOPs for the disposal of toxic and hazardous waste, WHO Laboratory Design and Maintenance, WHO Outbreak Preparedness and Resilience²⁷, respectively
- i) Ensures that all laboratories and research institutions involved in handling of infectious and potentially infectious agents, materials and microbial toxins have an emergency response plan (ERP), and that all personnel are aware of the plan²⁸

2.4.1.6 Occupational health

The institution shall have access to appropriate occupational health expertise and establish an occupational health programme commensurate with activities and risks of the institution²⁹ & ³⁰.

2.4.1.7 Facility management

Facilities manager(s) shall be appointed with responsibilities relevant to facilities and equipment determined in accordance with requirements set out in this policy and guidelines.

2.4.1.8 Security management

A security manager shall be designated with responsibilities determined in accordance with requirements set out in the WHO Biosafety manual³¹.

²⁵ National Security and Central Intelligence Act, 2002; Office of National Security

²⁶ Pharmacy and Drugs Act, 2001

²⁷ Section 7 Outbreak Preparedness and Resilience; Laboratory biosafety manual, fourth edition and associated monographs; WHO, 2020; page 38

²⁸ Section 8.7; Laboratory biosafety manual, fourth edition. Geneva: World Health Organization; 2020 (Laboratory biosafety manual, fourth edition and associated monographs). Licence: CC BY-NC-SA 3.0 IGO; page 87

²⁹ Section 4.9; Laboratory biosafety manual, fourth edition. Geneva: World Health Organization; 2020 (Laboratory biosafety manual, fourth edition and associated monographs). Licence: CC BY-NC-SA 3.0 IGO; 2020; page 55

³⁰ Factory Inspectorate OHS, Ministry of Labour and Social Security

³¹ Section 8; Laboratory biosafety manual, fourth edition. Geneva: World Health Organization; 2020 (Laboratory biosafety manual, fourth edition and associated monographs). Licence: CC BY-NC-SA 3.0 IGO; 2020; page 83

2.4.1.9 Animal handling

In laboratories where animals are maintained, an animal care manager shall be designated with responsibilities determined in accordance with requirements set out in the WOA manual³².

2.4.2 Personnel training, awareness and competence

The institution shall ensure that personnel that have responsibilities and/or perform tasks that may impact bio-risk management in the workplace are competent to do so. Competence levels shall be judged on appropriate education, training and experience.

The institution shall define required competency levels and shall maintain records verifying that staff members have attained and demonstrated those levels of competency for all relevant training as outlined by the WHO Biosafety manual³³.

2.4.2.1 Recruitment

The institution shall ensure that qualifications, experiences and aptitudes relating to bio-risk management are considered as part of the recruitment process.

NOTE: Prior to taking up an appointment the institution shall ensure that:

- a) All personnel should be subject to a formal selection process, including relevant background checks based on risk, e.g., employment references, security checks
- b) Appropriate controls are implemented if existing employees are transferred to areas where there may be an increased risk profile
- c) An assessment is made of the need for the above controls for non-core personnel, e.g., contractors, visitors, students; and measures implemented to ensure they are applied where necessary.

2.4.2.2 Competence

The institution shall ensure that personnel conduct activities within the facility under close supervision until competency has been demonstrated.

NOTE: Competence is defined in relation to appropriate education, training and / or experience,

³² Chapter 7.5; Article 7.5.1, 2008; OIE

³³ Laboratory biosafety manual, fourth edition. Geneva: World Health Organization; 2020 (Laboratory biosafety manual, fourth edition and associated monographs). Licence: CC BY-NC-SA 3.0 IGO

together with a demonstrable ability to perform the task in a safe / secure manner.

Procedures should address:

- a) Definition of competency needs
- b) Demonstration of successful completion of required training
- c) Demonstration of ability to perform tasks under supervision and unsupervised
- d) Restrictions on personnel who have not demonstrated competence to ensure they do not perform tasks for which they are not eligible
- e) Maintenance of adequate records

No worker should be exempt from demonstrating competence irrespective of rank, experience or background. Administrative controls should be instituted to ensure that only workers with the required competency are allowed to undertake specific tasks. Periodic competency training program should be available, and staff competency evaluated routinely.

2.4.2.3 Continuity and succession planning

The institution shall ensure that adequate back-up and contingency measures are in place to address the need for continuity and succession planning.

NOTE: The institution should identify roles and individuals and ensure that the integrity of the facility is not compromised through short or long-term absence. Such measures should include succession planning for personnel (technical, management and scientific, including contractors) to 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. The roles and responsibilities of all personnel should be clearly set out and understood³⁴.

³⁴Section 7.3; Laboratory biosafety manual, fourth edition. Geneva: World Health Organization; 2020 (Laboratory biosafety manual, fourth edition and associated monographs). Licence: CC BY-NC-SA 3.0 IGO

2.4.2.4 Training

The institution shall ensure that requirements and procedures for bio-risk-related training of personnel are identified, established and maintained

NOTE: Procedures should address:

- a) Definition of bio-risk training needs
- b) Provision of required bio-risk training
- c) Determination of effectiveness of bio-risk training
- d) Provision of refresher bio-risk training
- e) Restrictions on personnel to ensure they do not perform tasks for which they are not trained
- f) Maintain adequate records

Training should include raising personnel awareness of bio-risk issues including the relevance of human factors in bio-risk management.

2.4.3 Consultation and communication

The institution shall ensure that relevant bio-risk information relating to its activities is communicated to and from employees and other relevant parties. Employee involvement and consultation arrangements shall be documented. Personnel shall have access to adequate and up-to-date information pertaining to the bio-risks of the institution.

2.4.4 Operational control

Managing the operational aspects of a safety program requires clear definition of the responsibility and the authority of safety personnel and designation of the chain of command. The institution shall identify those operations and activities that are associated with possible biological risk and where control measures shall be applied. The institution shall plan these activities, including maintenance, and ensure that they are carried out under specified conditions.

