Summary of Changes to the World Health Organization Laboratory Biosafety Manual 4th Edition

This Summary of Changes was prepared by the ABSA International Technical and Regulatory Review Committee (TRR) in collaboration with the International Relations Committee. April 2022

*This Summary of Changes is not to be used as a substitute for the **WHO Laboratory Biosafety Manual 4th Edition***

Section 2 Risk assessment (page 5 -26)

The title to this section was simplified to Risk Assessment in the WHO LSM 4th edition, by removing the word "biological". This section has been enhanced to include considerations and examples for the different stages of the assessment. Each subsection reflects the steps included in the risk assessment framework.

2.1 Gather Information

This section addresses the step for gathering information by providing examples of key questions to ask in general, and when facing new or unknown biological agents.

2.2 Evaluate the risk

This section provides factors associated with the likelihood of an incident occurring, and factors that affect the consequences of an incident if it were to occur. This subsection presents the risk assessment matrix (Table 2.5) followed by establishing if the risks are acceptable.

2.3 Develop a risk control strategy

This section discusses developing a risk control strategy, it provides examples of risk control strategies, and strategies for risk reduction.

2.4 Select and implement risk control measures

This section provides considerations required for the selection and implementation of control measures. A tool for evaluating these factors and elements is provided in Table 2.7 which lists the procedure, the initial risk, the risk control measure, and the residual risk.

2.5 Review risks and risk control measures

The last subsection addresses continuous review of risks and risk control measures. Importantly, it provides a list of examples when the risk assessment should be updated as part of the continuous improvement.

Section 3 Core requirements (page 27-48)

In the 4th edition, the authors took elements from each section in the 3rd edition that pertained to best and minimal practices for working in clinical and diagnostic laboratories and combined them in this new Section 3- Core requirements.

This section included operation and physical elements that when combined ensures safe handling of the agents, and a safe working environment in clinical and diagnostic laboratories and must be part of the overall biosafety program management (described in Section 7) . Additional requirements necessary for agents requiring maximum containment are described in Sections 4 and 5.

3.1 Good Microbiological Practice and Procedure (GMPP)

GMPP is a term given for standard operating practices and procedures or a code of practice when working with biological agents. GMPP are essential in the control of laboratory acquired infections. This section goes on to describe the different elements of GMPP. This section includes best practices (behaviors to be followed to ensure a safe work environment), technical procedures (elements to consider for controlling the risk of exposure and cross contaminations)

3.2 Personal Competence and Training

This section enforces the importance of proper staff training including a table outlining the training that should be implemented for laboratory workers. The importance of staff understanding the guidelines and documentation. This section also mentioned the need for financial and administration support from laboratory management to enable the process.

3.3 Facility Design

This section list requirements a facility should meet for safe work and handling of biological agents. These include the type of finishing the laboratory should have (floor, walls, cabinetry, work surface), storage needed for supplies and samples, lighting and ventilation requirements, reliable electricity sources, emergency equipment (first aid), external threats from weather, geographical, fire, floods.

3.4. Specimen Receipt and Storage

This section covers the core requirements to minimize risk when receiving, storing, and inactivating specimens. Preparation of samples for transport and transfer is covered in Section 6. This section includes receiving specimens (core requirements that should be considered when receiving specimens such as ensure documentation is sufficient for the laboratory worker to be able to identify the specimens know what the potential hazard and test are needed), storage of specimens (specifications that storage containers should meet), inactivation (enforces the importance of having validated inactivation procedures before transferring samples to other area for manipulation).

3.5 Decontamination and waste management.

It is a core requirement of biosafety management programs to have processes in place for identification, segregation of contaminated material prior to decontamination/disposal.

When material cannot be decontaminated on site it must be properly packaged for transportation further information on transportation can be found in section 6.

Table 3.2 provides guidance on segregation and treatment of contaminated material.

This section also covers the criticality of having validated procedures of decontamination methods and consideration needs to be taken for non-biological material that may be contaminated such as work surfaces, sharps. This section goes on to describe the more common methods of decontamination used by laboratories. The Chemical Disinfection section includes information on when chemical disinfection can be applicable are given, including information on pre-cleaning for heavily soiled material as elements that will influence the chemical disinfection procedures. The section on Autoclaving covers the general principles of autoclaving. It describes the autoclaving process and elements to consider when preparing material for autoclaving. The

section on Incineration describes how this is an alternative method of decontamination and serves as a disposal method. Additional information can be found in the monograph: decontamination and waste management (22).

