African Union

AFRICA CDC
Centres for Disease Control and Prevention
Safeguarding Africa's Health

THE REGIONAL TRAINING AND CERTIFICATION PROGRAM FOR BIOSAFETY AND BIOSECURITY PROFESSIONALS

THE AFRICA CDC BIOSAFETY AND BIOSECURITY INITIATIVE

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Executive Summary

The lack of Biosafety and Biosecurity capacity among the African Union (AU) Members States is well documented in the World Health Organization (WHO) Joint External Evaluation (JEE) technical assessments conducted between 2016-2019[1] and the Global Health Security Index (GHSI) report of 2021[2]. In response, the Africa Centres for Disease Control and Prevention (Africa CDC), in collaboration with AU Member States, in 2019 launched the Regional Biosafety and Biosecurity Initiative (BBI)[3].

The goal of the BBI is to strengthen the biosafety and biosecurity systems of AU Member States in order to build their capacities to meet requirements for biosafety and biosecurity as well as comply with the international requirements and regulations such as the International Health Regulations (IHR) (2005)[4], the Biological Weapons Convention (BWC)[5], and United Nations Security Council Resolution (UNSCR) 1540[6]. To meet these requirements, adequate and appropriately skilled human resources is required.

Africa CDC, working with AU Member developed a Regional Training and Certification Program for Biosafety and Biosecurity Experts. The four areas of specialty identified and developed are (i) Selection, Installation, Maintenance and Certification of Biological Safety Cabinets (ii) Biorisk Management (iii) Design and Maintenance of Facilities Handling High Risk Pathogens (Biocontainment Engineering) and (iii) Biological Waste Management. Graduates of the training program will receive recognition and certification recognized by the African Union Member States under the Africa CDC Biosafety and Biosecurity Initiative. Qualified personnel would be incorporated into the African Union's Register of Biosafety and Biosecurity Professionals and available for deployment across the region when required.

[1] World Health Organization. Joint External evaluation mission reports. https://www.who.int/ihr/procedures/mission-reports-africa/en/
[2] Global Health Security Index. https://www.ghsindex.org/
[3] Africa CDC Biosafety and Biosecurity initiative. https://africacdc.org/programme/laboratory-systems-and-networks/biosafety-and-biosecurity/
[4] International Health Regulations (2005). https://www.who.int/publications/i/item/9789241580496
[5] The Biological Weapons Convention. https://www.un.org/disarmament/biological-weapons/
[6] United Nations Security Council Resolution 1540 (2004). https://www.un.org/disarmament/wmd/sc1540/

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Africa CDC is grateful to the National Institute of Communicable Disease (NICD), South Africa[7] who worked closely with the Africa CDC team to conduct the initial research and developed the draft 0 of the training and certification program, coordinated consultation meetings and compiled feedback received and edited the document and provided other support services.

Africa CDC would like to express its great appreciation to the African Society for Laboratory Medicine (ASLM)[8] and Global Affairs Canada Weapons Threat Reduction Program[9] for providing the resources to support the process of developing the framework.

[7] National Institute of Communicable Disease, South Africa. https://www.nicd.ac.za/
[8] African Society for Laboratory Medicine. https://aslm.org/
[9] Global Affairs Canada Weapons Threat Reduction Program . https://www.international.gc.ca/world-monde/issues_development-enjeux_developpement/peace_security-paix_securite/non_proliferation.aspx?lang=eng

Acronyms

ABSA	American Biosafety Association
Africa CDC	Africa Centers for Disease Control and Prevention
ASLM	African Society for Laboratory Medicine
Af-BBP	African Biosafety and Biosecurity Professional
AfSME	Africa Region Subject Matter Expert
APHL	Association of Public Health Laboratories
AU	African Union
BRM	Biorisk Management
BSC	Biological Safety Cabinet
BSL	Biological safety level
BWC	Biological Weapons and Toxins Convention
CDC	Centers for Disease Control and Prevention
CPD	Continuing Professional Development
DBB	Division of Biosafety and Biosecurity
DURC	Dual Use Research of Concern
ECC	Examination and Certification Committee
HBA	Hazardous Biological Agents
GBRMC	Global Biorisk Management Curriculum
GHS	Global Health Security
IFBA	International Federation of Biosafety Associations
JEE	Joint External Evaluation
MS	Member States
NICD	National Institute for Communicable Diseases
NHLS	National Health Laboratory Service
PC	Professional Certification
PPE	Personal protective equipment
SNL	Sandia National Laboratories
WHO	World Health Organization PPE
WM	Waste Management

Relevant Terms and Definitions[10][11][12][13]

The following terms and definitions are noted for the purposes of this document.

Accreditation: The assessment and attestation of competency.

Biological agent: A microorganism, virus, biological toxin, particle or otherwise infectious material, either naturally occurring or genetically modified, which may have the potential to cause infection, allergy, toxicity or otherwise create a hazard to humans, animals, or plants.

Biological waste: Waste that is suspected to contain or is contaminated with pathogens in sufficient concentration or quantity to cause disease.

Biological safety cabinet (BSC): An enclosed, ventilated working space designed to provide protection to the operator, the laboratory environment and/or the work materials for activities where there is an aerosol hazard. Containment is achieved by segregation of the work from the main area of the laboratory and/or through the use of controlled, directional airflow mechanisms. Exhaust air is passed through a high efficiency particulate air (HEPA) filter before recirculating into the laboratory or into the building's heating, ventilation and air conditioning system. There are different classes (I, II and III) of BSCs that provide different levels of containment.

Biosafety: Containment principles, technologies and practices that are implemented to prevent unintentional exposure to biological agents or their inadvertent release.

Biosecurity: Principles, technologies and practices that are implemented for the protection, control and accountability of biological materials and/or the equipment, skills and data related to their handling. Biosecurity aims to prevent their unauthorized access, loss, theft, misuse, diversion or release. (Not agricultural biosecurity, a widely used term in Africa).

Competency: A combination of knowledge, skills and abilities that are critical to performing a task effectively. (Defined by its specific use in the Af-BBP program.)

Containment: The combination of physical design parameters and operational practices that protect personnel, the immediate work environment and the community from exposure to biological agents. The term "biocontainment" is also used in this context.

Certification: Written confirmation that a person, product, or process conforms to specified requirements and standards. In this Af-BBP program, certification can be conferred by the ECC as designated by the Africa CDC to offer certification.

Dual use items: Certain materials, information and technologies that are intended for benefit, but which might be misapplied to do harm.

Expert: An individual who has mastered the principles, concepts and/or methodologies related to the competency and has had significant success in performing the most demanding assignments requiring the competency. Within the context of the competency, able to apply innovations to problem-solving and task completion. Individuals are able to synthesize, critique or teach the competency and are able to provide coaching and mentoring. (Defined by its specific use in the description for an AfSME in the Af-BBP program.)

Engineering controls: Risk control measures that are built into the design of a laboratory or laboratory equipment to contain the hazards. Biological safety cabinets (BSCs) and isolators are forms

[10] The Regional Biosafety and Biosecurity Legal Framework, for the African Union Member States, 2021
[11] WHO Laboratory Biosafety Manual, 4th edition - Core Document, 2020:
https://www.who.int/publications/i/item/9789240011311
[12] WHO Safe Management of Wastes from Health-care Activities, 2nd edition, 2014:
https://www.euro.who.int/__data/assets/pdf_file/0012/268779/Safe-management-of-wastes-from-health-care-activities-Eng.pdf
[13] The Laboratory Leadership Competency Framework, Global laboratory Leadership Programme (GLLP), 2019;.
https://apps.who.int/iris/rest/bitstreams/1243229/retrieve

of engineering control in order to minimize the risk of exposure to and/or unintended release of biological agents.

Examination and Certification Committee (ECC): A committee comprised of regional subject matter experts with diverse professional backgrounds and experience in one or more of the areas of specialization as described by the Af-BBP program.

Good microbiological practice and procedure (GMPP): A basic laboratory code of practice applicable to all types of laboratory activities with biological agents, including general behaviours and aseptic techniques that should always be observed in the laboratory. This code serves to protect laboratory personnel and the community from infection, prevent contamination of the environment, and provide protection for the work materials in use.

High Consequence Agents and Toxins: These are biological agents and toxins that have been determined to have the potential to pose a severe threat to both human, animal, and plant health.

Infectious substances: The term applied for the purposes of transport to any material, solid or liquid, which contains biological agents capable of causing infection in either humans, animals or both. Infectious substances can include patient specimens, biological cultures, medical or clinical wastes and/or biological products such as vaccines.

Pathogen: A microbiological agent capable of causing disease in humans, animals or plants. For example a virus, bacteria, fungi or parasite.

Personal protective equipment (PPE): Equipment and/or clothing worn by personnel to provide a primary or secondary barrier against biological agents, thereby minimizing the likelihood of exposure. PPE includes, but is not limited to, laboratory coats, gowns, full-body suits, gloves, protective footwear, safety glasses, safety goggles, masks and respirators. Selection of appropriate PPE is dependent on the routes of transmission being blocked.

Primary containment device (equipment): A contained workspace designed to provide protection to its operator, the laboratory environment and/or the work materials for activities where there is an aerosol hazard. Protection is achieved by segregation of the work from the main area of the laboratory and/or through the use of controlled, directional airflow mechanisms. Primary containment devices include biological safety cabinets (BSCs), isolators, local exhaust ventilators and ventilated working spaces.

Risk: A combination of the likelihood of an incident and the severity of the harm (consequences) if that incident were to occur.

Risk assessment: A systematic process of gathering information and evaluating the likelihood and consequences of exposure to or release of workplace hazard(s) and determining the appropriate risk control measures to reduce the risk to an acceptable risk.

Safety culture: A set of values, beliefs and patterns of behaviour instilled and facilitated in an open and trusting atmosphere by individuals and organizations working together to support or enhance best practice for laboratory biosafety, irrespective of whether it is stipulated in applicable codes of practice and/or regulations.

Standard operating procedures (SOPs): A set of well-documented and validated stepwise instructions outlining how to perform laboratory practices and procedures in a safe, timely and reliable manner, in line with institutional policies, best practice and applicable national or international regulations.

Treatment: Any method, technique or process for altering the biological, chemical or physical characteristics of waste to reduce the hazards it presents and facilitate, or reduce the costs of, disposal.

Waste management: All the activities, administrative and operational, involved in the handling, treatment, conditioning, storage and disposal of waste (including transportation).

Introduction

The Biosafety and Biosecurity Initiative was launched by the Africa Centers for Disease Control and Prevention (Africa CDC) in April 2019 with the aim of strengthening the African Union (AU) Member States' biosafety and biosecurity systems and enabling them to comply with international requirements[14] including the International Health Regulations (IHR) (2005)[15], the Biological Weapons Convention (BWC)[16], United Nations Security Council Resolution (UNSCR) 1540[17] and the multi-country Global Health Security Agenda (GHSA)[18]. Recent public health emergencies including the West African Ebola virus disease outbreaks and the COVID-19 SARS-CoV-2 global pandemic impressed the growing need for strengthening national systems for biosafety and biosecurity. Findings of the World Health Organization (WHO) Joint External Evaluations (JEE) and the Global Health Security Index (GHS Index) report have further demonstrated the inadequacies of current laboratory biosafety and biosecurity capacity on the African continent[19,20].

The concept of biosafety seeks to prevent the unintentional or accidental release of pathogens and toxins, primarily referring to the personnel handling the pathogens being at risk, with the general population/community and the environment secondarily affected. The focus of biosecurity differs from biosafety in intent. Biosecurity aims to thwart the deliberate theft, diversion or misuse of high-consequence biological agents, toxins, materials, equipment and technologies for malevolent purposes including bioterrorism or biological weapons proliferation. In order to ensure the safety and security of personnel and the dangerous biological agents and toxins with which they work, there is need for both appropriate physical security measures and technologies, and for adequate, appropriately trained and competent personnel.