2.4.4.1 General safety

35The institutions shall ensure that a formal process is in place to identify and manage risk associated with general safety. The institution should adopt a preventive and proactive approach to managing such sources of risk, both to protect workers from the direct hazards associated with their work and to address the implications for bio-risk in the event of an accident / incident resulting from such sources. Measures should be identified and implemented to detect, mitigate and respond to emergencies, taking into consideration potential implications for biological agents and toxins control in such measures.

Issues addressed should include but are not limited to:

- a) General laboratory safety
- b) Fire safety
- c) Electrical safety
- d) Radiation safety
- e) Chemical safety
- f) Use of gasses including risk of asphyxiation – oxygen deprivation
- g) Hot work and cold work
- h) Equipment under pressure
- i) Laboratory animal care and use
- j) General housekeeping, including storage requirements and tidiness³⁶.

Every institution, irrespective of size, should have a safety program, designed to ensure compliance with Occupational Safety and Health Administration (OSHA) requirements for health and safety, Nuclear Safety and Radiation Protection Authority -Sierra Leone (NSRPA-SL)

35 Biosafety programme management. Geneva: World Health Organization; 2020 (Laboratory biosafety manual, fourth edition and associated monographs). Licence: CC BY-NC-SA 3.0 IGO. Pg 31 section 3)

36 (<http://www.bu.edu/researchsupport/compliance/ibc/resources/biosafety-manual/chapter-05-laboratory-biosafety-practices/>)

37 requirements for safe handling of radioactive isotopes, Environmental Protection Agency (EPA) regulations designed to implement the Natural Resources Conservation etc.³⁸

Even when a safety program is already in effect, a new laboratory activity may require that the program be modified to address the following issues:

- The unique hazards introduced by the new activity
- The methods of controlling these hazards
- The new procedures needed, e.g., signs, waste disposal, and personnel monitoring
- The orientation/ training of personnel
- Ways of ensuring that the new procedures are followed.

NOTE: Not only should safety programs be a part of an institution's effort, but such an activity should be a central focus of a small office or clinical laboratory as well.³⁹

2.4.4.2 Biological agents and toxin inventory and information

The institution shall ensure that an accurate and up-to-date biological agents and toxin inventory is established and maintained. It shall ensure that records relating to the inventory of biological agents and toxins are current, complete and stored securely with adequate backup provision. It shall ensure that transfers of biological agents and toxins between laboratories at the facility or into and out of the facility are recorded and controlled in line with the level of the risk.

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

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

37 NSRPA –SL ACT 2012 Nuclear Safety and Radiation Protection Authority -Sierra Leone (NSRPA-SL)

38 <https://www.ncbi.nlm.nih.gov/books/NBK218637/>

39 <https://www.ncbi.nlm.nih.gov/books/NBK218637/>

- e) Segregating and storing biological agents and toxins according to risk using color coding; and/or unique identification numbers
- f) Determining what materials should be controlled, e.g., seed stocks, working stocks, infected animals, and what level of information should be captured in the inventory for those materials.

Inventory information should include: 40

- a) The name(s) of and contact information for the individual(s) responsible for the material and details of other personnel with access to the materials or immediate area based on the level of the risk
- b) Restricted access to the detailed inventory records to those individuals whose work requires access to that information
- c) Legible and robust identification numbers and other relevant identifiers
- d) Records of quantities / volumes of biological agents and toxins at an appropriate level and based on risk (i.e., for certain biological agents, location and responsible individual may be adequate while for others more detailed information may be necessary)
- e) Records of materials consumed, destroyed or removed from the facility where appropriate; indicating the precise reason(s), processes used and places.

Controls should be set in place to ensure that all the necessary checks and documented assurances are received to ensure that requests for biological agents and toxins originate from legitimate facilities and individuals making such requests are tracked. Material may only be brought into the facility or sent elsewhere if authorized by those responsible for the facility. For materials deemed high risk, more stringent controls including shipment tracking and verification of receipt are important considerations, as stipulated in the 41WHO Biosafety manual.

40 Laboratory biosafety manual, fourth edition. Geneva: World Health Organization; 2020 (Laboratory biosafety manual, fourth edition and associated monographs). Licence: CC BY-NC-SA 3.0 IGO

41 Laboratory biosafety manual, fourth edition. Geneva: World Health Organization; 2020 (Laboratory biosafety manual, fourth edition and associated monographs). Licence: CC BY-NC-SA 3.0 IGO.)

2.4.4.3 Work programme, planning and capacity

The institution shall ensure that the programme of work for the facility is defined, documented and reviewed. The institution 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.

The programme of work should include the nature of the activities authorized to be conducted in the facility and their definitions, e.g., diagnostics, research, small scale / large scale. All activities associated with the work programme should be specified and supported by formal SOPs approved in accordance with the requirements for controlled documents as defined by this policy and guidelines. Any changes to the programme of work should be subject to a formal change management process.

The resources needed to implement and maintain the bio-risk management system and continually improve its effectiveness, should be determined and provided by the responsible authorities of the institution. Additional information and guidance on how to successfully implement and manage a biosafety programme can be found in ⁴²the WHO Biosafety manual.

2.4.4.4 Change management

The institution 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. The changes should be reviewed, verified and validated as appropriate, and approved before implementation. This should include evaluation of the effect of the changes on the risk assessment.

The following change management process, stipulated in the WHO biosafety manual⁴³ should trigger a risk assessment:

- a) Modifications to buildings and equipment or their operation, which may or would have an effect on bio-risk

⁴² Laboratory biosafety manual, fourth edition. Geneva: World Health Organization; 2020 (Laboratory biosafety manual, fourth edition and associated monographs). Licence: [CC BY-NC-SA 3.0 IGO.](#))

⁴³ Laboratory biosafety manual, fourth edition. Geneva: World Health Organization; 2020 (Laboratory biosafety manual, fourth edition and associated monographs). Licence: [CC BY-NC-SA 3.0 IGO.](#))

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

2.4.4.5 Work practices, decontamination and personnel protection

2.4.4.5.1 Good microbiological procedures

The institution shall ensure that all personnel handling biological agents and toxins are competent in good microbiological techniques and that appropriate resources (including time and equipment) are available to ensure such practices can be adhered to effectively.