3.6 Personal Protective Equipment

This section covers the different types of Personal Protective Equipment (PPE) commonly used in the laboratory. It covers the importance of seize and brand used to ensure best protection to the user. PPE described in this section includes laboratory coat, footwear, gloves, eye protection, and respiratory protection. Additional information about PPE can be found in the monograph: Personal Protective Equipment (20).

3.7. Laboratory equipment

In this section the importance of proper use of laboratory equipment and GMPP is covered to ensure a safe work environment. Core elements are presented when considering the selection operation and maintenance of laboratory equipment. These include but are not limited to a budget for maintenance and service, equipment inventories, proper training of staff, appropriate facilities for the equipment. Consideration regarding routine and emergency decontamination and proper use of the equipment to include SOP, authorized users are also included in this section. Best practices are included for using specialized equipment such as centrifuges and pipettes.

3.8. Emergency/incident response

In this section information developing incidence response plans for all type of possible incidences that could occur in the laboratory as well as key elements that should be included such as individuals to contact, location of emergency response kits, procedures to follow and training of personnel. The subsection on biological spills provides a general procedure to follow in the case of a biological spill and elements to consider in the response. Additional information can be found in the monograph: decontamination and waste management (22).

3.9. Occupational Health

This section provides and overview of the role of an occupational health program in ensuring the health of laboratory worker, through prevention and when needed monitoring of employee health. Additional information can be found Monograph: biosafety program management (17).

Section 4 Heightened control measures

The risk assessment process has evolved whereby a laboratory's risk activities have changed from the 3rd edition into the 4th edition of the LBM by WHO. Topics related to BSL-2 and BSL-3 laboratories are covered in the new edition of the LBM as "Heightened control measures" and the BSL-4 as "Maximum containment measures", respectively. It is important to mention, that in the WHO 3rd edition of the Biosafety Manual, basic laboratories (biosafety levels 1 and 2) were covered from pages 9-19, containment laboratories (BSL-3) were covered from pages 20-24, and maximum containment laboratories (BSL-4) were covered from pages 25-27. Each one of these sections included a general code of practice, lab design, facilities and some other aspects such as lab equipment, occupational health, training, waste handling and general safety.

In the new edition of the LBM, the topics covered in section 4 and section 5 included several subsections like operational working practices and standard operating procedures; the importance of personnel competence and training; facility design (which is covered as a specific Monograph). In the same way, subject specific monographs were developed for specimen receipt and storage, decontamination and waste management, and personal protective equipment.

As it is detailed in the 4th ed., LBM, the operational working practices, and procedures from the core control measures will remain applicable in the heightened and maximum containment measures (including the good microbiological practices and procedures and the use of containment devices such as BSCs). In the same way, biosecurity measures must be considered to prevent the presence of non-authorized personnel, and a system to monitor and record the activities of personnel who is working inside of the facilities.

Another critical aspect that is detailed in this 4th ed., of the LBM are the emergency/incident response and occupational health surveillance. These topics are case-by-case scenario dependent as well as the availability of the organization/institutional resources. It is important to mention as well, that specific policies that were included in the 3rd edition of the WHO Biosafety manual (i.e., two-rule person at high containment facilities), continue in this new edition of the LBM.

In terms of personnel competence and training, it is important to provide all the necessary training to develop appropriate competence among the staff/personnel who is going to have access to these facilities but also, who is going to work with

biological agents or materials. Training must include specific agent SOPs, and activities related with emergency preparedness, response and recovering from critical situations.

Regarding the facility design, a complete monograph has been assigned to select heightened control measures, and considerations for the maximum containment facilities. This monograph details topics like separation and design features, controlled access, laboratory equipment, directional airflow, and inward airflow, wase disposal and emergency response. In addition, a complete section was considered for the operation and maintenance as well as the decommissioning process of laboratory facilities.