Rationale

Through various consultations between Africa CDC and AU Member States conducted between 2019-2021[21], the deficiency or limited availability of standardized and regionally recognized training programs available on the continent was consistently raised as an area for concern and a major limitation or challenge in biosafety and biosecurity capacity building efforts[22]. The need was therefore to develop sustainable, local, implementable, and accessible professional training and certification program that is both recognized and endorsed by AU Member States. The training program, described in this framework, focused specifically on four (4) areas of specialization, namely: (i) Selection, Installation, Maintenance and Certification of Biological Safety Cabinets (ii) Biorisk Management (iii) Design and Maintenance of Facilities Handling High Risk Pathogens (Biocontainment Engineering) and (iii) Biological Waste. The graduates of these training programs will receive recognition and certification and would be incorporated into an AU Register of Biosafety and Biosecurity Professionals (AfBBP). The proposed Regional Training and Certification Program for Biosafety and Biosecurity Professionals therefore seeks to expand the capacity for formally trained biosafety and biosecurity professionals

[14] Africa CDC. Africa CDC Biosafety and Biosecurity Initiative. https://africacdc.org/programme/laboratory-systems-and-networks/biosafety-and-biosecurity/
[15] International Health Regulations (2005). https://www.who.int/publications/i/item/9789241580496
[16] The Biological Weapons Convention. https://www.un.org/disarmament/biological-weapons/
[17] UN Security Council Resolution 1540 (2004). https://www.un.org/disarmament/wmd/sc1540/
[18] The Global Health Security Agenda. https://ghsagenda.org/
[19] Global Health Security Index. 2019 Global Health Security Index. https://www.ghsindex.org/
[20] World Health Organisation. Joint external evaluation tool: international health regulations, 2005. Available: http://apps.who.int/iris/handle/10665/204368
[21] Africa CDC Biosafety and Biosecurity Initiative Report on the Consultative Process to Identify Priorities for Strengthening Biosafety and Biosecurity. https://africacdc.org/download/africa-cdc-biosafety-and-biosecurity-initiative-report-on-the-consultative-process-to-identify-priorities-for-strengthening-biosafety-and-biosecurity/
[22] Africa CDC. Africa CDC Biosafety and Biosecurity Initiative Report on the Consultative Process to Identify Priorities for Strengthening Biosafety and Biosecurity. https://africacdc.org/download/africa-cdc-biosafety-and-biosecurity-initiative-report-on-the-consultative-process-to-identify-priorities-for-strengthening-biosafety-and-biosecurity/

using a regionally relevant, standardized and recognized training and certification program in efforts to elevate the field of biosafety and biosecurity as a recognized profession on the continent.

In the long term, the areas of specialty would be expanded based on changing needs of the Africa Region.

Objectives

i. To develop and train a knowledgebase for biosafety and biosecurity professionals on the African continent that aligns with international best practices and international equivalency certifications that are domesticated and relevant to the resource-constrained environments of the African environment.
ii. To develop a harmonised biosafety and biosecurity capacity building program that enables workforce development of bioscience practitioners with knowledge, skills and demonstrable competencies in biosafety and biosecurity to enhance safety and security with working with biological agents, toxins, materials and technologies.[23]
iii. To ensure that the continent has an established process for recognizing and certifying its biosafety and biosecurity professionals so that a database of these professionals may be called upon for all matters relating to biosafety and biosecurity on the continent.

Scope

i. To train and certify regional biosafety and biosecurity professionals in four (4) fields of specialization, namely: (i) Selection, Installation, Maintenance and Certification of Biological Safety Cabinets (ii) Biorisk Management (iii) Design and Maintenance of Facilities Handling High Risk Pathogens (Biocontainment Engineering) and (iii) Biological Waste.
ii. To develop African biorisk management professionals who are able to implement biosafety and biosecurity programs, to enhance safety and security with working with biological agents, consistent with the world's best practices with special focus on limited resource environments.

[23] Kenya Laboratory Biorisk Management Curriculum, 2nd edition, 2019. https://www.health.go.ke/kenya-laboratory-biorisk-management-curriculum-klbrmc/

Certification Levels[24;25]

The Regional Training and Certification Program for Biosafety and Biosecurity Professionals, for African Biosafety and Biosecurity Professionals (Af-BBP), will be based on a proficiency matrix intended for use as a guide in assessing individuals' competencies relative to the programs' four (4) areas of specialization as outlined in the scope of this proposed framework. Three (3) levels of proficiency are proposed, are namely:

Entry Level: The individual has basic or foundational knowledge of the principles, concepts and/or methodologies related to the area of specialization for which professional certification is sought through demonstrated competency attained through education or training (e.g., coursework detailed in this certification framework, mentorship, etc.). Entry level professionals generally perform a range of assignments under supervision of a level 2 or intermediate level professional or higher.

Intermediate Level: The individual has progressed from entry level through this proposed program or through accepted alternative pathway as determined by the Examination and Certification Committee (ECC) elected through the African CDC, ASLM and member states, and demonstrates advanced knowledge of the principles, concepts and/or methodologies related to the area of specialization for which professional certification is sought through demonstrated competency as attained through education or training (e.g., coursework detailed in this certification framework, completion of an improvement project, mentorship, etc.) and is able to perform a range of assignments under supervision, through mentorship and/or coaching or independently once competency has been demonstrated.

Senior Level: The individual analyses and independently applies principles, concepts and/or methodologies related to the competency as attained through education or training and successfully demonstrated experience in a variety of complex assignments. Experienced, senior level professionals should be able to synthesize, critique, develop and/or teach the listed competencies as applicable and is able to provide coaching and mentoring to entry and intermediate level professionals as described above

Each area of specialization, as per the Af-BBP program, has a stipulated number of domains that will be considered when making assessments. Within each of the domains, there are likely to be wide variations in range of activities that are undertaken. It is impractical to provide a prescriptive list of proficiency criteria within each domain that need to be "checked off" during assessments, thus the matrices are to be used broadly as a guideline of what is required from regional experts in the four (4) areas of specialization as outlined in the scope of this program. The criteria in the matrix, detailed in Appendix A and B, serves to guide assessors regarding what is to be considered as a reasonable expectation within each level, but the system also allows for some flexibility to the competency track record provided by the professional seeking certification. Figure 1 and 2 below details progression up the Af-BBP program in the different areas of specialty.

Africa Region Subject Matter Expert (AfSME): is an Individual that has mastered the principles, concepts and/or methodologies related to the areas of specialisation described above and has demonstrated significant success in performing the most demanding assignments requiring the competency. This knowledge and experience must be demonstrable and documented, with their expertise being recognized by their peers, regionally and/or internationally. AfSMEs will provide ongoing mentorship, conduct in-country competency evaluations and trainings in areas of their proven competencies.

[24] The Laboratory Leadership Competency Framework, Global laboratory Leadership Programme (GLLP), 2019; https://apps.who.int/iris/rest/bitstreams/1243229/retrieve
[25] Guidelines for Biosafety Laboratory Competency CDC and the Association of Public Health Laboratories; 2011. https://www.cdc.gov/mmwr/pdf/other/su6002.pdf

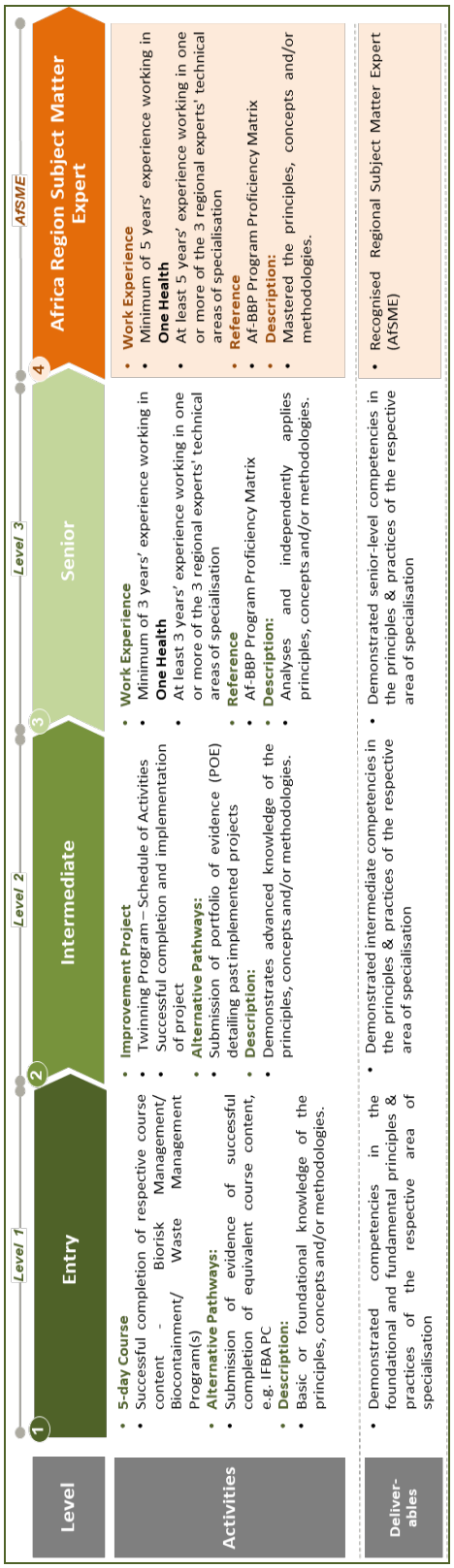

Figure 1 Summary of the Regional Training and Certification Program for Biorisk Management, Biocontainment Engineering and Biological Waste Management

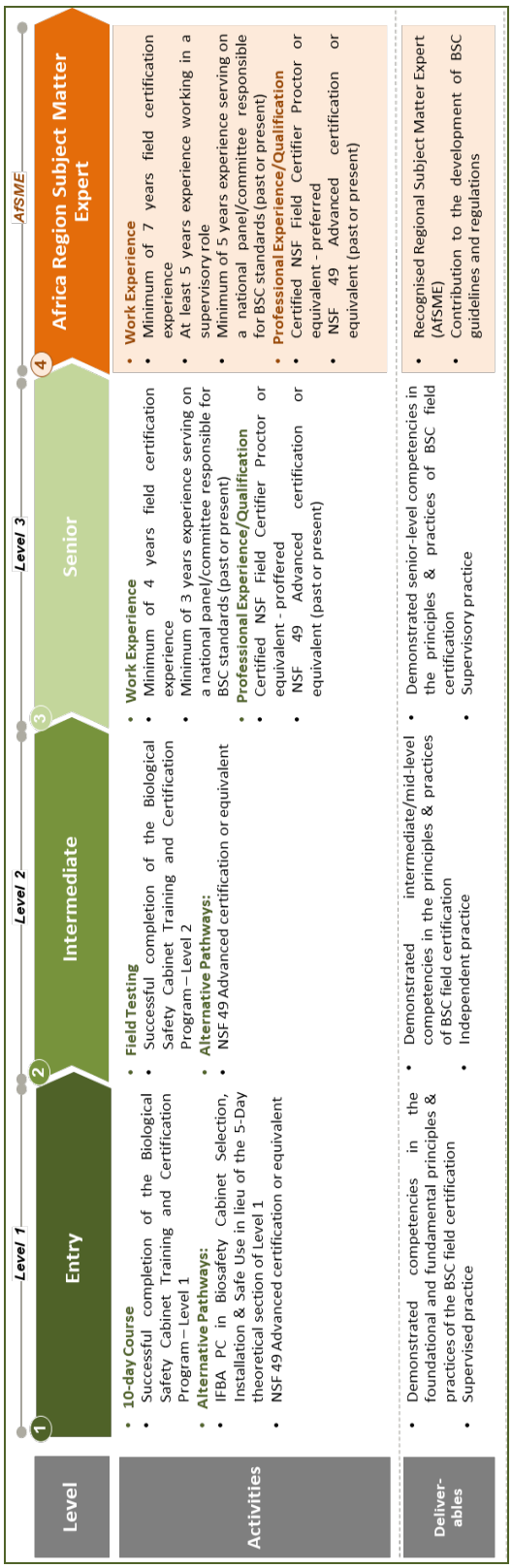

Figure 2: Summary of the Regional Training and Certification Program for Selection, Installation, Maintenance and Certification of Biological Safety Cabinets BSC

Note: The AfSME is not part of the Af-BBP program proficiency but has been included to illustrate the continuum of competencies across this field of practice.