NOTE: As appropriate, procedures should address risks associated with but not limited to the following:

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

NOTE: This list is neither exhaustive nor comprehensive and identifies only some activities that

may be employed during typical technical and field work. These activities should be undertaken in association with appropriate procedures and working practices to ensure the control measures are effective under all foreseeable and credible operating scenarios. Appropriate control measures should be identified during risk assessments, and these will vary depending on the biological agents and toxins being used and the activities to be undertaken, as stipulated in the 44WHO Biosafety manual

2.4.4.5.2 Inactivation of biological agents and toxins

The institution shall establish and maintain procedures to ensure that appropriate methods for disinfection and decontamination are chosen and implemented effectively. The institution 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 procedures are put in place to devise effective decontamination and other appropriate treatments.

Sources of contamination that should be considered include:

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

44 Laboratory biosafety manual, fourth edition. Geneva: World Health Organization; 2020 (Laboratory biosafety manual, fourth edition and associated monographs. Licence: CC BY-NC-SA 3.0 IGO).

- d) Animal carcasses and bedding
- e) Facilities

All potential waste streams and other sources of contamination should be identified and documented. Contaminated personnel may include core personnel working within the facility, contractors and emergency response personnel. Cultures and associated materials may be a source of contaminated supernatants, aspirates and culture media. Infected biological materials may also include infectious human, animal or plant specimens. In some instances, it may be necessary to hold contaminated dedicated equipment such as fire fighter apparel or ambulance tools on site if they cannot be effectively decontaminated.

Risk assessment should be an integral part of the process to identify and develop effective decontamination regimes.

NOTE: Whatever the biological agents and toxins handled, it is likely that a number of effective inactivation methods will be available. The institution should ensure that there are data available to demonstrate that the methodology selected is capable of inactivating the biological agents and toxins under the specific conditions encountered in the facility. Validation measures should consider issues including

- a) The nature of the material being treated, e.g., volume, presence of protein / other potentially inhibitory substances
- b) Contact times, materials compatibility issues, e.g., interaction with stainless steel or rubber seals
- c) Potential health hazards associated with the disinfectant
- d) The need to maintain the required level of active compound, including deterioration over time, including shelf-life

In planning and conducting decontamination activities the organization should consider the following, as stipulated in the WHO Monograph: decontamination and waste management 45:

45 Decontamination and waste management. Geneva: World Health Organization; 2020 (Laboratory biosafety manual, fourth edition and associated monographs). License: CC BY-NC-SA 3.0 IGO.

- a) Ensuring all disinfectants used contain sufficient active compound to address the working conditions under which they will be applied, and that such concentrations are maintained throughout the process, including conducting specific validation activities where necessary
- b) Providing adequate facilities and procedures for the storage of waste including short term storage
- c) Ensuring methods are available for effective decontamination of mixed waste, e.g., infected animals that have received radioactive materials
- d) Ensuring that where appropriate, methods are available for decontamination of sensitive equipment or that which is not suitable for autoclaving, e.g., computers
- e) Implementing monitoring measures to ensure the methods have been effective, e.g., cycle recording and use of indicators in autoclaves
- f) Decontaminating protective clothing by appropriate means prior to leaving the facility
- g) Ensuring adequate methods and resources are available to deal with routine work and any spillages or other incidents during handling and transport of materials inside and outside the facility
- h) Implementing programs to ensure the amount of contaminated waste is minimized

2.4.4.5.3 Waste Management

The institution shall establish and maintain an appropriate waste management policy for biological agents and toxins as detailed in the WHO Decontamination and Waste Management Manual⁴⁶ and 47Environment Protection Agency Act (2008) of Sierra Leone

⁴⁶ Decontamination and waste management. Geneva: World Health Organization; 2020 (Laboratory biosafety manual, fourth edition and associated monographs). Licence: [CC BY-NC-SA 3.0 IGO](#)

⁴⁷ Environment Protection Agency Sierra Leone Act, 2008, Section 24 – First Schedule

2.4.4.5.4 Clothing and Personal Protective Equipment (PPE)

The institution shall ensure that PPE needs are identified and suitable equipment is specified, made available, used and maintained appropriately within the facility. This should be in line with 48The WHO manual on Personal Protective Equipment details requirements for PPE

2.4.4.6 Worker Health programme

The institution shall ensure that risk to worker health, and that of other personnel whose health could be directly impacted by exposure to biological agents and toxins, is managed effectively including prevention and protection measures.

NOTE: Insurance is necessary in the case of eventuality

The requirements of the health surveillance programme, as stipulated in the WHO Laboratory Biosafety Manual⁴⁹ shall be determined by a defined health hazard identification and risk assessment process involving all relevant personnel

2.4.4.6.1 Vaccination of personnel

Based on risk, the need for vaccination shall be identified and shall cover groups identified as being potentially exposed to biological agents or toxins. The institution 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 vaccination policy, as outlined in the 50WHO Laboratory Biosafety Manual.

2.4.4.7 Behavioral factors and control of workers

The institution shall establish and maintain a programme to address risk associated with human behavior, including the management of how workers interact with the facility and its equipment.

48 The WHO manual on Personal Protective Equipment details requirements for PPE. (Personal protective equipment. Geneva: World Health Organization; 2020 (Laboratory biosafety manual, fourth edition and associated monographs). Licence: [CC BY-NC-SA 3.0 IGO.](#))

49 Laboratory biosafety manual, fourth edition. Geneva: World Health Organization; 2020 (Laboratory biosafety manual, fourth edition and associated monographs). License: CC BY-NC-SA 3.0 IGO

50 WHO Laboratory Biosafety Manual; section 3.9 page 47(Laboratory biosafety manual, fourth edition. Geneva: World Health Organization; 2020 (Laboratory biosafety manual, fourth edition and associated monographs). Licence: CC BY-NC-SA 3.0 IGO).

2.4.4.7.1 Personnel reliability

The institution shall ensure that a personnel reliability policy is defined and implemented, and that access to facilities or work is controlled for individuals according to the policy

2.4.4.7.2 Contractors, Visitors and Suppliers

The institution shall ensure that facilities, equipment and processes are designed and run in a safe and secure way in accordance with bio-risk management.