As it was previously mentioned, part of the new perspective of the heightened and maximum containment control measures are based on the risk assessment and nature of the work that is going to be done. These two control measures will be chosen if the core requirements are not fully covered, or if the organization/institution, and each one of the interested parties require additional control measures and mitigation controls for the identified risks. On the other hand, the risk assessment will be based on the location and availability of resources (technological, material, infrastructure, and human factor) of the involved institutions. Another interesting aspect of these new regulations is that these documents can be used where national regulations exist, as this will serve to comply with international requirements.

However, independently of the type of control measures (heightened or maximum), everything will require to be evaluated periodically as well as, the effectiveness of the risk control measures every certain time through lab inspections, reports, and external evaluations.

Regarding the specimen receipt and storage, decontamination and waste management and personal protective equipment, specific monographs were created and detailed based on the level and needs from the institution/organization. It has been emphasized that decontamination and waste management should preferably be decontaminated onsite, or close to the laboratory to minimize the risk of exposure during transportation for the heightened and maximum containment facilities. In terms of personal protective equipment, specialized PPE and protocols should be included and after conducting a risk assessment process.

Finally, the new heightened and maximum containment measures present a novel approach that allows to each organization/institution to take a feasible and most effective combination of risk control measures based on their resources,

experience, and local context. In addition, this will support and help these institutions to attain a much desired equitable, adequate, and sustainable access to laboratory services (i.e., diagnostic, reference, research) to promote the safe and secure handling of biological materials that require this level of protection under the highest quality and safety standards.

Section 5 Maximum containment measures p.59-64

The maximum containment measures section describes two types of containment measures or laboratory designs that can be used when handling biosafety level 4 agents. One facility is referred to as a Suit Laboratory named after the positive pressure suits worn by the staff. The other facility is a Line Laboratory (referred to as a Cabinet Laboratory in the BMBL) where all work is performed in a single or a series of interconnected Class III biosafety cabinets or gloveboxes. In both cases, the laboratory facility must be under negative pressure to its surrounding space. There are nine subsections and three comparative tables to this chapter. Each subsection is very brief and can be considered prescriptive requirements with little operational detail.

Section 5.1 is entitled “operational working practices and procedures.” This section adds additional measures to the core requirements described in Section 3.

Section 5.2, personnel competence and training is a short paragraph that states only highly-trained and competent individuals should be allowed to work in a maximum containment lab.

Section 5.3 entitles “facility design,” contains the three comparative tables that show how Suit and Line laboratories differ in design requirements. The three tables describe & compare Primary Features, Entry & Access features, and HVAC features for the two types of laboratory facilities.

Section 5.4, “specimen receipt and storage” is a single paragraph containing four (4) requirements that must be implemented.

Section 5.5, decontamination and waste management, describes requirements for laboratory infrastructure such as a double door autoclave and requirements for waste treatment.

Section 5.6 entitled Personal Protective Equipment describes the need for specific SOPs and PPE maintenance programs within a Suit laboratory.

Section 5.7, Laboratory equipment, specifically requires dedicated equipment and sharps policies.

Section 5.8 is entitled “emergency/incident response” requires a separate manual for emergency response be developed. Emergency response exercises should be conducted and, in some cases, include local and national authorities.

Section 5.9 is the final section and describes Occupational Health requirements. Included in these requirements is a requirement for 24-hour medical assistance. Multiple other requirements are listed.

SECTION 6 Transfer and transportation p. 65-76

Versions v. 3 and v.4 of the WHO LSM cover the packaging, labeling, transfer and transport of infectious material and potential infectious material. The goal is to ensure safe and secure transfer/transport of potentially infectious biological materials without exposing the shipper, handler and the receiver (and/or any other public who comes across the way of transport).

.Version 4 of the WHO LSM details the transport type, such as, 1) Transfer within the laboratory, 2) Transfer within a building, 3) Transfer between buildings on the same site, 4) Off-site transport of infectious substances. The other major change noted in version 4is the detailed classification of infectious substances (with UN numbers) and the summary of categorization, documentation, packaging and labelling of infectious substances for transport.

Version 4 also describes the triple packaging system in much more details; the figure of the triple packaging system is detailed and describes in P65 the system for carrying biological substances clearly.