5.1 Part 1: Day 1-10-Day Course Curriculum Details

Regional biosafety and biosecurity professionals will undergo training[26] in one or more of the four (4) fields of specialization, with the foundational/entry-level course(s) consisting of a structured 5-10 Day didactic course with relevant facilitated activities, followed by an examination at the end of the course. The successful completion of any of the 5-10 day course/s (*or equivalency to be assessed on an individual applicant basis*) with an exam pass, is the pre-requisite that would enable professional candidates to attain Af-BBP Entry Level certification for the specific area of specialization. Table 1 and Table 2 summarizes the course content, with a detailed description in Appendix A and B.

A. Selection, Installation, Maintenance and Certification of Biological Safety Cabinets - Biological safety cabinets (BSC) are widely used in laboratories as primary containment devices, designed to protect laboratory workers and the environment against potentially harmful and infectious pathogens. BSCs mitigate possible exposure to aerosols from infectious biologicals to laboratory personnel, the environment, and protect the material being worked on from possible contamination . As an engineering control, BSCs are used to mitigate the risks inherent in the handling of pathogens in the laboratory environment. As such, BSCs need to be appropriately selected, properly installed and used, and undergo regular maintenance and certification by suitably qualified personnel. Certification of BSCs requires compliance with international standards such as the National Sanitation Foundation (NSF) Standards appropriately trained and certified personnel.

Target Participant Group - It is critical to have the correct candidate with the right aptitude for BSC certification, i.e. candidates with mathematics and some basic mechanical skills generally fare well in the training process . This training and certification program has been developed in line with international standards for both theoretical and practical forms of competency assessment, which will upon successful completion will result in either Level 1 (entry) or Level 2 (advanced) certification.

- Candidates with at least a high school diploma or equivalent (Technical Qualification/Vocational education for technical diploma) with mathematics and mechanical and/or electrical subjects passed are eligible. Understanding of ISO 17025 ISO Standard, familiarity to testing equipment for BSC validations and at least one (1) year exposure to laboratory environments are desirable
- IFBA Professional Certification in Biosafety Cabinet Selection, Installation & Safe Use

[26] Biosafety and biosecurity capacity building: insights from implementation of the NUITM-KEMRI biosafety training model, B Muriithi · 2018: https://tropmedhealth.biomedcentral.com/articles/10.1186/s41182-018-0108-7

Table 1: Training Content of the Selection, Installation, Maintenance and Certification of Biological Safety Cabinets BSC course

Stage	Timeline	Training Content	Alternative Pathways/ Resources
Level 1	5 Days	**Theoretical Section - 5-Day Didactic Lectures**	IFBA Professional Certification in Biosafety Cabinet Selection, Installation & Safe Use
		-Understanding of basic laboratory practices, BSCs as engineering controls	
		-legal requirements and the different applicable standards	
		Types, operation, functions, features, selection and placement of BSCs	
		-Types, operation, functions, features of test equipment, and testing methods	
		-Safe use, maintenance and certification of BSCs	
		- BSC decontamination method, Power protective devices - Report writing for cabinet certification	
	5 Days	**Practical Section: 5-Day Demonstration and Practice**	NSF 49 Advanced certification or equivalent
		- Setting up and proper use of test equipment	
		- Maintenance, filter replacement	
		- Airflow measurements, volumetric measurement and calculations, airflow pattern visualisation and interpretation	
		- HEPA filter testing	
		- Application of BSC decontamination method - HEPA filter patching methods - Power protective devices and basic electrical troubleshooting - Airflow balance troubleshooting	
		Exam and certificate issuing	
Level 2	6 Months	**Post- Level 1 course Requirements**	**Resources:** During this period, designated regional experts (or course instructors) will provide mentorship and technical support remotely.
		- Candidates must have access to test equipment	
		- Candidates must have the means to facilitate remote mentorship	
		- Completion of BSC certification/validation and discussion with mentor for signoff	
		- Candidates should test at least ten (10) BSCs during this period (i.e. >10 in 6 months)	
		- At least 50% of the BSCs tested must be from a state laboratory	Deviations to this requirement can be considered at the discretion of the ASLM-ACDC - Examination and Certification Committee (ECC) on a case-by-case basis.
		Field Experience: In-country Assessment	**Resources:** Practical and competency evaluations shall be conducted in-country by designated local or regional experts.
		- Practical demonstration of BSC troubleshooting, repairing and HEPA filter replacement	
		- Practical demonstration of BSC decontamination and testing	

B. Biorisk Management - To address principles and practices of how to work safely and securely with biological agents and toxins that are of high consequence, if released intentionally (addressing the biosecurity aspects of BRM) or unintentionally (addressing the biosafety aspects

of BRM) from a biological laboratory setting (special emphasis on the "one health" concept) – i.e. human, animal and plant.

i. Target Participant Group - The Biorisk Management course will primarily target laboratory personnel handling biological materials (i.e. scientists, technologists and laboratory technicians), field epidemiologists, biorisk management advisors (also referred to as biosafety officers), institutional leadership and administrative or support service laboratory personnel (e.g. laboratory assistants, research assistants and interns/students). Although this course may be rather technical (i.e. delving into specific examples of mitigation strategies and how they are suited to the assessed risks), policy makers, and government officials responsible for laboratory regulations or laboratory auditors are encouraged to pursue this foundational course in order to develop a fundamental and foundational understanding of Biorisk management and risk mitigation.

C. **Design and Maintenance of Facilities Handling High Risk Pathogens (Biocontainment Engineering)** - Introduces the fundamental biocontainment engineering principles for the design, construction, commissioning, certification and operation of high containment laboratory facilities handling high risk pathogens. It aims to address sustainability as it applies to the management of the daily operations (safe and secure) and maintenance of these facilities and ensuring that they are certified as being fit for purpose.

ii. Target Group - The Design and Maintenance of Institutions Handling High Risk Pathogens (Biocontainment) training program will target biorisk management advisors, engineers (design, mechanical, biomedical engineers etc.), architects, facility maintenance personnel, laboratory personnel (particularly those who work within containment facilities), and institutional leadership. Policy makers and government officials responsible for development and implementation of laboratory regulations, or laboratory auditors are encouraged to pursue this foundational course in order to develop a fundamental and foundational understanding of design and maintenance of facilities handling high risk pathogens (Biocontainment Engineering).

D. **Biological Waste Management** - waste includes a number of waste categories including general, infectious, hazardous, chemical, sharp and radioactive waste generated by laboratory and/or clinical setting facilities (both in human and animal sector health) as well as other institutions handling hazardous or infectious agents and toxins (such as universities and research institutions) and generating hazardous biological (and associated) waste.

iii. Target Group - The Waste Management course will target all personnel handling biological materials, biorisk management advisors, laboratory support personnel, environmental health officers/ practitioners, safety, health and environment officers, hospital personnel, auditors, compliance officers and policy makers.

Table 2: 5-Day Didactic Course Details for Biorisk Management, Biocontainment Engineering and Biological Waste Management Courses

Training Day	Biorisk Management	Biocontainment Engineering	Waste Management
Day 1	Introduction to Biorisk Management (BRM)	Introduction to Biorisk Management (BRM)	Introduction to Biorisk Management (BRM)
	Elements of a biorisk management system (BRMS)	Elements of a biorisk management system (BRMS)	Elements of a biorisk management system (BRMS)
	International regulations, laws, frameworks,	Brief overview/introduction of risk assessment, risk mitigation and performance	Brief overview/introduction of risk assessment, risk mitigation and performance review (AMP model)

Training Day	Biorisk Management	Biocontainment Engineering	Waste Management
	standards and guidelines that pertain to Biorisk Management	review (AMP model)	
	The ISO 35001 standard and its precursor the CWA15793	Risk Assessments	Risk Assessments
		Mitigation Strategies	Mitigation Strategies
Day 2	Concepts in laboratory safety and the hierarchy of control (theory)	Biocontainment Facility Features	Classification of hazardous biological waste
	Concepts in laboratory safety and the hierarchy of control (practical)	Regulations, guidelines and standards governing the design and operation of high containment facilities	Introduction to Managing Biological Waste Identification and characterization of waste
			Segregation and packaging methods
Day 3	Biosecurity, dual use research of concern, and bioethics	Laboratory Design Process	Storage requirements Internal transportation
		Basic biocontainment engineering principles of facility design and construction	Off-site transportation requirements Treatment technologies
Day 4	Introduction of risk assessment, risk mitigation and performance review (AMP model) (theory)	Facility commissioning performance and verification testing requirements – certification and recertification	Disposal Methods Introduction to Developing and Implementing a Waste Management Program
	Performing risk assessments using the AMP model and identifying mitigation strategies (practical)		National and Facility Waste Management programs
			Legislation and policies for Waste Management
Day 5	Reflection on learning material	Biocontainment Operations & Maintenance	Monitoring a Waste Management Program
			Emergency Response Plan for Waste Management

Part 2: Practical – Improvement Project

A. Biorisk Management, Biocontainment Engineering and Biological Waste Management Courses

Upon completion of the Entry-level 5-day didactic course/s and examination as described above, participants will be required to engage in a six (6) to twelve (12)-month twinning or mentorship program to develop and implement an "improvement project" in their home country in order to progress to the next level of professional recognition and certification, i.e. to move from an Entry Level professional to an Intermediate Level professional. Table 4 below details the program of activities during this period.

Table 4: Twinning Program – Schedule of Activities for the Biorisk Management, Biocontainment Engineering and Biological Waste Management Courses

Stage	Timeline	Program Activities
Post Level 1 Training	At least 4 weeks after the course attendance	**Inception Meetings**
		- Meetings between twin participants (virtually or in-person) to get to know one another and to discuss each other's goals & objectives.
		- Complete the project initiation worksheets, share amongst each other with feedback provided.
		- Finalize the project initiation worksheet (once final, this worksheet is now the Project Plan).
Participation and Project Execution	10 Months	**Implement Project Plan**
		- Record progress and progress checks on the Project Progress log.
		- Check in with twin at a frequency defined in the Project Plan.
		- Share and document lessons-learned and challenges twins are struggling to overcome.
		Project Document Review
		- Submit project document for review by partner-twin.
		- Twin to provide constructive feedback based on the rubric(s) in the toolbox and their own experience.
		- Update project document based on mutually agreed upon changes.
Project Completion and Evaluation	1 - 4 weeks Evaluation	**Project Evaluation**
		- Submit project documents for review by Regional Experts as appointed by ASLM-ACDC - Examination and Certification Committee (ECC).
		- Regional experts will use the rubric(s) plus their experience to provide feedback.
		- After considering the expert feedback and making any changes, share the final document with twin for any last comments and feedback.
		- Submit for final grading, the grade will be based on the rubric(s) and final expert feedback.