3.4.4.7.3 Exclusion

The institution 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.

3.4.4.8 Infrastructure and operational management

The institution shall ensure that facilities, equipment and processes are designed and run in a safe and secure way in accordance with bio-risk management.

3.4.4.8.1 Planning, design and verification

The institution shall ensure that a formal planning, design and redesign process is adopted for the facility, based upon an assessment of risk associated with the materials to be used and activities undertaken, as provided for in the WHO laboratory design and maintenance manual⁵¹.

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. For example, the construction of a laboratory facility requires that you carry out environmental impact assessment and acquire an 52EIA license from the Ministry of Environment; follow the building code from the Ministry of Works and public Assets and the Ministry of Lands and Country Planning⁵³.

⁵¹ Laboratory design and maintenance. Geneva: World Health Organization; 2020 (Laboratory biosafety manual, fourth edition and associated monographs). License: CC BY-NC-SA 3.0 IGO).

⁵² EPA-SL Act 2008 Amended 2010

⁵³ National Land Policy of Sierra Leone 2015

The design process shall identify and consult all relevant parties associated with the facility and its operation. All design features, construction techniques, materials and equipment selected shall be documented in line with the need to provide sufficiently specific and detailed instruction and information on the design specification. The institution shall ensure that new construction and physical facility modifications are carried out according to an approved plan.

A formal design process means a structured and documented approach whereby the needs of the facility are determined through risk assessment. Engineering and operational solutions shall be incorporated that are consistent with the risk posed by the properties of materials that will be stored and handled in the facility and the nature of the work to be carried out.

The design process should include the identification and review of relevant legislation, e.g., EIA license acquisition from the EPA-SL, Institution of Engineers; and codes of practice including building codes from the Ministries of Works and Lands as well as those relating to laboratory biosafety / laboratory biosecurity and risk assessments. The requirements identified from these sources should be incorporated into the design plans. The design should be fully documented, including a description of the tests and the standards of acceptance to assure performance. The process should be documented and transparent to provide an assurance that it has been comprehensive and thorough.

The design process should include the identification of and consultation with individuals involved in planning, construction and operation of the facility.

The following roles and responsibilities of individuals should be considered in terms of information requirements and need for consultation:

- a) Scientific personnel and other end users
- b) Bio-risk management advisor, bio-risk management committee
- c) Biosecurity and/or security personnel
- d) Designers (architects and engineers)
- e) Building engineers

- f) Maintenance engineers
- g) Materials and equipment suppliers
- h) Commissioning agents
- i) Certifiers
- j) Regulators
- k) First responders
- l) Other relevant parties identified in risk assessments

If justified on the basis on the nature of the work, a peer review process involving independent, competent third parties should be conducted to ensure the design specification;

- a) Is in line with accepted good practice
- b) Incorporates features capable of providing assurance for control of biological agents and toxins
- c) And ensures relevant legislative requirements, and, standards, and risk assessment findings have been incorporated into the design.

3.4.4.8.2 Commissioning and decommissioning

The institution shall ensure that there is a formal process for initial commissioning of new facilities and the final decommissioning of existing ones, as provided for in the Sierra Leone Public Health Ordinance 1960⁵⁴ and the WHO laboratory design and maintenance manual⁵⁵

Commissioning will ensure that the facility is constructed and performs as intended. The commissioning process should start at the design phase at the first stage of science programme definition to assure that the expectations for the building are achievable. The commissioning plan

⁵⁴Public Health Ordinance 1960

⁵⁵ Laboratory design and maintenance. Geneva: World Health Organization; 2020 (Laboratory biosafety manual, fourth edition and associated monographs). Licence: CC BY-NC-SA 3.0 IGO.

should develop in detail in parallel with the physical concept to assure that the expectations for the building are measurable.

The commissioning plan should clearly identify, with examples, all steps from beginning to end including conditions of acceptance of each step, as a pre-requisite of proceeding to the next. The commissioning plan should identify all steps required before operation is commenced initially or resumed after temporary shutdown. The commissioning process should provide the benchmark for acceptable facility operation and the description of the programme to be put in place to maintain that level of performance.

The decommissioning process should identify the decontamination procedures and security-related measures that have to be in place for temporary or final shut down of the facility. The decommissioning programme should not only describe the procedures to be undertaken, but also, the standards of acceptance when those procedures are performed. This may be documented through clearance certificates and permits to work, which identify when and under what conditions the decommissioned facility can be re-entered.

3.4.4.8.3 Maintenance, control, calibration, certification and validation

The institution shall establish and maintain documented procedures to ensure equipment and elements of the physical plant that may impact on bio-risk be identified, purchased, maintained, calibrated, certified or validated in a manner consistent with the intent and requirements of the bio-risk management programme. This is carried out as per The WHO laboratory design and maintenance manual⁵⁶

The maintenance programme should apply to all aspects of the physical structure (including finishes and seals where appropriate) and equipment therein. All materials used should be specified to ensure they can perform in line with predetermined criteria. An appropriate maintenance plan will be addressed as part of that specification process.⁵⁷

⁵⁶ Laboratory design and maintenance. Geneva: World Health Organization; 2020 (Laboratory biosafety manual, fourth edition and associated monographs). Licence: CC BY-NC-SA 3.0 IGO).