Section 7 Biosafety programme management p. 77-82

This section describes the roles and responsibilities of nations, along with individual research organizations and institutions for an effective management of biological risks by applying nation-wide regulatory networks. The management system for an appropriate bio-risk management consists of, a) commitment and support from upper/senior management to address and manage the risk, b)proper risk identification and containment planning, c) control measures and procedure implementation and monitoring, d) framework for appropriate training of personnel, e) clear distinction of roles and responsibilities, and f) ensuring adherence to the national and international guidelines and regulations.

The section iterates the importance of having a biosafety program; either as a part of an overarching safety program or a standalone. The different components of the program consist, a)Biosafety culture, b) Biosafety policy, c) Assigned roles and responsibilities of senior management, a biosafety committee, the biosafety officer, lab personnel and support personnel, d) Biosafety manual, e) Biosafety and biosecurity risk assessment f) Supporting programs and plans, g) Reports and reviews (including incident reports/audits and inspections/and other reports).

The major change in this version (v.4 vs. v.3) is the organization of this section. In the previous version of the manual, the role of biosafety officer and the biosafety committee was covered as a unit under the part 'Safety organization and training'. The rest of the details (mentioned in above paragraphs) was not a part of (the v.3 of the WHO) manual.

Section 8 Laboratory biosecurity p. 83

The WHO LSM 3th Edition defined biosecurity as institutional and personal security measures designed to prevent the loss, theft, misuse, diversion or intentional release of pathogens and toxins. The WHO LSM 4th Edition defines now biosecurity as institutional and personnel security measures
designed to prevent the loss, theft, misuse, diversion or intentional release of biological
agents being handled in the laboratory, leaving toxins out of the definition.

8.1 Biosecurity Risk Management

The WHO LSM 4th Edition provides definitions for each step of the biosecurity risk assessment following the same steps for conducting risk assessment provided in Section 2.

8.2 Inventory Control

This section provides information on how to maintain an inventory of at-risk biological agents.

8.3 Information Control

This section provides the definition of "Confidential" and provides rationale for establishing procedures to protect data.

8.4 Personnel Control

This section provides information for establishing personnel management programs, and elements to be included in biosecurity training courses.

8.5 Physical Security Control

This section provides the elements to be included in an effective physical security system.

8.6 Transport Control

This section provides the elements to consider when transferring biological agents domestically or internationally.

8.7 Emergency/Incident Response

This section outlines what should be included in the incident response plan, and the importance of conducting drills and exercises as part of preparation and planning.

8.8 Emerging Biological Risks

This section outlines additional risks that should be considered when drafting a biosecurity plan to ensure the responsible conduct of research.

SECTION 9 National/international biosafety oversight p. 91- 94

National/International Biosafety Oversight

This short section is important in that it recognizes Biosafety and Biosecurity as a needed control for the global protection of human health. There is also a recognition of the need for cooperation on both a national and international level.

Some highlights of this section include an understanding that national regulations should strive for a balance between ensuring risk mitigation and allowing flexibility to operate sustainably and to continue effective research and development.

The WHO LBM expresses that national level risk assessments be performed before national regulations are created. This assessment should include the size and resources of the scientific enterprise and the potential impact a release may have on agriculture, human health and the ecosystem. Successful development of national regulations should include all stakeholders.

Importantly, regulations should not be considered static as research and development are dynamic processes. Regulations should be revisited on a regular basis.

Monographs

Risk assessment 132 pages

This monograph is designed to accompany the WHO LSM 4th Edition. This monograph contains additional details, examples and scenarios for conducting risk assessments in support of the risk- and evidence- approach to biosafety and biosecurity intended by the WHO LSM 4th edition.

This monograph is divided in four sections:

Section 1 introduces the monograph, scope and how to use the monograph.

Section 2 provides information on considerations to form the risk assessment team and completing the assessment.

Section 3 provides the application of the 5-step process presented in the manual and in section 2 of the monograph using real-life examples of events occurring in biological laboratories and examples of ways to modify experiments to decrease risks.

Section 4 provides case-scenarios where risk assessments are conducted, it includes scenarios such as a lab-acquired infection, a near-miss and situation involving an laboratorian's health status.

This monograph also includes several Annexes:

Annex 1 is an abbreviated template for risk assessment using the 5-step process.

Annex 2 is the long form for conducting a risk assessment using the 5-step process. This template includes considerations and questions to ask in bullet-point format for each step.