Examples of Improvement Projects for the Biorisk Management, Biocontainment Engineering and Biological Waste Management Courses

Participants should plan to develop relevant projects to the discipline they wish to pursue.

1. Biorisk Management

- A facility relevant risk assessment with appropriate mitigation strategies, including the formulation and implementation of a plan; or
- A policy document/manual to support Biorisk Management implementation in home organization and associated training at the home organization ; or
- At least five (5) Biosafety- and/or biosecurity-related Standard Operation Procedures and associated training of personnel at a home organization.
- Other areas which need to be agreed upon by the assigned Regional Expert

2. Biocontainment Engineering

- Develop an operational manual and maintenance plan for the biocontainment facility with associated training of personnel in applicable aspects at a home organization; or
- At least 5 Standard Operating Procedures and associated training related to maintenance of selected biosafety and biosecurity equipment at the home organization
- Other areas which has to be agreed upon by the assigned Regional Expert

3. Waste Management

- A waste management manual/policy for the facility/institution that covers all types and forms of waste generated in a laboratory setting. The manual/policy should incorporate references to country-specific legislation relating to waste management as well as universal best practices. This plan should indicate a clear path for its implementation. This should be accompanied with training of personnel at the home organization.
- At least 5 Standard Operating Procedures and associated training related to biological waste management at the home organization
- Other areas which has to be agreed upon by the assigned Regional Expert

The projects listed above are examples of projects that could be used to demonstrate the application of knowledge in each of the three areas of specialization. Additional options for demonstrating the application of knowledge can be considered at the discretion of the regional subject matter expert assigned to "supervise" or mentor the entry level professional and may differ on a case-by-case basis. An Improvement Project Template is provided in Appendix D

B. Selection, Installation, Maintenance and Certification of Biological Safety Cabinets BSC
This will be achieved following successful completion of post-Level 1 requirements and an in-country practical and competency assessment to be conducted by designated local or regional experts. The program of activities, detailed in Table 3.

Table 3: Twinning Program – Schedule of Activities for the Biorisk Management, Biocontainment Engineering and Biological Waste Management Courses

Stage	Timeline	Schedule of activities
Level 2	6 Months	**Post- Level 1 course Requirements**
		- Candidates must have access to test equipment
		- Candidates must have the means to facilitate remote mentorship
		- Completion of BSC certification/validation and discussion with mentor for signoff
		- Candidates should test at least ten (10) BSCs during this period (i.e. >10 in 6 months)
		- At least 50% of the BSCs tested must be from a state laboratory
		Field Experience: In-country Assessment - Practical demonstration of BSC troubleshooting, repairing and HEPA filter replacement - Practical demonstration of BSC decontamination and testing

A competency evaluation checklist must be completed by the field examiner/Regional Subject Matter expert and submitted for review and approval. Appendix E

Examination and Certification Committee

Africa CDC shall establish Examination and Certification Committee (ECC) composed of AfSMEs with diverse professional backgrounds and experience in one or more of the areas of specialization as described by the Af-BBP program. Other factors to be considered when selecting the ECC, include past experience in regional committees, geographical representation, gender balance, and diversity of expertise. In this regard, Africa CDC will establish the ECC as follows:

i. Develop terms of reference for the convening and function of the ECC, which will guide the participation of nominated AfSMEs as independent and impartial experts.

ii. Nominated AfSMEs to serve on the ECC are recruited through a rigorous processes designed to ensure that the highest standard of experts meeting the required criteria and minimum requirements are selected, as elaborated in the proficiency matrix. It is of high importance that these experts who are identified have the necessary experience, technical ability, and interpersonal skills to contribute effectively to the ECC.

iii. Develop and maintain a roster of certified biosafety and biosecurity professionals (through the Af-BBP program) as a consolidated source of locally available regional capacity, i.e. the African Union's Register of Biosafety and Biosecurity Professionals. To this end, the ECC shall establish and implement a formal system for Continuing Professional Development (CPD) and renewal of certification.

Continuing Professional Development (CPD)[27;28;29]

To remain competent in one or more of the four specified areas of practice, Af-BBPs need to develop and apply their knowledge, experience and expertise with associated skills or they may lose their proficiency. Af-BBPs would be required to maintain their professional certification by participation in

[27] ABSA International Professional Credentials in Biosafety: https://absa.org/credentials/
[28] Engineering Council of South Africa (ECSA), Continuing Professional Development (CPD): https://engineeringcouncilsa.microsoftcrmportals.com/
[29] South African Institute of Occupational Safety and Health (SAIOSH), Continuing Professional Development (CPD) Policy, 2018: https://www.saiosh.co.za/page/CPD

professional development activities over and above their daily biological safety (and biosecurity) activities encountered as part of their job function. In order to administrate and evaluate the compliance of registered professionals with this requirement to accumulate a predetermined number of CPD points in order to maintain professional certification, the ECC may establish an accreditation board that oversees activities or may "outsource" this function to a relevant and appropriate organisation, association or collaborating body as applicable.

Af-BBP would be required to collect a pre-determined number of CPD points in a 5-year cycle period. CPD points are to be collected through participation in any CPD accredited program or activity. CPD activity must advance the individual in the following ways: 1) ensure that core skills are maintained (as prescribed by the proficiency matrix), 2) obtain or develop new technical / specialty areas and transferable skills in biosafety and biosecurity, as well as in other community spheres. These activities should fall into the following categories:

i. Developmental activities - attendance of validated structured educational development activities such as conferences, congresses, seminars, workshops, lectures, refresher-training courses. This can be benchmarked on the American Biosafety Association's (ABSA International) model (see List of accredited activities: https://absa.org/biopdalist/) and can draw influence from local and regional similar professional accreditation bodies).

ii. Work-based activities – related work activities in a specified field of practice, and/or mentoring in the workplace (e.g. an Intermediate Level professional mentoring an Entry Level professional).

iii. Individual activities – membership of recognised associations in the specified areas of practice, or other activities as determined through the accreditation program.

It is emphasized that many countries have similar requirements for professionals to ensure continual professional development, therefore the CPD activities proposed herein should align with "in country" CPD activities and requirements where they are applicable, e.g. in some countries medical scientists need to be registered with the Health Professions Councils/local board and must accumulate a set number of CPD points in a specified cycle or period.

Appendix A: Proficiency Matrix for the Biorisk Management, Biocontainment Engineering and Biological Waste Management Courses[30;31;32;33;34]

Proficiency Criteria	Target Audience	Objectives	Proficiency Levels			Africa Region Subject Matter Expert
			Entry	Intermediate	Senior	
Knowledge		Academic Qualifications	3-4 year degree/diploma; *or*	3-4 year degree/diploma; *or*	3-4 year degree/diploma; *or*	3-4 year degree/diploma; *or*
			3-5 years "in practice" experience	3-5 years "in practice" experience; *or*	3-5 years "in practice" experience; *or*	3-5 years "in practice" experience; *or*
				Post-graduate qualification (e.g. Master's degree)	Post-graduate qualification (e.g. Master's degree, PhD)	Post-graduate qualification (e.g. Master's degree, PhD)
		Experience	1-2 years post-qualification experience (including internship)	2-4 years post-qualification experience	4-7 years post-qualification experience	> 7 years post-qualification experience
				Minimum of 2 years experience working in public health	Minimum of 3 years experience working in public health	Minimum of 5 years experience working in public health
				At least 1 years experience working in one or more of the 3 regional experts' technical areas of specialisation	At least 3 years experience working in one or more of the 3 regional experts' technical areas of specialisation	At least 5 years experience working in one or more of the 3 regional experts' technical areas of specialisation
					*Masters degree counts for 1 year towards the 3 year requirement	*PhD counts for 3 years towards the 5 year requirement

[30] The Laboratory Leadership Competency Framework, Global laboratory Leadership Programme (GLLP), 2019; https://apps.who.int/iris/rest/bitstreams/1243229/retrieve
[31] Guidelines for Biosafety Laboratory Competency CDC and the Association of Public Health Laboratories; 2011; https://www.cdc.gov/mmwr/pdf/other/su6002.pdf
[32] ABSA International Professional Credentials in Biosafety; https://absa.org/credentials/
[33] International Federation of Biosafety Associations (IFBA) Professional Certification Program; https://internationalbiosafety.org/certification/certification/
[34] The Regional Biosafety and Biosecurity Legal Framework, for the African Union Member States, 2021

Proficiency Criteria	Target Audience	Objectives	Proficiency Levels			Africa Region Subject Matter Expert
			Entry	Intermediate	Senior	
Biorisk Management	Personnel handling biological materials, biosafety officers, laboratory personnel and policy makers	**Domains**	**Demonstrated competencies in the foundational and fundamental principles & practices of biorisk management.**			
		Fundamentals and elements of Biorisk Management Systems	**Outline** laboratory biorisk management principles. **Outline** the steps involved in a BRM risk assessment. **Describe** common laboratory BRM control measures and procedures.	**Implement** principles of laboratory biorisk management. **Implement** a BRM risk assessment to reduce risk. **Apply** BRM control measures and procedures.	**Evaluate** principles of laboratory biorisk management. **Evaluate** BRM risk assessment tools and apply relevant tools to a local context. **Evaluate** risk mitigation measures for their suitability in addressing identified risks	**Develop** BRM risk assessment tools and apply relevant tools to a local context. **Evaluate** risk mitigation measures for their suitability in addressing identified risks and develop new techniques for risk mitigation (wherever possible).
		Regional Biosafety and Biosecurity Legal Framework	**Outline** national biosafety and Biosecurity rules and regulations and international guidance	**Implement** national biosafety and biosecurity rules and regulations and international guidance.	**Evaluate** compliance with national biosafety and biosecurity rules and regulations and international guidance applicable to local context.	**Assess** compliance with national regulatory requirements for biosafety and biosecurity *or* **be consulted as a subject matter expert** providing input into updates into national and/or regional policies.