⁵⁷ Weight and measures Act No 5 2010

In planning and conducting maintenance activities, the institution should consider:

- a) Adequately maintaining the physical integrity of the facility and its fixtures and fittings
- b) Ensuring maintenance activities are performed by competent individuals, and that risks associated with the work have been subjected to risk assessment
- c) Identifying and recording maintenance requirements at time of construction of facilities, purchase / acquisition of equipment
- d) Creating and maintaining a maintenance register for all applicable equipment
- e) Identifying and conducting planned maintenance activities at an appropriate frequency
- f) Ensuring adequate provision for unplanned (breakdown) maintenance to ensure integrity of the facility is maintained at all times
- g) Determining and monitoring predictive maintenance requirements and associated indicators and monitors
- h) Ensuring essential spare parts are available in line with a frequency appropriate to the risk of failure and need for replacement
- i) A pest control programme
- j) Equipment officer

In planning and conducting equipment controls, the institution should consider:

- a) Identifying equipment in line with identified work needs, which can be demonstrated as fit for purpose
- b) Controlling purchase / acquisition of equipment to ensure all necessary risk assessments are completed and approvals authorized by competent personnel
- c) Controlling entry and exit of equipment to and from the facility, including decontamination requirements (e.g., air locks and decontamination)
- d) Standardization of equipment used in specific broad areas to ease use

NOTE: In planning and conducting calibration activities, the institution should consider:

- a) identifying and recording calibration requirements at time of purchase / acquisition
- b) identifying the standards / tests that will be used to ensure the equipment is correctly calibrated
- c) creating a documented and up-to-date calibration register for all applicable equipment
- d) Ensuring calibration is scheduled and conducted in line with manufacturer's requirements and / or other specified intervals as identified by risk assessment

NOTE: In planning and conducting certification activities the institution should consider:

- a) identifying and recording certification requirements at time of purchase / acquisition of equipment, including relevant and current standards against which to certify;
- b) ensuring competent and independent certifiers are used for the certification process;
- c) Ensuring certification is scheduled and conducted in line with manufacturer's requirements and / or other specified intervals as identified by risk assessment.

NOTE: In planning and conducting validation activities, the institution should consider:

- a) Identifying and recording validation requirements at time of purchase/acquisition
- b) Identifying the standards/tests that will be used to ensure the equipment is correctly validated
- c) Creating a documented and up-to-date validation register for all applicable equipment
- d) Ensuring validation is scheduled and conducted in the line with manufacturer's requirements and / or other specified intervals as identified by risk assessment
- e) Ensuring competent and independent validation companies are used for the validation process

For physical security systems, the analogous concept is performance testing; evaluating the entire physical security system (equipment, policies, procedures, and people) to ensure the system works as designed.

3.4.4.8.4 Physical security

Physical security systems promote not only biosecurity objectives, but also directly support biosafety by limiting access to the laboratory and other potentially hazardous areas. An effective physical security system incorporates a variety of elements to enhance a facility's capability to deter, detect, assess, delay, respond to, and recover from a security incident. These elements are outlined in 58WHO Biosafety manual. The NaSCIA 200259 can be consulted for advice on physical security

The institution 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.

NOTE: Measures should be set in place to minimize the potential for release or removal of biological agents from the facility due to a breach in security. This should involve proactive measures to identify vulnerabilities and implementation of effective control and monitoring mechanisms.

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

- a) Theft or diversion of biological agents and toxins or related equipment, documents or data
- b) Sabotage including vandalism and tampering
- c) Break-in and intrusion
- d) Labor issues and disputes
- e) Weather-related emergencies (i.e., earthquake, tsunami, flood, tornado, and hurricane)
- f) Workplace violence
- g) Utilities failure
- h) Picketing, occupation and barricade
- i) Screening and isolation of suspect packages
- j) Acts of terrorism

58 Laboratory biosafety manual, fourth edition. Geneva: World Health Organization; 2020 (Laboratory biosafety manual, fourth edition and associated monographs). Licence: CC BY-NC-SA 3.0 IGO) section 4 page 69 point 4.1

59 National Security and Central Intelligence Act 2002

- k) Civil unrest or war

NOTE: Care should be taken to coordinate biosecurity measures with those of biosafety to manage and minimize conflicting priorities.

3.4.4.8.5 Information security

Information management and security policies and procedures are created to protect sensitive information from unauthorized access or theft and to ensure the appropriate level of confidentiality. Information management and security policies should govern the classification and handling of sensitive information and address how the information is collected, documented, transmitted, accessed, and destroyed; following guidance and examples provided in national and international documents like the Canadian biosafety handbook – second edition⁶⁰.

The institution 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.

NOTE: The information generated by a laboratory can be as valuable and/or dangerous as the biological agents and toxins stored at the facility. Adequate measures to prevent unauthorized release of such information are critical. Procedures addressing information security should consider:

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

⁶⁰<https://www.canada.ca/en/public-health/services/canadian-biosafety-standards-guidelines/handbook-second-edition.html>

3.4.4.8.6 Control of supplies

The institutions shall ensure that purchases (including services) conform to specified requirements, including, National Public Procurement Authority Act 2020, National Medical Supplies Agency Act, Pharmacy and drugs act 2001. Controls shall be applied depending on potential impact on the bio-risk involved.

The institutions shall ensure suppliers are evaluated and selected based on their ability to provide products / services that meet the requirements of this policy and guidelines. 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.

NOTE: While not all suppliers will provide products / services that may impact on bio-risk, there are many that may. Suppliers that should be considered include, but are not limited to, those that provide:

- a) Cleaning services
- b) Laboratory equipment
- c) Waste management or disposal services
- d) IT support services
- e) Equipment and facility maintenance services
- f) Security services

3.4.4.9 Transport of biological agents, chemicals and toxins

Transportation of infectious substances may be subject to various national and/or international regulations, depending on the origin, destination and/or the mode of transport being used. Independent operators involved in the process such as couriers, airlines or logistics services, may also request additional protocols. Irrespective of the regulations that apply, the aim is always to reduce the likelihood of an exposure to and/or a release of the infectious substances/biological agents in order to protect personnel, the community and/or the surrounding environment.

Section 6 of the WHO Biosafety manual⁶¹ outlines consideration for transfer and transportation of biological agents and toxins by levels of transfer.

The institutions shall ensure that procedures for the safe and secure transport of cultures, specimens, samples and contaminated and potentially contaminated materials are established and maintained in accordance with legal requirements for the transport of dangerous goods.

NOTE: In planning and conducting transport activities the institutions should consider:

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

Detailed guidance on the transport of infectious specimens can be found in the WHO Guidance on regulations for the transport of infectious substances⁶² and any subsequent updates of this document. Health care workers and those involved in taking, packaging and transporting

61 Laboratory biosafety manual, fourth edition. Geneva: World Health Organization; 2020 (Laboratory biosafety manual, fourth edition and associated monographs). Licence: CC BY-NC-SA 3.0 IGO.)