Annex 3 and Annex 4 provide two completed risk assessments using the short form provided in Annex 1;

Annex 5 and Annex 6 provide two completed risk assessments using the long form provided in Annex 2.

Laboratory design and maintenance 88 pages

Laboratory Design and Maintenance is one of the monographs for the fourth edition of the World Health Organization (WHO) Laboratory Biosafety manual (core document). This monograph contains 10 sections. The sections 1-4 cover design considerations for different levels of laboratories. Design features for core requirement laboratories must be incorporated in all laboratories. Additional risk control measures, design features or modifications are necessary for laboratories where a risk assessment has determined that heightened control measures or maximum containment measures are required to maintain a safe working environment. The sections 1-4 also emphasize the importance of the risk assessment and needs assessment in considerations of design features.

The sections 5-10 cover the different phases of laboratory design and operation, including planning, design, construction, operation, and maintenance, as well as decommissioning of laboratory facilities. These sections expand and illustrate the steps and stages in the framework at each main stage. Some important elements require careful attention, especially budgets, personnel, and schedules. Before the construction, repurposing or renovation process can begin, a detailed risk assessment must be carried out to determine the specific risk control measures that need to be implemented. In addition, a facility-specific needs assessment is required to define all other design features needed for the laboratory.

Each section between 6-9 contains a project flowchart according to the corresponding phase, from planning to operation and maintenance. The end of this monograph has two annexes with titles “Examples of a user requirement brief” and “Examples of a user requirement specification”.

The monograph adopts a risk- and evidence-based approach to biosafety ensure that laboratory facilities, safety equipment and work practices are not only proportionate to needs but also sustainable. The risk- and evidence-based approach aims to facilitate laboratory design and ways of operating that ensure greater sustainability while maintaining adequate and appropriate control of biosafety.

The people who are involved in any stage of the laboratory design and operation are the targeted readership for this monograph, including senior management, laboratory manager, biosafety officer, architects, designers, construction engineers and builders.

Biological safety cabinets and other primary containment devices 50 pages

Biological safety cabinets and other primary containment devices are presented as a subject-specific monograph with WHO Laboratory Biosafety Manual (LBM) 4th edition. It was under part III laboratory equipment's in section 10 and 11 (18 pages document) in WHO LBM 3rd edition.

This monograph explains the different types of BSC and other primary containment devices and the best practice for working with these devices. The technical features of primary containment devices, such as directional airflow, are explained and methods for their decontamination are discussed. The information in this monograph on biological safety cabinets and other primary containment devices is designed to accompany and support the fourth edition of the WHO Laboratory biosafety manual (core document) and other associated monographs. The manual and the monographs adopt a risk- and evidence-based approach to biosafety rather than a prescriptive approach to ensure that laboratory facilities, safety equipment and work practices are locally relevant, proportionate to needs and sustainable. This is a new approach facilitate the importance of a sustainable safety culture with adequate and appropriate control of biosafety.

Section 1 provides a detailed description of Biosafety cabinets, isolators and Ooher local exhaust ventilation devices are provided in the introductory session.

Section 2 describes how to use the primary containment. The topics included are, best practice for working with open-fronted devices and additional considerations while working with enclosed devices.

A detailed description of decontamination of safety cabinets and isolators including liquid and vapor decontamination are also included in this section.

Section 3 describes the direction of airflow. The topics included are high efficiency particulate air filtration, direct recirculation, hard ducting, and anti-blowback valves.

Section 4 provides the selection process of a primary containment device. A summary table for reference of the selection process is provided in this section. A detailed working mechanism of BSCs with illustrations and summary table is also provided. This section also provides a working mechanism of containment isolators with other local exhaust ventilation types.

The PPE recommendations while using the BSC's were provided in the other associated monograph titled "personal protective equipment".

Personal protective equipment 96 pages

This monograph was not present in the WHO Laboratory Biosafety Manual 3rd edition. This covers in more detail information provided in section 11 of the 3rd edition. Personal Protective Equipment (PPE) is discussed in all sections of the current edition; however, the information is general and broad to that section.

In this monograph each type of PPE, (e.g. gloves, respirators, gowns, lab coat, eye protection, foot protection) is presented in detail.