Proficiency Criteria	Target Audience	Objectives	Proficiency Levels			Africa Region Subject Matter Expert
			Entry	Intermediate	Senior	
		Implementing a Biorisk Management System	**Identify** laboratory BRM policies and procedures. **Describe** the structure of a comprehensive laboratory BRM programme and the essential elements of a BRM manual. **Describe** the essential elements of staff BRM training. **Outline** the components of a BRM incident reporting and management system	**Apply** laboratory BRM policies and procedures; **Implement** a BRM programme that includes a BRM manual; **Implement** staff BRM training; **Apply** BRM incident management.	**Evaluate** laboratory BRM policies and procedures; **Design** strategic and implementation plans for the establishment of a laboratory BRM programme, including development of a BRM manual; **Develop** a framework for staff BRM training; **Develop** policies and procedures for BRM incident response and reporting.	**Develop** laboratory BRM policies and procedures; **Design** strategic and implementation plans for the establishment of a laboratory BRM programme, including development of a BRM manual and advise others on how to do as such; **Assist** in development of a curriculum for BRM training institutionally, nationally, or regionally; **Develop** policies and procedures for BRM incident response and reporting at an Institutional, National or Regional level.
		Shipping of dangerous infectious materials	**Outline** various national and international regulations that may be applicable to the transport of dangerous goods within country and across national borders;	**Apply** national and international regulations pertaining to the transport of dangerous goods within country and in regional contexts; **Apply** dangerous goods classifications to materials that may be found in, or are applicable to, laboratory	**Evaluate** compliance with national and internationally applicable regulations pertaining to the transport of dangerous goods; **Develop** standard processes and procedures to address	**Evaluate** compliance with national and internationally applicable regulations pertaining to the transport of dangerous goods; **Develop** standard processes and procedures to address

Proficiency Criteria	Target Audience	Objectives	Proficiency Levels			Africa Region Subject Matter Expert
			Entry	Intermediate	Senior	
			Outline the different classes of dangerous goods and provide general examples for each class; **Outline** the different biological substance categories and the classification of infectious substances; **Describe** basic elements of triple packaging for infectious substances and list the most common marks, labels and documents required; **List** the most important topics to be included in a training programme on dangerous goods transportation.	operations; **Apply** categories and classification groups to potential infectious substances present in the local laboratory context; **Explain** how the packaging, marking, labelling and documentation of infectious substances contribute to safety and containment; and **Analyse** the content of various training options and/or programmes that impart knowledge about dangerous goods transportation.	dangerous goods classification requirements in the local laboratory context; **Develop** standard processes and procedures that address the use of infectious substance classification in the local laboratory context; **Design** scenarios which illustrate the differences between the packaging, marking, labelling and documentation of different infectious substance classifications; **Evaluate** the effect of training on the competency and proficiency of shippers involved in the transportation of dangerous goods.	dangerous goods classification requirements in an institutional, national or regional laboratory context; **Develop** standard processes and procedures that address the use of infectious substance classification in an institutional, national or regional context; **Design** scenarios which illustrate the differences between the packaging, marking, labelling and documentation of different infectious substance classifications; **Train and certify** others on shipping of dangerous goods; **Evaluate** the effect of training on the competency and proficiency of shippers involved in the transportation of

Proficiency Criteria	Target Audience	Objectives	Proficiency Levels			Africa Region Subject Matter Expert
			Entry	Intermediate	Senior	
						dangerous goods.
		Bioethics and DURC	**Describe** processes and procedures for identifying, prioritizing and controlling sensitive information, agents and technology.	**Apply** processes and procedures for identifying, prioritizing and controlling sensitive information, agents and technology	**Develop** policies, processes and procedures for identifying, prioritizing and controlling sensitive information, agents and technology.	**Develop** policies, processes and procedures for identifying, prioritizing and controlling sensitive information, agents and technology, and serve on Institutional, National or international expert committees.
Biocontainment Engineering	Engineers (design, mechanical, biomedical engineers etc.), architects, facility maintenance personnel, and laboratory personnel	**Domains**	**Demonstrated competencies in the fundamental principles & practices of biocontainment engineering design, construction, commissioning, certification and operations (including maintenance) of facilities handling high risk pathogens.**			
		Regulatory and Certification Frameworks for Institutions Handling High Risk Pathogens	**Identify** the regulations and available guidance for containment facility engineering design, creation and use. **Outline** national biosafety and biosecurity regulations for the certification of facilities handling	**Apply** regulations and available guidance for containment facility engineering design, creation and use. **Implement** national biosafety and biosecurity regulations for the certification of facilities handling high risk pathogens.	**Evaluate** the application of regulations and available guidance related to containment facility engineering design, creation and use. **Evaluate** compliance with national biosafety and biosecurity regulations for the certification of facilities	**Assess c**ompliance with national biosafety and Biosecurity regulations for the certification of facilities handling high risk pathogens *or* **be consulted as a subject matter expert** providing input into updates into national and/or regional policies.

Proficiency Criteria	Target Audience	Objectives	Proficiency Levels			Africa Region Subject Matter Expert
			Entry	Intermediate	Senior	
			high risk pathogens.		handling high risk pathogens.	
		Design and construction	**Define** basic laboratory design and maintenance requirements. **Describe** the design and operation controls of the laboratory facility pathogen containment areas. **Describe the** process for routine monitoring of facility and facility engineering control systems, and recognize when facility engineering controls are compromised or not functioning properly. **Describe** facility design differences and the types of containment barriers applied.	**Implement a** process for designing and maintaining a laboratory. **Apply** the appropriate components of laboratory operations to workflow. **Demonstrate** knowledge of the laboratory facility engineering controls designed to prevent exposure or release of hazardous materials. **Implement** process for routine monitoring of facility and facility engineering control systems.	**Evaluate** laboratory design and maintenance requirements to address changing needs. **Evaluate** the components of laboratory operations related to workflow. **Ensure** facility safeguards that prevent accidental release of an infectious agent from the laboratory function properly **Develop** response procedures to address any compromise in facility engineering controls.	**Evaluate** the laboratory design and **ensure** that the facility safeguards in place are adequate to prevent accidental and/or intentional release of an infectious agent from the laboratory. These engineering controls need to be **assessed** based on the facility specific risk assessment. **Assess** the response procedures to address any compromise in facility engineering controls.

Proficiency Criteria	Target Audience	Objectives	Proficiency Levels			Africa Region Subject Matter Expert
			Entry	Intermediate	Senior	
		Commissioning performance and verification testing requirements – certification and recertification	**Outline** containment systems (including equipment calibration) verification and validation. **Describe** facility certification requirements and applicable regulations.	**Implement** containment systems (including equipment calibration) verification and validation plans. **Implement** facility certification requirements and applicable regulations.	**Develop** plans for containment systems (including equipment calibration) verification and validation. **Design** and **evaluate** processes for facility recertification.	Critically **assess** and **evaluate** the facility certification program and **ensure** the sufficiency of the verification tests and frequency for critical containment components.
		Facility Operations & Maintenance	**Describe** the essential components of a preventive maintenance programme for equipment. **Describe** the policies, processes and procedures for preventive maintenance, service, troubleshooting and repair.	**Analyse** the effectiveness of a preventive maintenance programme for equipment. **Apply** the policies, processes and procedures for preventive maintenance, service, troubleshooting and repair.	**Develop** and/or **evaluate** the preventive maintenance programme for equipment. **Design** and **evaluate** processes for preventive equipment maintenance, service, troubleshooting and repair. **Ensure** continuous maintenance and required recertification of facility and facility engineering control systems.	**Assess** the policies, processes and procedures for maintenance, both preventive and breakdown maintenance.

Proficiency Criteria	Target Audience	Objectives	Proficiency Levels			Africa Region Subject Matter Expert
			Entry	Intermediate	Senior	
Waste Management	Personnel handling biological materials, biosafety officers, laboratory personnel and policy makers	**Domains**	**Demonstrated competencies in the fundamental principles & practices of managing biological waste generated from laboratories.**			
		Biological waste management	**Describe** the different types of waste management and decontamination procedures.	**Implement** waste management and decontamination procedures.	Establish waste management practices and procedures to ensure compliance with policies, rules and regulations.	**Evaluate** waste management practices and procedures to **ensure** compliance with policies, rules and regulations.
		Legislation and policies for Waste Management	**Describe** the regulatory requirements for biological waste management	**Implement** the regulatory requirements for biological waste management	**Describe** the regulatory requirements for biological waste management	**Assess** compliance with national regulatory requirements for biological waste management *or* **be consulted as a subject matter expert** providing input into updates into national and/or regional policies.
		Implementing a waste management program	**Describe** the biological validation and efficacy monitoring methods applicable to different types of biological waste treatment options;**Describe** the procedures for proper documentation and	**Implement** the biological validation and efficacy monitoring methods applicable to different types of biological waste treatment options;**Implement** the procedures for proper documentation and record keeping of validation and efficacy monitoring;**Apply** and select the appropriate	**Evaluate** the biological validation and efficacy monitoring methods applicable to different types of biological waste treatment options;**Evaluate** the procedures for proper documentation and record keeping of validation and efficacy monitoring;**Develop**	**Evaluate** the critical components of the waste management program.

Proficiency Criteria	Target Audience	Objectives	Proficiency Levels			Africa Region Subject Matter Expert
			Entry	Intermediate	Senior	
			record keeping of validation and efficacy monitoring;**Understand** how to evaluate and select the appropriate biological indicator for its intended use (e.g. liquid versus dry loads, self-contained system, enzyme-based rapid method); and,**Describe** procedures for the proper use of biological indicators to establish effective operating parameters for autoclaves using representative loads and determining their processing times.	biological indicator for its intended use (e.g. liquid versus dry loads, self-contained system, enzyme-based rapid method); and,**Implement** procedures for the proper use of biological indicators to establish effective operating parameters for autoclaves using representative loads and determining their processing times.	evaluation and selection criteria of appropriate biological indicatoras per intended use (e.g. liquid versus dry loads, self-contained system, enzyme-based rapid method); and,**Evaluate** procedures for the proper use of biological indicators to establish effective operating parameters for autoclaves using representative loads and determining their processing times (i.e. develop a validation process).	

Appendix B: Proficiency Matrix for the Selection, Installation, Maintenance and Certification of Biological Safety Cabinets BSC

Stage	Timeline	Program Activities	Course Details	Alternative Pathways/ Resources
Level 1	Pre-Course	**Requirements**		IFBA Professional Certification in Biosafety Cabinet Selection, Installation & Safe Use
		- High School Diploma or equivalent (Technical Qualification NQF 4/Vocational education for technical diploma) with mathematics and mechanical and/or electrical subjects passed.		
		Desirable		
		- Understanding of ISO 17025 for quality and calibration of equipment		
		- Familiarity to testing equipment for BSC validations		
		- Exposure to laboratory environments (as staff or contractor)		
	5 Days	**Theoretical Section - 5-Day Didactic Lectures**	- Understanding of basic laboratory practices. Biosafety and Biosecurity implications. - Legal requirements and applicable standards (ANSI/NSF49 and EN12469:2000). - HEPA/ULPA filter Theory, Filtration principles, materials employed, installation and remedial works allowed. -Fan Theory,centrifugal fans (single/double inlet, plug fans), axial fans. - Aerosol dispersion, Thermal and Laskin generating technologies. - Alternative filter penetration testing technologies. - Function of aerosol photometers. - Air movement, use of scrim filters, diffusers, airflow	
		- Understanding of basic laboratory practices, BSCs as engineering controls		
		- Legal requirements and the different applicable standards		
		- Types, operation, functions, features, selection and placement of BSCs		
		- Types, operation, functions, features of test equipment, and testing methods		
		- Safe use, maintenance and certification of BSCs		
		- BSC decontamination methods		

Stage	Timeline	Program Activities	Course Details	Alternative Pathways/ Resources
			measurement - Airflow visualisation and determining the safety of airflow patterns. - Function of anemometers. - Function of pitot tubes and manometers. - Use of direct inflow measurement (DIM equipment) and limitations. - Alternative or secondary inflow measurement, including exhaust velocity measurement and constricted velocity measurement. - Difference between down flow velocity measurements and volumetric flow measurements. - Location assessment for placement of BSC's. - External influences affecting the safe operation of BSC's. - Decontamination of BSC's, including the chemical risks, biological risks, safe practices and alternative technologies. - Ddecontamination, interpretation of chemical/biological. - Understanding validated indicators for decontamination. - Exhaust ventilations, Thimble connection vs hard-ducted connection. - Ventilation of laboratories. - Differential pressures of rooms. - Requirements of external exhaust fans and filtration. - Effect of room pressures on BSC performance. - Electrical safety andrepairs, Electronic controls, KI Discus tests. - Setup to initial microbiological testing for cabinet models and the importance.	
	5 Days	**Practical Section: 5-Day Demonstration and Practice** - Setting up and proper use of test equipment	- Setting up Anemometer; Accessing pre-filters and paper catches. - BSC placement and influence measurements. - Mounting of anemometer probe on stand and inflow	NSF 49 Advanced certification or equivalent