62 Geneva: World Health Organization; 2019 (WHO/WHE/CPI/2019.20) (<https://apps.who.int/iris/bitstream/handle/10665/325884/WHO-WHE-CPI-2019.20-eng.pdf?ua=1>, accessed 6 December 2019)

specimens must be trained on all procedures necessary for the safe execution of all tasks and for compliance with national and international regulations ⁶³

3.4.4.10 Personal security

The institution shall have a policy in place to provide personal security support services to staff members that include, where appropriate, personal security awareness training.

NOTE: Personal security is concerned with staff security during off-duty hours while away from the facility. During these times, staff members are vulnerable because of their function or position.

3.4.5. Biosecurity emergency response and contingency plans

Authority

A Biosecurity Emergency Preparedness and Response Plan shall maintain procedures to identify the potential for incidents and emergency situations involving biological agents (including invasive species), toxins and materials, to prevent their occurrence, to respond to emergency situations and to limit the likelihood for illness or other damage that may be associated with them. Emergency planning shall cover all aspects of bio-risk management and include general safety, security and medical issues.

The Biosecurity Emergency Preparedness and Response Plan is prepared by a Biosafety and Biosecurity technical working group, submitted through the National One Health technical committee to the One Health Coordinating Committee for endorsement.

A Response Planning Guide shall be developed to reflect contemporary incident management arrangements and the content and style of the Biosecurity Incident Management System.

Purpose

The purpose of this plan is to provide guidance on contemporary response planning practices and processes that could be followed during the response to biosecurity incidents, in supplementary

⁶³The ICAO's Technical instructions for the safe transport of dangerous goods by air (Technical instructions for the safe transport of dangerous goods by air (Doc 9284), 2017-2018 edition. Montreal: International Civil Aviation Organization; 2017 (<https://www.icao.int/safety/DangerousGoods/AddendumCorrigendum%20to%20the%20Technical%20Instructions/Doc%209284-2017-2018.AddendumNo2.en.pdf>, accessed 6 December 2019)))

to other emergency preparedness and response plans of the pertinent Institutions. Also, the plan may be used as a training aid in preparation for the response to biosecurity incidents, as well as a reference document for staff working within operations centers at the national, regional and field levels, during the response to all types of biosecurity incidents.

3.4.5.1 Emergency scenarios

This plan will ensure that all credible and foreseeable emergency scenarios that may influence the institution's biosafety and biosecurity be identified, as stipulated in the 64WHO manual on outbreak preparedness and resilience. To ensure this is achieved, all credible emergency scenarios will be envisaged and planned for. Although all potential scenarios may not be credible, all reasonable threats should be considered, recorded and where appropriate, the rationale as to why issues were dismissed

Scenarios considered should include:

- a) Infected and/or potentially infected worker or other contact, e.g., family member, emergency responder or community member
- b) Accident or illness to worker and need for evacuation
- c) Fire
- d) Flood
- e) Reach of security
- f) Explosion
- g) Potential loss of biological agents or toxins through theft or any other reason
- h) Unexpected virulence – unknown biological agents or biological agents expected to be a virulent
- i) Physical facility and equipment failure, including control system failure
- j) Failure of disinfection regime
- k) Utility failure including electricity, gas, steam and water supplies
- l) Major spillage / aerosol release
- m) Environmental release

64 Outbreak preparedness and resilience. Geneva: World Health Organization; 2020 (Laboratory biosafety manual, fourth edition and associated monographs). License: CC BY-NC-SA 3.0 IGO.

- n) Natural disaster, e.g., earthquake, extreme weather conditions, disease pandemics
- o) Act of terrorism or deliberate vandalism
- p) Intense media attention

3.4.5.2 Emergency plans

All institutions whose work has inherent potential to cause bio-risk events shall ensure that bio-risk management is taken into account when preparing and implementing emergency plans. The institutions shall ensure a system is established to effectively manage medical and/or environmental emergencies, including, but not limited to, the identification of potentially exposed workers and provision of immediate medical care to infected, ill or injured workers. There shall also be control measures in place that is commensurate to the scale and nature of the anticipated 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.

The Biosecurity Emergency Management plan established by any of the pertinent institutions is to address as a minimum:

- a) Identification of those responsible for devising, implementing and testing the control measures specified
- b) Response during out-of-hours emergencies as well as those that occur during normal working hours
- c) Provision for periods of reduced staff availability, e.g., during weekends and holiday periods
- d) Emergency access /exit, including the ability to override access controls as appropriate
- e) Emergency exit routes to avoid evacuating people through areas of higher biosafety or biosecurity
- f) Provision for safe removal, transport, transfer, treatment and accommodation of contaminated persons/ objects

In the event of an emergency, there may be a requirement to involve parties external to the institution. Based upon the credible scenarios identified, the institution should identify such

agencies to establish their role in responding to a given situation. The institution may choose to sign memoranda of understanding or agreements with key local responders. It may also be necessary to inform and educate such parties as to their role and any risk exposures they may face and ensure that their actions will not unnecessarily increase the risk associated with the emergency, e.g., uncontrolled use of the water canon). A database of the relevant institution should be established and made available to personnel responsible for coordinating the emergency response activity.

External agencies/parties consulted may include:

- a) Ministry of Health and Sanitation (NPHA, NEMS)
- b) The Office of National Security
- c) National Disaster Management Agency
- d) The National Fire Force
- e) Ministry of Local government and Rural Development
- f) Ministry of Environment-(EPA).
- g) Ministry of Agriculture and Forestry
- h) Third parties – Development partners, Civil Society Organizations, Local and International NGOs, among others

3.4.5.3 Emergency exercises and simulations

The institution 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. Exercises should be planned and every effort made to ensure they are realistic representations of the events they are designed to simulate. However, such activities should also be conducted under controlled conditions and not be allowed to become a source of risk in their own right. The results of the exercise should be documented and reviewed for lessons learned, and feedback provided to appropriate personnel on performance. Any actions arising should be recorded, allocated to named individuals and measures set in place to ensure they are closed out effectively.