The preface provides a glossary of terms

Section 1 provides a generic presentation of the document including the principles of selection and use of PPE. This section also includes national and international standards and regulations on PPE.

Section 2 provides information needed to appropriately select PPE based on the work conducted and risk assessment, agent used, availability of PPE, type of work, additional hazards present, combination of PPE, and user feedback.

Sections 3- provides the definitions of the core requirement, the suggestion of PPE core requirements and the description of GMPP.

Section 4 This section explains how PPE are used for heightened control measures and additional PPE may be required alternatively as part of the risk control. PPE described here include lab coats, aprons, gown, coveralls, footwear, eyer protection, and respiratory protection

Section 5 This section gives a fundamental introduction to facilities that bring the highest level of protection and specification on PPE needed in different containments levels including cabinet line facilities and positive-pressure suits.

Section 6 This section starts with general information about protective garments Reference to ISO standards are made and table 6.1 provides guidance on the type of protective clothing and use. Details are provided for pre-checks, donning and doffing of protective clothing.

Section 7 provides a description of appropriate laboratory footwear. Considerations to take in account when selecting appropriate footwear based on the work conducted and environment. Footwear must offer protection to the user against potential exposures including chemicals and prevent slips and falls. They also must be comfortable and of the appropriate seize for example.

Section 8 provides a general description of "why" gloves are used, sizing and different material available. It continues in more detail about the different type of gloves available, covers the protection factors of gloves and reusable gloves that may be used for other laboratory hazards such as heat/cold protection, cut-resistant or puncture-resistance gloves. Consideration for limitation in dexterity and need for training is covered as well. Pre-check, donning and doffing techniques are presented.

Section 9. This section covers the use of eye protection against splashed and particles as well as UV light. In this section information about the specification eye protection must meet are provided. How to properly put on and use eye protection is describes as well as how to properly remove eye protection. A figure 9.1 illustrates donning and doffing.

Section 10 This section covers the different type of respiratory protection worn in laboratory settings. A general overview of respiratory protection is provided including when these can be used based on risk assessment.

Section 11 In this section information is provided about the type of head cover that can be used in the laboratory, the importance of properly tying back hair to prevent hand to head contact and the possibility of combining head cover with respiratory protection. The determination and selection of the appropriate head cover should be based on a risk assessment.

Section 12 is specific to hand hygiene. This section covers the importance of proper hand hygiene and the best practices to follow. Figure 12.1. describes proper hand washing and drying.

Section 13 covers cleaning, maintenance and disposal of PPE based on the type used. This section covers information on cleaning and disinfecting of reusable PPE, the maintenance and storage of PPE to ensure proper functioning, covers the maintenance and storage of reusable and disposable laboratory coats, and other practices for PPE maintenance.

Section 14 covers standards and regulations around the use of PPE. This section describes a set of principles intended for PPE to ensure that a minimum level of protection is achieved, that PPE is selected and used correctly as well as providing examples of standards.

Decontamination and waste management 62 pages

This monograph provides more specific information regarding decontamination and waste than is found in the LBM as it builds off of the generalities found within. The monograph is broken into 4 sections, each containing a small number of subsections.

Section 1: Introduction

Section 2: Methods of decontamination with 6 subsections, each containing a specified method of decontamination. The methods of decontamination described are broken down and categorized. For example, Chemical methods of decontamination are further broken into gas/vapor or liquid categories. From there each one, such as “peroxides” is explained in detail.

Section 3: Waste Management and decontamination of waste products with 3 subsections.

As with the previous chapter, each type of waste is broken down into a category, such as biological, sharp, or chemical. From there the categories are further delineated. Important for each local is to know and understand the regulatory complexities of your site.

Section 4: Methods of Inactivation with subsections. Inactivation is provided in terms of methods such as nucleic acid extraction, formalin treatment, thermal inactivation, and ionizing radiation.

The information provided can be used to assist lab personnel in developing site-specific procedures for biological wastes.

Biosafety Programme Management 98 pages

This Monograph is divided in five sections, namely Introduction, Management Cycle, Biosafety Culture, Roles and responsibilities and, Developing a Biosafety Programme.

Section 1: A biosafety programme is a collection of information and associated actions that include: an institutional policy to describe the scope, purpose, and objectives of the biosafety programme.