Stage	Timeline	Program Activities	Course Details	Alternative Pathways/ Resources
		- Maintenance, filter replacement	measurement attachment. - Implementation of measurement grid for downflow and alternative inflow measurements. - Measurement of air velocities for volumetric measurements, downflow and exhaust. - Volumetric calculations, Measurement constants and the implementation. - Retrieval and access to required measurement grids and velocities. - Adjustments of dampers and baffles. - Setting up aerosol photometer and programming for different test parameters. - Preparation of BSC for filter penetration testing. - Test aerosol introduction to BSC. - Measurement of aerosol concentration upstream of HEPA/ULPA filters. - Scanning of HEPA/ULPA filters for penetration testing. - Validating the penetration tests to ensure consistency of test parameters. - Interpretation of penetration test data and recording of data. - Airflow visualisation and interpretation of airflow characteristics. - Thimble connection airflow adequacy tests. - Accessing the HEPA/ULPA filters and handling of the filters. - Accessing and replacing the fan assembly. - Balancing airflow; Electronic control (interlock), alarm adjustments. - Decontamination of BSC's.	
		- Airflow measurements, volumetric measurement and calculations, airflow pattern visualisation and interpretation		
		- HEPA filter testing		
		- Application of BSC decontamination methods		
		Exam and certificate issuing		

Stage	Timeline	Program Activities	Course Details	Alternative Pathways/ Resources
Level 2	6 Months	**Post- Level 1 course Requirements**	**Resources:** During this period, designated regional experts (or course instructors) will provide mentorship and technical support remotely.	**Resources:** During this period, designated regional experts (or course instructors) will provide mentorship and technical support remotely.
		- Candidate access to test equipment and means to facilitate remote mentorship		
		- Completion of BSC certification guided by mentor		
		- Candidates should test at least ten (10) BSCs during this period (i.e. >10 in 6 months)		
		- At least 50% of the BSCs tested are from government		
		Field Experience: In-country Assessment	- Duct traverse airflow measurements,Concurrent balance value tests. - Vibration, light-intensity and noise-level tests. - Decontamination of BSC's, Cabinet leak tests. - Practical demonstration of BSC troubleshooting, repairing and HEPA filter replacement - Practical demonstration of BSC decontamination and testing	**Resources:** Practical and competency evaluations shall be conducted in-country by designated local or regional experts.

Appendix C: Course Content Description

A. Selection, Installation, Maintenance and Certification of Biological Safety Cabinets BSC

Introduction

BSCs require regular inspection and certification so that they remain within performance specifications and provide protection to users.[35] There are a number of standards that can be used for certification of BSCs, with the two (2) most common standards used by the laboratories being NSF/ANSI49[36] and EN12469:2000.[37] As such, the Af-BSCCP will fundamentally be based on these two (2) international standards with the flexibility of incorporating locally available standards e.g. the VC8041[38] in South Africa. IFBA's Professional Certification (PC) in Biosafety Cabinet Selection, Installation and Safe Use[39] is also based on these two (2) international standards. This PC in Biosafety Cabinet Selection, Installation & Safe Use identifies individuals with demonstrated knowledge in the fundamental principles and practices of selecting and safely using biosafety cabinets for the handling of infectious materials.

To follow is a table detailing the comparison of these two (2) predominately-used international standards and additionally the South Africa VC 8041 (SABS 10226) as regulatory standard.

Table 4: Comparison of the VC8041/ EN12469:2000/ NSF/ANSI 49 Standards

Test/ Parameter Description	VC8041 (Specific to Class II)	EN 12469:2000 (Specific to Class II)	NSF/ANSI 49 (Specific to Class II, Type A2)
Acceptable Filter leakage	0.03% based on polydispersed test particles	0.01% at MPPS* or 99.97% filter efficiency	Penetration shall not exceed 0.01% based on polydispersed test particles
Inflow Velocity (operator protection)	Not less than 0.40m/s	Not less than 0.40m/s (KI Discus test dependent) Manufacturers specifications also applies	Not less than 0.51m/s
Downflow Velocity (sample/specimen protection)	Between 0.45 and 0.50m/s	Between 0.25 and 0.50m/s (KI Discus test dependent) Manufacturers specifications also applies	Determined by the initial microbiological challenge tests **

[35] WHO Regional Office for Africa. Report on the Status of EPDLN BSL-3 in Select Countries in the African Region, 2016: https://www.afro.who.int/sites/default/files/2017-08/Report%20on%20the%20Status%20of%20EDPLN%20BSL-3%20in%20Select%20Countries%20in%20the%20African%20Region.pdf
[36] Biosafety Cabinetry: Design, Construction, Performance, and Field Certification. NSF/ANSI 49. 2019
[37] Biotechnology: Performance Criteria for Microbiological Safety Cabinets. EN 12469.2000
[38] South African Bureau of Standards (SABS). VC 8041: Compulsory specification for microbiological safety cabinets (Classes I, II and III), 2001
[39] International Federation of Biosafety Associations (IFBA): https://internationalbiosafety.org/certification/certification/

Test/ Parameter Description	VC8041 (Specific to Class II)	EN 12469:2000 (Specific to Class II)	NSF/ANSI 49 (Specific to Class II, Type A2)
Smoke tests / Barrier tests	Simple smoke test in front of work aperture, 0.03% leakage of test aerosol into work surface ***	Airflow visualisation (check airflow patterns) no further guidance given	4 smoke tests providing results for the following: External influence test, sash retention (air curtain) test, sash seal test and downflow (smoke split – cross-contamination) test
Decontaminatio n pre-testing	Not specified in document, filter covers not suitable for circulating decontaminant.	Gaseous decontamination (Annex J) Circulation of decontaminant not covered	Gaseous decontamination as per NSF field certifier training program

** MPPS – Most Penetrable Particle Size.*
*** The initial microbiological challenge tests cover personnel, product (sample/specimen) and cross-contamination protection. The BSC's are setup according to these test conditions, thus referred to the microbiological validation.*
**** Aerosol leakage into work surface is not practically possible; as this would interfere with building fire/smoke detection systems, pose a health risk to the person performing the test and other personnel in the vicinity. Additional to the above comments, the aerosol is measured internally thus covering the product (sample/specimen) protection but not personnel protection.*

Learning Outcomes

The expected learning outcomes of this program:

i. Understand the safe use of different types of biological safety cabinets based on risk assessment
ii. Have knowledge and demonstrable competency on management of biological safety cabinets from selection, installation, certification and maintenance

Module Scope & Content Descriptions

A 10-day training program comprising of theoretical and practical sessions is to be conducted at a designated facility that meets the minimum requirements for a training facility.

1. **Theoretical Section: 5-days of didactic Lectures** – allowing for discussion and demonstration by instructors basic laboratory practices, types of BSCs, applicable standards and legal requirements (ANSI/NSF49 and EN12469:2000), HEPA/ULPA filter Theory, selection of appropriate BSC based on risk assessment, installation and certification/validation requirements, user and engineer maintenance, filter penetration testing technologies, airflow movement and measurements including secondary inflows, exhaust velocity and downflow velocities, , airflow, use of manometers and pilot tubes, decontamination of BSCs, exhaust and fans requirements, electricity safety and controls.
2. **Practical Section: Day 6-10, demonstration and practice** – comprising of demonstration by instructors, demonstration by candidates and hands-on practice/testing by candidates in BSC setting up Anemometer; BSC placement and influence measurements, mounting of anemometer probe on stand and inflow measurement attachment, measurement of grid for

downflow, alternative inflow measurements, air velocities for volumetric measurements, downflow and exhaust, adjustments of dampers and baffles and aerosol concentration upstream of HEPA/ULPA filters, setting up aerosol photometer and programming for different test parameters, preparation of BSC for filter penetration testing, test aerosol introduction to BSC, scanning of HEPA/ULPA filters for penetration testing, validating the penetration tests to ensure consistency of test parameters, Interpretation of penetration test data and recording of data, airflow visualisation and interpretation of airflow characteristics, thimble connection airflow adequacy tests, accessing the HEPA/ULPA filters and handling of the filters and fan assembly, balancing airflow; Electronic control (interlock), alarm adjustments, decontamination of BSC's.

Infrastructure Requirements for the designated training venue

The following minimum infrastructure requirements are specified for training venue

1. Training laboratory/room – suitable for ten (10) students and two (2) instructors.
    - Approximately 60sqm in area
    - Suitably air-conditioned space with adjustable ambient conditions (particularly temperature)
    - Basic laboratory fixtures, i.e. hand wash basin, eyewash station etc.;
    - Access to a dedicated PPE change room/area
    - Data connectivity – network points or Wi-Fi available
    - Work benches/ workstations (tables and chairs) – for twelve (12) people
    - Projection and audio system facilities available
2. BSC training laboratory (ideally adjacent to and visible from the training laboratory) - suitable for ten (10) students and two (2) instructors
    - Approximately 100sqm in area;
    - Suitably air-conditioned space with adjustable ambient conditions (particularly temperature)
        - Ducted supply air terminal;
        - Split air-conditioning unit;
        - Facilitate ease of demonstration of various practical aspects of the course curriculum.
    - Basic laboratory fixtures, i.e. hand wash basin, eyewash station etc.;
    - Five (5) x Class II A2 BSC; and at least one (1) of each – Class III; Class II B2; Class I BSCs; Thimble connected exhaust demonstration station (Refer to section 5.5.2 for details);
    - Fridge/Freezer and storage cabinets available;
    - Enhanced video facilities to capture and project activities e.g. during virtual lectures;
    - All equipment to be on emergency back-up generator power.

Training needs

Ideally, the first instance of this training should be for trainers or instructors, identified Member State (MS), who will be developed into regional experts in support of the sustainability of this program. Details of the essential equipment required to host a class size of ten (10) participants, and used to determine the performance of the BSCs in the six (6) primary tests necessary for certification, are listed in the table below.

Table 5 Training equipment and personnel requirements

Equipment Description	Details	Quantity
Administration:		
Instructors	Regional experts (incl mentorship and remote facilitation)	2
Course Administration	Meals, preparation of materials, IT support etc.	Unit
Biosafety Cabinets (BSCs):		
Class I BSC	Demonstration unit available	1
Class II A2 BSC	With at least one (1) unit to have a thimble exhaust connection	5
Class II B2	Complete with ducting and operational exhaust fan (can either be connected to room extraction or dedicated with external filtration (BIBO) as optional)	1
Class III	Complete with ducting and operational exhaust fan (secondary exhaust BIBO housing is optional, but desirable)	1
Test Equipment:		
Aerosol generator (Powered)	With sparge pipe kit	5
Aerosol Photometer	Particle penetration test	5
Hotwire anemometer	Airflow measurement	5
Sound level meter	Sound Measurement	2
Lux meter	Light level measurement	2
Multi-meter	Electrical supply measurement	2
Vibration Meter.	Vibration measurement	2
KI Discus Test apparatus	KI Discus protection factor apparatus	1

Certification Levels for the Selection, Installation, Maintenance and Certification of Biological Safety Cabinets BSC course

Level 1

Certification will be issued upon successful completion of a written exam and practical demonstration by candidates. Candidates who have successfully completed Level 1 certification cannot sign off on the certification of a BSC independently (refer to post-Level requirements below). Appendix C details the course content to be covered.

Level 2

This will be achieved following successful completion of post-Level 1 requirements and an in-country practical and competency assessment to be conducted by designated local or regional experts. The program of activities, will be scheduled as follow:

1. **Post Level 1 Requirements:**
    a. Six (6) months of supervised maintenance and certification of BSCs. During this period, designated local or regional experts will provide mentorship and technical support remotely to candidates.
    b. Candidates should test at least ten (10) BSCs during this period (i.e. >10 in 6 months), and at least 50% of these must be at state laboratories.