3.4.5.4 Contingency Plans

The institution 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.

NOTE: In the event of an emergency or unforeseen event there may be disruption to normal operating conditions. This could range from the need to safely shut down work in the event of a power failure, to obtaining alternative storage conditions in the event of a breakdown. Such eventualities should be considered proactively and contingency plans set in place. Activities should address the need for adequate redundancy, replacement and other measures, which could involve the availability of alternative facilities or personnel, the introduction of backup systems, e.g., power supplies, alternative means of decontaminating materials in the event of failure of critical systems or equipment, e.g., kill tanks or autoclaves, or the complete safe shut down of operations in extreme situations.

3.5 Checking and corrective action

All institutions and organizations are required to work under national standards and/or the standards stipulated in the International Standards Organization (ISO) standards for quality control of their management systems.

International standards stipulated by ISO include: ISO/IEC 17025:2017⁶⁵ for veterinary and pharmaceutical institutions, ISO 15189:2012⁶⁶ for medical (clinical and public health) laboratories, ISO 14000 family (ISO 14001:2015⁶⁷, ISO 14004:2016⁶⁸ and ISO 14005:2019⁶⁹) for environmental management systems, ISO 45001:2018⁷⁰ and ISO 45005:2020⁷¹ for occupational

⁶⁵ ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories

⁶⁶ ISO 15189:2012 Medical laboratories — Requirements for quality and competence

⁶⁷ ISO 14001:2015 Environmental management systems - Requirements with guidance for use

⁶⁸ ISO 14004:2016 Environmental management systems - Requirements general guidelines on implementation

⁶⁹ ISO 14005:2019 Environmental management systems - G

⁷⁰ ISO 45001:2018 Occupational health and safety management systems - Requirements with guidance for use

⁷¹ ISO 45005:2020 Occupational health and safety management

health and safety, ISO 22000:2018⁷² and ISO 22003:2013⁷³ for the assurance of food safety at all levels, and ISO 9001:2015⁷⁴ for general quality management systems shall be applied.

3.5.1 Performance, measurement and analysis of data

The institution shall ensure that appropriate data are determined, collected and analysed 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, and, from other sources. Such analyses should be conducted at least quarterly and more often if justified by the risks and the scope of operations. The results of the analysis should be applied in the management review.

3.5.2 Records, document and data control

The institution shall ensure that records, documents and data are established, controlled and maintained to provide evidence of conformity to the requirements of this policy and guidelines and that they remain legible, readily identifiable and retrievable.

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

- a) Risk assessments, standard operating procedures (SOPs) and safety manuals
- b) Job hazard analyses and charts of authority
- c) Design records and commissioning, test plans, maintenance plans and records and all associated data
- d) Audit and inspection checklists
- e) Laboratory biosecurity manuals and risk assessments, authorizations and other security documents
- f) Training records
- g) Containment equipment certifications, for example, calibration of equipment.

⁷² ISO 22000:2018 Food safety management systems - Requirements for any organization in the food chain

⁷³ ISO 22003:2013 Food safety management systems - Requirements for bodies providing audit and certification of food safety management systems

⁷⁴ ISO 9001:2015 Quality management systems - Requirements

The list of controlled documents is neither exhaustive nor comprehensive but includes some of the main areas that should be formally recorded and subject to document control. Data should be construed as documents in this context. A procedure should be established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposal of records. A procedure should be established to define the controls needed to approve documents prior to issue or public release to ensure sensitive information such as specific freezer locations of pathogen repositories is not inadvertently released. Procedures should also be established to define the controls for review, update and re-approval of documents, and for the change control and revision process.

3.5.3 Inventory, monitoring and control

The institution shall ensure that a review of the inventory is conducted at least annually based on risk and at a level and frequency whereby materials can be accounted for in an appropriate manner. The institution shall ensure that the measures are put in place to minimize the quantities of biological agents and toxins that make up the inventory.

NOTE: The nature of the inventory and associated controls should be based upon the nature of the material held and the risk of harm should it be misplaced or removed with the intention of misuse. For many biological, chemical agents and toxins, the checks may be of a lower frequency and stringency than for others with greater potential for causing harm. Such measures may include numbered sequences of tubes, periodic inspections and crosschecks with records of materials held. The institution 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. Procedures should be in place to investigate potentially missing biological, chemical agents, and toxins appropriate for the level of risk.

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

3.5.4.1 Accident / incident investigation

The institution shall establish and maintain documented procedures to define, record, analyse and learn from accidents and incidents involving biological agents, chemicals and toxins.

NOTE: Procedures should be set in place to ensure that what constitutes an accident or incident is clearly defined and communicated to all relevant personnel and may include events of exposure and accidental release. Accidents and incidents provide an indication that the systems designed to manage bio-risk may have failed, and it is essential that lessons are learned, and improvements are made where possible. As a minimum, the accident / incident investigation process should include:

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

3.5.4.2 Control of nonconformities

The institution shall ensure that situations that do not conform to the requirements of this policy and guidelines are identified and controlled to prevent undesirable consequences. Records of the nature of the non-conformity and any subsequent action taken shall be maintained.

NOTE: The controls and related responsibilities and authorities for dealing with non-conforming situations should be defined in a procedure.

3.5.4.3 Corrective action

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

NOTE: A procedure should be established to define requirements for:

- a) Reviewing the non-conformities
- b) Determining the cause of non-conformities
- c) Evaluating the need for action to ensure that non-conformities do not recur
- d) Determining and implementing action needed
- e) Recording results of action taken
- f) Reviewing corrective actions taken

3.5.4.4 Preventive action

The institution shall ensure action is taken to identify and eliminate the causes of potential nonconformities in order to prevent their recurrence. Preventive actions shall be appropriate to the effects of the potential nonconformities.