The information in this monograph on biosafety programme management is designed to accompany and support the fourth edition of the WHO Laboratory biosafety manual (core document) and other associated monographs. The manual and the monographs adopt a risk- and evidence-based approach to biosafety rather than a prescriptive approach to ensure that laboratory facilities, safety equipment and work practices are locally relevant, proportionate to needs and sustainable.

Section 2: Management cycle

Effective management of a biosafety programme can be achieved by implementing the following project management cycle: planning – assessment – implementation – review and improvement (PDCA). The four stages of the cycle should be carried out in all types of facilities.

Section 3: Biosafety Culture

A biosafety culture is not easily achieved. It requires factors such as

- time,
- clearly defined roles and responsibilities within the organization;
- a biosafety manual that outlines risk control measures for the risks associated with biological hazards; and comprehensive procedures to support the safety policy.
- commitment and diligence from all personnel, supervisors and senior management, in an environment of respect and trust.

- early consultation with and cooperation between those responsible for the development of a biosafety programme and those directly affected by or working within this programme will support a successful working relationship where the common goal of biosafety is achieved.

Section 4: Roles and Responsibilities

- The subsections describe the key roles and responsibilities of institutional personnel in the development and maintenance of the organization's biosafety programme.
- Depending on the size and complexity of the organization, roles and responsibilities may overlap.
- For example, in a smaller facility, the laboratory director may also be a member of the organization's senior management team, and the responsibilities of the biosafety officer may be performed by laboratory personnel (quality manager) or amalgamated with other aspects of safety (such as chemical, ergonomic, electrical) in the role of an overarching safety officer.

Section 5: Developing a Biosafety Programme

- Regardless of the size and complexity of the organization, the foundational elements of a biosafety programme remain the same.
- All stages of the biosafety programme management cycle (planning, assessment, implementation, and review and improvement) should be carried out in all facility types, and the elements associated with each phase should be defined and represented.
- What these elements look like and how they are implemented will vary between organizations, facilities and individual laboratories.

Outbreak preparedness and resilience 80 pages

This monograph addresses preparedness for global outbreaks including new and unknown pathogens. It is intended to be used in the context of risk- and evidence-based decision making. It also draws recommendations and lessons learned from the early stages of recent outbreaks such as Ebola and SARS-CoV-2.

This monograph starts with a glossary section that sets the stage for the considerations provided in the following sections:

Section 1 describes in detail the stages of an outbreak.

Section 2 applies the 5-step process for risk assessment when planning for outbreaks.

Section 3 provides considerations for adapting facilities in preparation for an outbreak, including graphs with red, amber and green zones and traffic flows. It also describes the use of mobile laboratories, how to integrate laboratories during the planning process and the importance of involving key stakeholders. Lastly, it discusses the use of laboratory equipment during outbreaks.

Section 4 discusses personnel to be involved in the response to an outbreak. This section also provides considerations for recruiting, training, assessing competency, requirements for deployment if an outbreak were to occur.

Section 5 is about PPE considerations from the planning perspective, what PPE could be needed, standards to be maintained and disposal of used PPE, to name a few.

Section 6 describes workflows and spaces that need to be adapted during outbreaks. This section has illustrations to show different arrangements for diagnostic laboratories and has tables with suggestions for collection of patient data. Considerations are provided for sample inactivation and the engineering controls, PPE, and practices that should be assessed. This section also provides details on decontamination and waste management, including the use and maintenance of the autoclave, if available.

Section 7 describes specimen transfer and transport considering that samples during an outbreak may not be done as for known substances.

Section 8 describes accident and incident response when handling samples during an outbreak. Examples of incident responses are provided.

Section 9 provides stressor factors to consider when personnel are responding to an outbreak. Occupational health and medical response considerations for before, during, and follow-up after the response to the outbreak.are provided to ensure a comprehensive support to laboratory workers.

Section 10 provides considerations for ensuring laboratory biosecurity regarding specimen handling. Section 11 describes the practices and consideration when the outbreak or epidemic has been contained and cases are

decreasing. These considerations include communications to stakeholders, lessons learned, strategies to continue providing services, and potential laboratory decommissioning and questions to ask regarding the specimens in hand.