2. In-country Competency assessment – will be arranged and conducted on successful completion of 1. Above. This process will involve practical demonstration and competency assessment of the candidates by designated local or regional experts based on the competency evaluation checklist and acceptance criteria. Appendix E.

Level 2 certification will be issued to candidates upon successful completion of the in-country assessment based on the competency evaluation checklist and acceptance criteria. Upon successful completion of Level 2 certification, candidates will be authorised to sign off on the certification of a BSC independently.

Competency evaluation process the Biorisk Management, Biocontainment Engineering and Biological Waste Management Courses

The Af-BSCCP will have three (3) levels of proficiency to be used as a guide in assessing individuals' competencies based on the competency evaluation checklist and acceptance criteria (refer to Appendix B). The three (3) levels of proficiency (refer to Figure 1 below) are namely:

Level 1: Obtained by the successful completion of 10-day Af-BSCCP course, or meeting the recognized alternative pathways. The individual has the pre-requisite knowledge of the principles, concepts and/or methodologies related to BSC maintenance and certification, and generally performs the same under supervision. This level of certification does not permit an individual to certify a BSC independently.

Level 2: Obtained by the successful completion of field testing component of the Af-BSCCP, or meeting the recognized alternative pathways. The individual has advanced knowledge of the principles, concepts and/or methodologies related to BSC maintenance and certification, and generally performs the same under independently. This level of certification permits an individual to certify a BSC independently.

Senior Level: The individual analyses and independently applies principles, concepts and/or methodologies related BSC maintenance, certification, and has successfully demonstrated experience in supervisory practice. Experienced professional able to synthesize, critique or teach the listed competencies and is able to provide coaching and mentoring

Continued Professional Development (CPD)[40]

To maintain Af-BSCCP certification, certified professionals need to develop and apply their knowledge, experience and expertise with associated skills through demonstrated practice of BSC field certification and related activities. To maintain certification, professionals will primarily be required to certify a minimum of ten (10) BSCs per year (at least 50% should be from a public health/government facility). Certification shall be renewed at intervals not to exceed five (5) years. Renewal of certification shall be by written and practical examination (as per Level 2 certification above), or a minimum thirty-five (35) continued professional development (CPD) requalification units shall be accumulated within the five-year requalification period.

In order to administrate and evaluate the compliance of certified professionals with this requirement to accumulate CPD points in order to maintain professional certification, the Examination and Certification Committee (ECC)[41] may establish or assign an accreditation board that oversees activities. CPD points are to be collected through participation in any CPD accredited program or activity. CPD activity must occur in three (3) areas, namely: maintaining core skills (as prescribed by the proficiency matrix), obtaining new technical / specialty areas and transferable skills that are used in BSC field maintenance and certification, as well as in other community spheres.

[40] Biosafety Cabinetry: Design, Construction, Performance, and Field Certification. NSF/ANSI 49. 2019
[41] ASLM-Africa CDC: Regional Training and Certification Program for Biosafety and Biosecurity Expert

These activities should fall into the following categories, and can be benchmarked on the Accreditation Policies, NSF/ANSI 49, 2008 requirements:

i. Developmental activities - attendance of validated structured educational development activities such as conferences, congresses, seminars, workshops, lectures, refresher-training courses.
ii. Work-based activities – related work activities in BSC field maintenance and certification, and/or mentoring in the workplace.
iii. Individual activities – membership of recognised associations related to BSC certification practice, or other activities as determined through the accreditation program.

Key Messages

1. Correct BSC need to be selected, appropriately installed and validated before use to ensure safety of users and the environment.
2. Biological Safety Cabinets require regular and scheduled user and engineer maintenance checks and certification to ensure they continue to protect the uses and the environment

B. Biorisk Management[42;43;44;45;46;47;48;49]

Introduction

The primary goal of the course is to create a foundational and fundamental understanding and appreciation for BRM for participants who work with Hazardous Biological Agents (HBAs). The course is aimed, but not exclusive to, **entry level** laboratory personnel as a first step in becoming a recognised and certified Af-BBP. Through guided discussions and interactive exercises, students leave the course with relevant and applicable knowledge in BRM that they can return to their 'home' countries and facilities and contribute to growing and implementing Biorisk management culture in their own settings.

Learning Outcomes

The expected learning outcomes of this program:

iii. Understand the term "Biorisk Management" and have an understanding of the key components of such a system;
iv. Have the knowledge on role and importance of biorisk assessments, approaches for biorisk assessments, identification of risk mitigation and implement strategies, in the context of resource strained environments.
v. Use available relevant Standards, Guidelines, Frameworks and implementation of Regulations towards an effective biorisk management system.
vi. Recognize research of dual use concern and awareness of bioethical concerns and obligations for conducting science responsibly.

[42] Global Biorisk Management Curriculum (GBRMC) library, Sandia National Laboratories
[43] The Laboratory Leadership Competency Framework, Global laboratory Leadership Programme (GLLP), 2019; https://apps.who.int/iris/rest/bitstreams/1243229/retrieve
[44] Kenya Laboratory Biorisk Management Curriculum, 2nd edition, 2019: https://www.health.go.ke/kenya-laboratory-biorisk-management-curriculum-klbrmc/
[45] BioRisk Association of the Philippines (BRAP) Biosafety Credentialing and Competency Program: https://bioriskassociationphilippines.files.wordpress.com/2020/08/3-page-brap-bccp-3-session-module-2020-for-enhancement_ed.pdf
[46] Guidelines for Biosafety Laboratory Competency CDC and the Association of Public Health Laboratories; 2011; https://www.cdc.gov/mmwr/pdf/other/su6002.pdf
[47] International Federation of Biosafety Associations (IFBA) Professional Certification Program; https://internationalbiosafety.org/certification/certification/
[48] WHO Laboratory Biosafety Manual, 4th edition - Core Document, 2020: https://www.who.int/publications/i/item/9789240011311
[49] The Regional Biosafety and Biosecurity Legal Framework, for the African Union Member States, 2021

Module Scope & Content Descriptions

The program will be delivered through a 5-day interactive, face-to-face course covering the five (5) domain areas as specified under the Entry Proficiency Level, i.e. Fundamentals and elements of biorisk management systems; Regional Biosafety and Biosecurity Legal Framework; implementing a biorisk management system; shipping of dangerous infectious materials; and bioethics and DURC:

1. **Days 1** covering an introduction to biorisk management (BRM) basic principles, risk assessment models and risk mitigation strategies for the successful reduction of identified risks. Participants will be introduced to international regulations, laws, frameworks, standards and guidelines that pertain to BRM. The training will focus on how a participant would go about implementing these standards in their own facilities.
2. **Day 2** Theoretical concepts will be delivered in a series of relevant, current and interactive lectures tailored for resource-constrained environments. Practical demonstrations and activities are very important for demonstrating the mitigation strategies implemented in a laboratory and in practice, for example, participants would be trained on how to correctly work in a biological safety cabinet (BSC); would be trained on PPE donning and doffing procedures and on drafting biosafety and biosecurity risk assessments and SOPs. Participants would be trained on how to determine what mitigation strategies are most achievable, implementable and sustainable in their own setting and how to ensure that biosafety and biosecurity are consistently maintained. International requirements for the shipping of infectious and potentially infectious materials will be discussed with practical demonstration of appropriate packaging and shipping practices.
3. **Day 3** will cover biosecurity risk assessments and mitigation strategies for safeguarding against deliberate misuse of biological materials. It would be dedicated to creating an awareness of the danger of scientific technologies, facilities and equipment as well as biological agents being potentially misused. It would seek to create a sense of responsibility in researchers and all laboratory personnel. The course is structured to give a brief introduction into bioethics, the dual-use dilemma, Dual Use Research of Concern (DURC), and the roles and responsibilities of scientists in conducting research responsibly – particularly how to identify research with the potential for misuse and what to do when potential for misuse has been identified.
4. **Day 4** will cover an introduction to risk assessment, risk mitigation and performance review (AMP model). A description of the AMP model will be given and it will be demonstrated how the model can be adapted and used in different work settings. The practical elements of the course will involve training participants to identify hazards and associated risks and threats; to characterize these by considering the likelihood and consequences; to evaluate the risks based on facility, operator and country specific factors; and to determine whether or not the precautions in place are adequate to lower the risk through using case studies and examples.
5. **Day 5** will involve a reflection on the learning material presented throughout the week to reinforce the key messages of the course and integration of concepts through case studies and examples. Participants will also complete a competency assessment and a course evaluation.

Key Messages

3. Biorisk management is a systematic management approach to achieve safe and secure biological laboratories.
4. Biorisk assessments are a vital first step in the implementation of effective mitigation strategies aimed at reducing biological risks or the outcomes of the risks.
5. There are a variety of resources available (i.e. guidelines and standards) to assist facilities with developing and maintaining a biorisk management system.
6. Understand the importance of biosafety and biosecurity to reduce risks associated with hazardous agents.

All research has the potential for misuse, it is important for researcher to be cognizant of the risks and to conduct research in a responsible manner that minimizes the risks as much as is practicably possible.

C. Design and Maintenance of Facilities Handling High Risk Pathogens (Biocontainment Engineering) [50;51;52;53;54;55;56;57]

Introduction

The primary goal of the course, is to create a foundational and fundamental understanding and appreciation of the basic principles and considerations for biocontainment facility design, construction and operation. The course is aimed at an Entry Level for early career biocontainment engineering personnel as a first step in becoming a recognised and certified Af-BBP Biocontainment Engineering professional. Through guided discussions and interactive exercises, students leave the course with relevant and applicable knowledge in the *Design and Maintenance of Facilities Handling High Risk Pathogens (Biocontainment Engineering)* for implementation in their own settings (with an emphasis on low-resource settings).

Learning Outcomes

The expected learning outcomes for the specified audience as appropriate to their roles, responsibilities, and contribution to biocontainment engineering are to:

i. Describe applicable regulations, guidelines and standards governing the design and operation of biocontainment facilities and apply an evidence-and-risk-based facility design approach as appropriate in biorisk mitigation.
ii. Outline biocontainment facility features and describe the engineering control features of primary and secondary containment barriers.
iii. Describe containment facility commissioning, performance and verification testing requirements – certification.

[50] Global Biorisk Management Curriculum (GBRMC) library, Sandia National Laboratories
[51] WHO Laboratory Biosafety Manual, 4th edition - Core Document, 2020: https://www.who.int/publications/i/item/9789240011311
International Federation of Biosafety Associations (IFBA) Professional Certification Program; https://internationalbiosafety.org/certification/certification/
[52] WHO Laboratory Biosafety Manual, 4th edition - Laboratory Design and Maintenance, 2020: https://www.who.int/publications/i/item/9789240011397
[53] The Laboratory Leadership Competency Framework, Global laboratory Leadership Programme (GLLP), 2019; https://apps.who.int/iris/rest/bitstreams/1243229/retrieve
[54] Kenya Laboratory Biorisk Management Curriculum, 2nd edition, 2019: https://www.health.go.ke/kenya-laboratory-biorisk-management-curriculum-klbrmc/
[55] Guidelines for Biosafety Laboratory Competency CDC and the Association of Public Health Laboratories; 2011; https://www.cdc.gov/mmwr/pdf/other/su6002.pdf
[56] International Federation of Biosafety Associations (IFBA) Professional Certification Program; https://internationalbiosafety.org/certification/certification/
[57] The Regional Biosafety and Biosecurity Legal Framework, for the African Union Member States, 2021

iv. Outline the important aspects of the management of the daily operations and maintenance of biocontainment facilities.