NOTE: A procedure should be established to define requirements for:

- a) Determining the potential non-conformities and their causes
- b) Evaluating the need for action to prevent recurrence of non-conformities
- c) Determining and implementing action needed
- d) Recording of the results of action taken
- e) Reviewing preventive action taken

3.6 Review

3.6.1 Bio-risk management review

Top management shall review the institution's bio-risk management system at planned intervals, to ensure its continuing suitability, adequacy and effectiveness, using 75 ISO/IEC 17025: 2017 as provided by Sierra Leone Standards Bureau to guide the review process. The review shall include

assessing opportunities for improvement and the need for changes to the system, procedures, policies and objectives. Records from the management review shall be maintained.

NOTE: The management review should be conducted at a defined frequency determined by the needs of the institution. It is recommended that the review be held at least annually.

The review input should include information on:

- a) Results of audits
- b) Compliance with SOPs and work instructions
- c) Status of risk assessment activities
- d) Status of preventive and corrective actions
- e) Follow-up actions from previous management reviews
- f) Changes that could affect the system
- g) Recommendations for improvement
- h) Results of accident and/ incident investigations.⁷⁶

The review output should include decisions and actions related to:

- a) Improvement of the effectiveness of the bio-risk management system
- b) Improvement related to the requirements and risk assessments
- c) Resource needs

⁷⁶ Laboratory biosafety manual, fourth edition. Geneva: World Health Organization; 2020 (Laboratory biosafety manual, fourth edition and associated monographs). Licence: CC BY-NC-SA 3.0 IGO

References

- apps.who.int/iris/bitstream/handle/10665/325884/WHO-WHE-CPI-2019.20-eng.pdf?ua=1, accessed 6 December 2019)
- Basel Convention on Transboundary Movement of Hazardous Waste and Their Disposal
- Biosafety programme management. Geneva: World Health Organization; 2020 (Laboratory biosafety manual, fourth edition and associated monographs). License: CC BY-NC-SA 3.0 IGO
- CEN Workshop Agreement (CWA) 15793:2011 was prepared by CEN Workshop 31
- [Cbd.int/doc/legal/catagena-protocol-en.pdf](https://cbd.int/doc/legal/catagena-protocol-en.pdf)
- Decontamination and waste management. Geneva: World Health Organization; 2020 (Laboratory biosafety manual, fourth edition and associated monographs). License: CC BY-NC-SA 3.0 IGO.
- Environment Protection Agency Sierra Leone Act, 2008, Section 24 – First Schedule
- EPA-SL Act 2008 Amended 2010
- [Epa.gov.sl](https://epa.gov.sl)
- Hazardous chemicals and pesticides control and management Bill, 2016
<http://www.basel.int/TheConvention/Overview/TextoftheConvention/tabid/1275/Default.aspx>
- <http://www.bu.edu/researchsupport/compliance/ibc/resources/biosafety-manual/chapter-05-laboratory-biosafety-practices/>
- <https://www.canada.ca/en/public-health/services/canadian-biosafety-standards-guidelines/handbook-second-edition.html>
- <https://www.ncbi.nlm.nih.gov/books/NBK218637/>
- <https://www.informea.org/en/treaties/bamako/text>
- International Plant Protection Convention
- ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories
- ISO 15189:2012 Medical laboratories — Requirements for quality and competence
- ISO 14001:2015 Environmental management systems - Requirements with guidance for use
- ISO 14004:2016 Environmental management systems - Requirements general guidelines on implementation
- ISO 14005:2019 Environmental management systems - Guidelines for a flexible approach to phased implementation
- ISO 45005:2020 Occupational health and safety management systems - Requirements with guidance for use
- ISO 45005:2020 Occupational health and safety management
- ISO 22000:2018 Food safety management systems - Requirements for any organization in the food chain

- ISO 22003:2013 Food safety management systems - Requirements for bodies providing audit and certification of food safety management systems
- ISO 9001:2015 Quality management systems - Requirements
- ISO/IEC 17025: 2017 – General Requirements for The Competence Of Testing And Calibration Laboratories
- Laboratory biosafety manual, fourth edition. Geneva: World Health Organization; 2020 (Laboratory biosafety manual, fourth edition and associated monographs). Licence: CC BY-NC-SA 3.0 IGO
- Laboratory design and maintenance. Geneva: World Health Organization; 2020 (Laboratory biosafety manual, fourth edition and associated monographs). Licence: CC BY-NC-SA 3.0 IGO).
- Ministry of Labour and Social Security Factory Inspectorate OHS
- National Land Policy of Sierra Leone 2015
- National Security and Central Intelligence Act 2002
- Nuclear Safety and Radiation Protection Authority -Sierra Leone ACT 2012
- Outbreak preparedness and resilience. Geneva: World Health Organization; 2020 (Laboratory biosafety manual, fourth edition and associated monographs). License: CC BY-NC-SA 3.0 IGO.
- WOA.int/en/home/
- Pharmacy and Drugs Act, 2001
- Public Health Ordinance 1960
- Risk assessment. Geneva: World Health Organization; 2020 (Laboratory biosafety manual, fourth edition and associated monographs). License: CC BY-NC-SA 3.0 IGO
- The Animal Diseases Act 1961, Statutory Instrument 38 – 4, revised Animal Health Bill, 2020.
- Toxic and hazardous waste substances regulation, 2016 (under development)
- The WHO manual on Personal Protective Equipment details requirements for PPE. (Personal protective equipment. Geneva: World Health Organization; 2020 (Laboratory biosafety manual, fourth edition and associated monographs). License: CC BY-NC-SA 3.0 IGO.)
- The ICAO's Technical instructions for the safe transport of dangerous goods by air (Technical instructions for the safe transport of dangerous goods by air (Doc 9284), 2017-2018 edition. Montreal: International Civil Aviation Organization; 2017 (<https://www.icao.int/safety/DangerousGoods/AddendumCorrigendum%20to%20the%20Technical%20Instructions/Doc%209284-2017-2018.AddendumNo2.en.pdf>, accessed 6 December 2019)))
- Weight and measures Act No 5 2010
- Who.int/publications/i/item/9789241580496
- World Health Organization; 2019 (WHO/WHE/CPI/2019.20) (<https://www.pharmacyboard.gov.sl>)