Module Scope & Content Descriptions

This course focuses on the application of evidence-and-risk-based facility design approach for facilities handling high risk pathogens in resource-constrained environments. The Biocontainment Engineering component will be delivered through a 5-day interactive course covering the four (4) domain areas as specified under the Entry Proficiency Level, i.e. Regulatory and certification frameworks for institutions handling high risk pathogens; Design and construction; Commissioning performance and verification testing requirements – certification and recertification; and Facility operations and maintenance:

1. **Day 1** covering an introduction to biorisk management (BRM) basic principles, risk assessment models and risk mitigation strategies for the successful reduction of identified risks. Reviews applicable regulations, guidelines and standards governing the design and operation of biocontainment facilities and introduces an evidence-and-risk-based facility design approach to applied biorisk mitigation.
2. **Day 2** would cover laboratory biosecurity, as well as delve into field biosafety and biosecurity, measures, particularly technologies, biorisk protocols, procedures and processes required to ensure safe handling, security and accounting for biological materials. Biocontainment facility features and the concept of primary and secondary containment barriers will be introduced. Through guided discussions and interactive exercises, participants will use risk assessments for agents and procedures to define the appropriate facility features necessary for risk mitigation.
3. **Day 3** would focus on the laboratory design process and the biocontainment engineering principles of facility design and construction. Provide a methodology for developing, analyzing, refining laboratory designs, increasing awareness of laboratory design issues and analytical processes, which are critical for developing laboratory layouts, and to provide examples of well-designed laboratories. The course offers an understanding of the activities that should be carried out prior to and during the design process for a laboratory facility. Demonstrate how good design practice works to enhance both biosafety and biosecurity. Demonstration of the application of biocontainment engineering principles in the design of high containment laboratories for sustainable operation.
4. **Day 4** would be dedicated to biocontainment facility commissioning performance and verification testing requirements, i.e. for certification and recertification. Understanding that: Facility commissioning – is the verification of the physical construction, i.e. a process designed to ensure that the finished facility, equipment and systems will operate in accordance with the design intent and construction; and that Certification – is the verification that the facility and operational protocols meet applicable guidelines and standards (and continues to comply with these in the case of recertification).
5. **Day 5** would focus mainly on biocontainment facility operations and maintenance. Outlining the important aspects of the management of the daily operations of high containment facilities. Discussion concepts will include: training and competencies of maintenance support; maintenance of the HVAC, safety and security systems, and physical facility infrastructure; routine checks on the facility's systems to render the facility safe to enter (including in emergency situations).

Key Messages

1. Risk assessments are a vital first step in the implementation of effective mitigation strategies aimed at reducing biological risks.
2. Appropriate facility features for biocontainment laboratory designs (such as equipment placement, containment barriers and airflow strategy) that are evidence-and-risk-based for effective and sustainable biorisk mitigation.
3. Identify applicable compliance requirements for the design and operation of biocontainment facilities.
4. Plan for biocontainment facility operation and maintenance, and periodic assessments of performance and verification testing.

D. Waste Management [58;59;60;61;62;63;64;65]

Introduction

Waste Management is developed to provide participants with a basic understanding of the different types of laboratory and/or clinically-generated waste; safe-handling and treatment of this hazardous waste; development and implementation of a waste management program; legislation, policy and guidelines relevant to management of waste. The course will also explore the waste management process from point of generation to final treatment and/or disposal to avoid or reduce the potential negative impact on human health and the environment. Students will create, through guided discussion and interactive exercises, a matrix of acceptable methods to segregate, package, label, collect, store, transport, treat, and dispose of various types of waste.

Learning Outcomes

The expected learning outcomes for the specified audience as appropriate to their roles, responsibilities, and contribution to waste management are to:

i. Categorize the different types of waste
ii. Apply the waste management process to the different types of waste
iii. Explain the risks associated with handling/treating care waste
iv. Select the appropriate approach/methods for each step of the waste management process
v. Understand the factors that influence the selection of treatment and disposal approaches and technologies

Module Scope & Content Descriptions

1. **Day 1** covering an introduction to biorisk management (BRM) basic principles, risk assessment models and risk mitigation strategies for the successful reduction of identified risks. Theoretical

[58] WHO Laboratory Biosafety Manual, 4th edition - Core Document, 2020:
https://www.who.int/publications/i/item/9789240011311
Kenya, Guide for Training Health Workers in Health Care Waste Management, 2015
[59] WHO Laboratory Biosafety Manual, 4th edition - Decontamination and Waste Management, 2020:
https://www.who.int/publications/i/item/9789240011359
[60] WHO Safe Management of Wastes from Health-care Activities, 2nd edition, 2014:
https://www.euro.who.int/__data/assets/pdf_file/0012/268779/Safe-management-of-wastes-from-health-care-activities-Eng.pdf
[61] Swaziland Health Laboratory Services, Laboratory Waste Management Guidelines: Proper Management of Health Care Risk Waste Derived from a Laboratory Environment, 2013
[62] Kenya, Guide for Training Health Workers in Health Care Waste Management, 2015
[63] Global Biorisk Management Curriculum (GBRMC) library, Sandia National Laboratories
[64] International Federation of Biosafety Associations (IFBA) Professional Certification Program;
https://internationalbiosafety.org/certification/certification/
[65] The Regional Biosafety and Biosecurity Legal Framework, for the African Union Member States, 2021

concepts would be delivered in a series of relevant, current and interactive lectures based on the material adapted for the African setting (e.g. the GBRMC). Practical demonstrations and activities are very important for demonstrating the mitigation strategies implemented in a laboratory and in practice. The focused examples could be either one or a combination of the mitigation strategies in use depending on the facility at which the training is being conducted and the target audience's resource availability so that the strategies taught are relevant and easy to replicate in the participant's home country.

2. **Day 2** covers an introduction to managing waste, including the classification of hazardous biological waste, its identification and characterization. Terminology used and developing an understanding of the fundamental principles of disinfection, decontamination, incineration, and sterilization. Understand how to evaluate different risks associated with wastes generated from diverse settings including clinical laboratories, research laboratories, microbiological production laboratories, and animal facilities. Outlining of the basic elements of a comprehensive waste management system (including segregation, packaging, labelling, collection, storage, transport, treatment, and disposal) and identifying different types of waste.
3. **Day 3** would focus on understanding how the risks (both biosafety and biosecurity-related) dictate the methods of storing the waste until final disposal and destruction. Differentiate between internal and off-site transportation requirements and describe procedures for the segregation, packaging, labelling, collection (including the maintenance of chain of custody and appropriate records), storage, transport, treatment, and disposal of different types of waste generated from diverse settings including clinical laboratories, research laboratories, microbiological production laboratories, and animal facilities. Treatment technologies will be explored, the basic principles, advantages and limitations of treatment and disposal options for waste including steam autoclaving, irradiation, incineration, chemical disinfection and decontamination, gaseous decontamination, and effluent treatment systems. In addition, participants will be trained on verification and validation of inactivation/sterilization/decontamination techniques to prove kill/inactivation of pathogens prior to removal for off-site disposal.
4. **Day 4** would cover an introduction into developing and implementing a waste management program, advantages and disadvantages of different disposal methods, and compliance to legislative requirements in this regard. Describe the safety measures (e.g. personal hygiene, personal protective equipment) and security measures (e.g. physical security, restricted access) needed to manage untreated wastes. Develop an understanding of the applicability of local and/or national regulations and regulatory frameworks that govern the management, treatment and disposal of waste.
5. **Day 5** would be dedicated to performance management of the waste management program and on how to establish emergency response procedures in this regard. Describe the biological and/or chemical validation and efficacy monitoring methods applicable to different types of waste treatment options, and procedures for proper documentation and record keeping of validation and efficacy monitoring. Develop an understanding of how to establish emergency response procedures for responding to accidents and incidents involving waste and how to establish contingency plans for dealing with the disruption or inoperability of waste treatment and disposal methods.

Key Messages

1. Waste should be identified and segregated into appropriate waste types.
2. Different methods for packaging and storage of waste are necessary for different types of waste.
3. The type of treatment and disposal methods used depends on the risk posed by the type of waste as determined by rigorous risk assessment process.
4. Although legal requirements vary according to location, the basic principles of waste disposal and treatment remain the same due to the risk associated with each type of waste.

Appendix D: Improvement Project Report Format

1.0 Project Title: Conducting a Biosafety and Biosecurity Risk assessment For Facility X and development and implementation of appropriate mitigation strategies.

2.0 Introduction

1. A brief description and background of the IP area
2. What led the to the selection of the project area
3. What you intend to achieve out of the project (Aim and Objectives) e.g.

   Aim: To conduct a risk assessment for Facility X and develop and implement appropriate mitigation strategies by xx, xx 2022

   Objectives

   - To conduct a risk assessment for facility xx
   - Identify appropriate mitigation measures for the identified risks
   - Implement mitigation measures for the identified risks
   - Determine effectiveness of mitigation measures

2.0 Methodology

1. Where was the project being conducted?
2. How was the IP conducted (data collection methods, data collection tools, frequency of collection and who was collecting and how the data will be analyzed)
3. What improvements were implemented, by whom and how?
4. For how long was the project conducted?

3.0 Results

1. Describe the results:
2. Analysis of the results

4.0 Conclusion

1. What are/is the conclusion(s) based on results

5.0 Challenges

6.0 Recommendations

Appendix E: Competency Evaluation Checklist for the B. Selection, Installation, Maintenance and Certification of Biological Safety Cabinets BSC

Date of assessment:_____ **Assessor name:**_____

Method procedure Used:_____

Name and Serial Number of Equipment Validated/Certified:_____

Name of Institution Assessment conducted:_____

Name, designation and Contacts of In-Charge of the Facility:

Stage	Criteria	Requirements	Yes	Partial	No	N/A	Comments
	Exam and Practical Demonstration	Passed written exam and practical demonstration					
		OR: NSF 49 Advanced certification or equivalent					
Level 2	**Post-Level 1 Field Testing**	Test reports - >10 over a period not less than 6 months					
		> 50% of the reports were conducted on BSCs at state laboratories					
	Administration	Safety policies followed					
		Preparation of work area					
		Work area neat and organized					
		Correct completion of test reports and BSC labeling (following successful testing)					
	Equipment	Equipment: Candidate should have adequate equipment to carry out BSC maintenance and certification duties					
		Equipment inventory supplied/available (complete with calibration documentation) and visually checked by assesor					
		Preparation/handling of equipment and maintenance activities					
		Setting up and proper use of test equipment					
			Airflow measurements and calculations				
		Downflow velocity – using a adequately rigidly-mounted hot-wire anemometer; proper point marking on work space					
		Primary method: Inflow velocity (direct inflow measurement) –					

Stage	Criteria	Requirements	Yes	Partial	No	N/A	Comments
		using a calibrated balometer connected to the BSC air intake.					
		Secondary/Alternative Method: Inflow velocity (exhaust velocity measurement)					
	Field Test - Primary Tests (Assessed through Direct Observation)	HEPA filter leak test – using a calibrated photometer and a calibrated aerosol generator					
		Airflow smoke patterns – use an appropriate smoke generating device to verify that the air flows smoothly downwards with no dead spots or reflux and that it does not escape from the BSC					
		Site installation assessment					
		Alarm function verification					
		Decontamination methods – paraformaldehyde or equivalent (e.g. hydrogen peroxide)					
	Field Test - Optional Tests (Assessed through Direct Observation)	Lighting intensity					
		Vibration test					
		Noise level test					
		Electrical tests (leakage, ground circuit resistance, and polarity)					

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